PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2026 PBAC MEETING

The PBAC outcomes and recommendations are presented in alphabetical order by drug name.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
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 pen Amgevita® AMGEN AUSTRALIA PTY LIMITED Category 4 (New PBS listing) PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Crohn disease Ulcerative colitis Active juvenile idiopathic arthritis Complex refractory fistulising Crohn disease Active rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Chronic plaque psoriasis Hidradenitis suppurativa	To request listing of four new higher concentration forms of the Amgevita biosimilar brand of adalimumab that mirror the current PBS-listed adalimumab brands with the same strengths and forms. Authority Required	Recommended	The PBAC recommended the listing of adalimumab (Amgevita HC®) in the forms and strengths of strengths of 20 mg in 0.2 mL, 40 mg in 0.4 mL, pre-filled syringe (PFS) and 40 mg in 0.4 mL, 80 mg in 0.8 mL pre-filled pen (PFP) under the same circumstances as the currently PBS listed reference biologic, Humira® and other brands of adalimumab. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost effectiveness of Amgevita PFS and PFP would be acceptable if it were cost minimised to Humira PFS and PFP and all other biosimilar brands and formulations of adalimumab. The PBAC advised the equi effective doses to be 1 mg of Amgevita = 1 mg of Humira and all other biosimilar brands and formulations of adalimumab. The PBAC advised that Amgevita HC 20 mg/0.2 mL and 40 mg/0.4 mL PFS, and 40 mg/0.4 mL and 80 mg/0.8 mL PFP should be treated as equivalent to Humira and other adalimumab brands in the same form and strengths for the purposes of substitution (i.e. 'a'-flagged in the Schedule). The PBAC also advised that Amgevita HC 40 mg/0.4 mL PFS and PFP should be considered equivalent for substitution with adalimumab 40 mg/0.8 mL PFS and PFP, respectively. In addition, Amgevita HC 20 mg/0.2 mL PFS and PFP are considered equivalent to adalimumab 20 mg/0.4 mL PFS and PFP. The PBAC noted and welcomed the input from the Australasian Society of Clinical Immunology and Allergy and individuals. The PBAC acknowledge the new strengths and

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				forms of Amgevita would improve quality of life and financial burden to patients. and the healthcare system.
ADALIMUMAB Injection 20 mg in 0.2 mL single use pre-filled syringe Yuflyma® CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 4 (New PBS listing) PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Moderate to severe ulcerative colitis Severe juvenile idiopathic arthritis Severe chronic plaque psoriasis Severe Crohn disease Vision-threatening non-infectious uveitis	To request listing of a new form of the Yuflyma biosimilar brand of adalimumab that mirrors the originator brand's current listings with the same form. Authority Required	Recommended	The PBAC recommended the listing of adalimumab (Yuflyma) in the form of 20 mg in 0.2 mL pre-filled syringe (PFS) under the same circumstances as the PBS-listed reference biologic Humira 20 mg in 0.2 mL PFS and biosimilar brand Amgevita 20 mg in 0.4mL PFS. The PBAC recommended Yuflyma should also be listed for the treatment of enthesitis/spondylitis related juvenile idiopathic arthritis. The PBAC advised Yuflyma, Amgevita and Humira should be considered equivalent for the purposes of substitution (i.e. 'a'-flagged in the Schedule).
ADRENALINE (EPINEPHRINE) Nasal spray device 1 mg in 1 actuation Nasal spray device 2 mg in 1 actuation Neffy® SEQIRUS (AUSTRALIA) PTY LTD	Acute allergic reaction with anaphylaxis	To request listing of a new form of adrenaline (epinephrine) for the emergency treatment of acute severe allergic reactions in children or adults at significant risk of anaphylaxis.	Recommended	The PBAC recommended the listing of neffy® nasal spray, a new form of adrenaline (epinephrine), for the emergency treatment of acute severe allergic reactions in children (over 4 years and 15 kg) or adults at significant risk of anaphylaxis. The PBAC considered there was a clinical need for an alternative adrenaline product to the auto-injectable form EpiPen, given previous shortages with supply of adrenaline auto-injector pens. The PBAC welcomed input from health care organisations and a health care professional. This included input from a

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Category 2 (New PBS listing) PBS General Schedule		Authority Required (Telephone/Online)		clinical nurse consultant and multiple consumer and medical organisations (the National Allergy Council, the Australasian Society of Clinical Immunology and Allergy (ASCIA), Allergy & Anaphylaxis Australia (A&AA), National Paediatric Medicines Forum (NPMF), Pharmaceutical Society of Australia and National Aboriginal Community Controlled Health Organisation (NACCHO)). The PBAC acknowledged that neffy was more stable to temperature variations and has a longer shelf life than EpiPen. The PBAC accepted this could result in less frequent replacements, which is particularly important for rural and remote communities. Additionally, the PBAC noted that a needle-free option of adrenaline (epinephrine) may also be easier to carry and use for some patients. The PBAC noted the submission's claim that adrenaline is underused in treating anaphylaxis, and delayed administration is associated with poorer clinical outcomes. The PBAC considered that this new form of adrenaline (epinephrine) was as effective as EpiPen, in alleviating symptoms of anaphylaxis. The PBAC considered that there were potential reductions in hospital admissions from improvements in appropriate and timely use of neffy compared to EpiPen. Also, it noted potential cost savings from reduced prescription refills for expired devices. Overall, the PBAC considered a small price premium for neffy over EpiPen was justified. The equi-effective doses of neffy and EpiPen are a one-for-one substitution: • EpiPen 0.3 mg/0.3 mL = neffy 2 mg/0.1 mL

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				• EpiPen 0.15 mg/0.3 mL = neffy 1 mg/0.1 mL The PBAC advised that the restriction wording for neffy should align with the existing restrictions except for the differences in age and weight, and noted that flow-on restriction changes to the Caution and Administrative notes for the auto-injector pens are required to acknowledge the different administration devices and techniques.
ALECTINIB Capsule 150 mg Alecensa® ROCHE PRODUCTS PTY LTD Matters arising from the minutes (Change to existing listing) PBS General Schedule	Non-small cell lung cancer (NSCLC)	To consider the sponsor's proposal for listing alectinib for adjuvant treatment of adult patients following tumour resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). This item was previously recommended by the PBAC at its May 2025 meeting. To consider consumer input regarding re-treatment with an ALK inhibitor in the metastatic setting following adjuvant alectinib treatment. Authority Required (Telephone/Online)	Advice Provided	The PBAC reaffirmed its May 2025 recommendation that alectinib be made available for the treatment of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumours ≥4 cm or node positive) as adjuvant therapy after tumour resection. The PBAC provided additional advice on eligibility for access in the locally advanced/metastatic setting so that if alectinib is used following surgery to reduce the risk of cancer coming back, a different ALK inhibitor may be used later if needed. The PBAC recalled that it had previously wanted to increase patient access to ALK inhibitor treatment for locally advanced/metastatic cancer following treatment with alectinib after surgery but had not received enough evidence to make this recommendation. The PBAC welcomed the input provided by ALK-positive Australia and Medical Oncology Group of Australia, noting the equity issues associated with preventing re-treatment with an ALK inhibitor, the clinical rationale and expected outcomes of re-treatment with an ALK inhibitor after treatment with alectinib following surgery, and that the financial impact to the PBS of allowing re-treatment with an ALK inhibitor following treatment with alectinib would likely be minimal. After considering the additional input received from consumer and clinical groups,

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				the PBAC advised that listing alectinib for ALK-positive NSCLC and allowing re-treatment with another ALK inhibitor if the cancer advances, would be cost-effective.
AMIVANTAMAB Solution concentrate for I.V. infusion 350 mg in 7 mL Rybrevant® JANSSEN-CILAG PTY LTD Category 2 (Change to existing listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Non-small cell lung cancer (NSCLC)	To request listing of amivantamab for use in combination with platinum-based chemotherapy for the treatment of adult patients with locally advanced or metastatic NSCLC with an epidermal growth factor receptor (EGFR) gene mutation, whose condition has progressed on or after treatment with osimertinib. Authority Required (Telephone/Online)	Recommended	The PBAC recommended the listing of amivantamab, in combination with platinum-based doublet chemotherapy (PDC), for the treatment of patients with epidermal growth factor receptor gene mutated (EGFRm) locally advanced/metastatic non-small cell lung cancer (NSCLC), where the condition has progressed during or after treatment with osimertinib, a medicine commonly used for patients with EGFRm NSCLC. The PBAC welcomed input from individuals, health care professionals and organisations. Input from individuals expressed hope that amivantamab could improve quality of life and prolong survival noting that there were significant negative side-effects such as lethargy, pain, difficulty breathing and reduced mobility associated with currently available treatment options. Input from health care professionals indicated that amivantamab would provide meaningful benefits for patients, helping people live longer and slowing the progression of their disease. The PBAC considered that the patient population most likely to be treated with amivantamab would have similar characteristics (patients who are otherwise well but whose cancer is widespread) to the patient population that is currently treated with atezolizumab plus bevacizumab with carboplatin and paclitaxel (ABCP), a currently available treatment option. The PBAC considered that based on the clinical evidence

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				presented in the submission, amivantamab in combination with PDC was more effective than a currently available treatment option of PDC alone. The PBAC considered the benefit was modest and was associated with increased adverse events. However, the PBAC noted there was not enough clinical data available to determine whether amivantamab in combination with PDC provides additional benefit to patients compared with the existing treatment ABCP. In this context, the PBAC considered that amivantamab for the treatment of EGFRm patients would be cost-effective if its price was based on the price of atezolizumab plus bevacizumab for the treatment of patients with non-squamous NSCLC, which includes patients with EGFRm. The PBAC considered amivantamab would be cost effective with a cost per 3-week treatment cycle no higher than that for atezolizumab plus bevacizumab. The PBAC considered the estimated number of patients who would be eligible for treatment with amivantamab presented in the submission was reasonable, but the submission overestimated the number of patients who would use the medicine.
ASCIMINIB Tablet 20 mg Tablet 40 mg NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED	Chronic myeloid leukaemia (CML)	To request listing of asciminib for the treatment of adult patients with newly diagnosed CML in chronic phase. Authority Required (Telephone/Online) for initial treatment Authority	Not applicable	This item was withdrawn.

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Category 2 (Change to existing listing) PBS General Schedule		Required (STREAMLINED) for continuing treatment		
ASCIMINIB Tablet 20 mg Tablet 40 mg Scemblix® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 4 (Change to existing listing) PBS General Schedule	Chronic myeloid leukaemia (CML)	To request a change to all listings of asciminib for the treatment of CML to allow prescribing by nurse practitioners. Authority Required	Recommended	The PBAC recommended the addition of nurse practitioners (NPs) as authorised prescribers for asciminib on the Pharmaceutical Benefits Scheme (PBS), in the continuing treatment phase of all current indications. Asciminib is currently listed on the PBS for patients with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (CP) or accelerated phase (AP), who had been previously treated with two or more tyrosine kinase inhibitors (TKIs). This is in the third-line setting or beyond. It is also PBS-listed for patients with Ph+ CML in CP or AP, who had been previously treated with one or more TKIs and harbouring the T315I mutation. This is in the second-line setting or beyond. The PBAC noted and welcomed input from individuals. The PBAC acknowledged CML as an insidious disease that brings emotional and physical pain to both patients and families. In its consideration, the PBAC recalled its July 2025 review of General Schedule oncology and haematology medicines, and whether these should be eligible for NP prescribing. Asciminib was not considered at this meeting as it had not been identified for review by stakeholders. For oncological or haematological conditions in general, the PBAC considered that the clinical work up required for a diagnosis and differential diagnosis may be complex and likely require that a patient's care be overseen by an oncologist or haematologist. As such, the PBAC was of a view that limiting NP prescribing to continuing therapy with a specific medicine was more suitable, rather than allowing NP prescribing in

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				both initiation and continuing settings. It considered that NPs sharing patient care with a medical practitioner would assist in mitigating potential risks. In its current decision, the PBAC advised that the listing for asciminib should follow precedent for other NP prescribing items for other drugs in this same class. The PBAC considered that its decision would result in no additional cost to the PBS.
AVACINCAPTAD PEGOL Solution for intravitreal injection 2 mg in 0.1 mL (20 mg per mL) Izervay® ASTELLAS PHARMA AUSTRALIA PTY LTD Category 1 (New PBS listing) PBS General Schedule	Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)	To request listing of avacincaptad pegol for the treatment of adult patients with GA secondary to AMD, who have an intact fovea and where central vision is threatened by GA lesion growth. Authority Required (Written or Telephone/Online) for initial treatment Authority Required (STREAMLINED) for continuing treatment	Recommended	The PBAC recommended PBS listing of avacincaptad pegol (ACP) for the treatment of geographic atrophy (GA) or dry AMD secondary to age related macular degeneration. The PBAC welcomed input from consumers, health care professionals and Macular Disease Foundation Australia. The PBAC noted mixed support from health care professionals. Some suggested delayed progression of GA would help patients retain their sight for longer. Others suggested the evidence showed only small delays in progression of GA which may not lead to meaningful benefits for patients. The PBAC noted the differing opinions and acknowledged that there was a high clinical need for treatments for GA, which is a leading cause of irreversible vision loss in older Australians. The PBAC noted that the clinical trials showed ACP reduced GA lesion growth when compared with placebo. The PBAC considered that, although the clinical trials did not demonstrate clear improvements in vision related activities, it was reasonable to assume that protecting the structure of the eye by slowing GA lesion growth would result in slower loss of functional vision than current care. Despite uncertainty about how large this benefit may be on preserving vision, the PBAC was satisfied that for some patients, ACP would provide a worthwhile improvement in efficacy over existing treatment options. The PBAC also noted

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				an increase in ocular adverse events, especially chorionic neovascularisation (CNV or "wet" AMD), in patients treated with ACP for GA and recommended that treatment be restricted to patients with monocular vision who stood the most to benefit from ACP. The PBAC considered there was some uncertainty about the extent to which benefits claimed by the sponsor in support of its proposed price would be realised in practice. The PBAC considered the benefits claimed by the Sponsor may be overestimated and, in particular, the extent to which delayed eye damage may translate to less vision loss. The PBAC therefore considered ACP would provide acceptable value for money if the proposed price was reduced. In addition, the PBAC considered a financial agreement with Astellas Pharma Australia would be required to manage uncertainty about how many patients would use ACP and to ensure PBS reimbursement was for treatment in one eye only. The PBAC noted it had already recommended similar treatment, pegcetacoplan, for the same disease at its November 2025 meeting. Although listing arrangements for pegcetacoplan were yet to be finalised at the time of the PBAC's consideration of ACP, the PBAC considered that it both medicines show similar benefits in delaying disease progression with neither medicine being more effective than the other. Therefore, should pegcetacoplan proceed to PBS listing, the PBAC advised that ACP should be price matched with pegcetacoplan. The PBAC noted the flow on changes to the pegcetacoplan listing, should pegcetacoplan be listed for this indication, with

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				amendments to the restriction wording for the listings outlined in Section 8 of the pegcetacoplan Public Summary Document (November 2025 PBAC meeting) in order to remove the numerical values associated with confirmation of lesion growth and location.
BUROSUMAB Solution for injection 10 mg in 1 mL Solution for injection 20 mg in 1 mL Solution for injection 30 mg in 1 mL Crysvita ® KYOWA KIRIN AUSTRALIA PTY LTD Category 2 (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Tumour induced osteomalacia (TIO)	To request listing of burosumab for the treatment of adult and paediatric patients with TIO, presenting with hypophosphataemia due to fibroblast growth factor 23 (FGF23), where phosphaturic mesenchymal tumours cannot be curatively resected or localised. Authority Required	Recommended	The PBAC recommended burosumab for the treatment of unresectable tumour induced osteomalacia (TIO), an ultrarare condition caused by certain tumours that lead to low levels of phosphate in the blood (hypophosphatemia) which weakens bones over time. The PBAC noted the high unmet clinical need for treatments for this condition, as current therapies are difficult to take given the side effects and are not always effective. The PBAC considered that burosumab was likely superior to conventional therapy (which consists of oral phosphorus and oral calcitriol) at normalising phosphate levels and has a different, but non-inferior, safety profile. The PBAC noted that with normalisation of phosphate levels, the long-term health benefits would potentially include correcting established skeletal damage, reducing pain and fatigue, and improving physical function and quality of life. The PBAC noted this was supported by the sponsor's hearing before the PBAC which included a testimonial from a patient who experienced substantial quality of life improvements from treatment with burosumab. The PBAC noted input from XLH Australia which described the success of burosumab in X-Linked hypophosphataemia (XLH) patients and strongly supported its potential benefit for people with TIO, who experience a very similar disease burden as those with XLH, including severe bone pain, muscle weakness, fractures, fatigue and long delays to diagnosis.

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				The PBAC accepted the submission's assumption that the incremental costs and benefits of burosumab compared to conventional therapy are likely similar for adult patients with unresectable TIO and XLH, and recommended listing at the same price per vial. The PBAC considered that the estimated financial impact was reasonable and advised that the proposed risk sharing arrangement was adequate to manage uncertainties relating to how long burosumab would be used by patients and the long-term gains in health. The PBAC recommended that for patients to be eligible to continue receiving burosumab they must have achieved normal phosphate levels in the blood or, where an adequate response cannot be demonstrated, the treating physician must confirm that continuing treatment is clinically required by a second specialist physician. The PBAC advised that the requirements for continuing treatment should flow on to the restrictions for XLH.
CANAKINUMAB Solution for injection 150 mg in 1 mL Ilaris® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 1 (New PBS listing)	Colchicine-resistant or intolerant Familial Mediterranean Fever (crFMF)	To request listing of canakinumab for the treatment of paediatric crFMF patients who continue canakinumab treatment into adulthood (provided they initiated canakinumab treatment before turning 18 years of age). Authority Required (Telephone/Online)	Recommended	The PBAC recommended listing of canakinumab for the treatment of colchicine resistant Familial Mediterranean Fever (FMF) in adults and children aged 2 years and older. FMF is rare genetic condition that causes recurrent febrile attacks (flares) and severe systemic inflammation, which leads to deterioration in kidney function. The PBAC welcomed input from individuals, health care professionals and consumer organisations. The PBAC acknowledged the debilitating nature of the disease and the benefit of flare reduction on improving patients' quality of life and life expectancy and the high unmet clinical need for treatment options for patients with FMF.

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PBS Section 100 (Highly Specialised Drugs Program)				The PBAC noted the clinical evidence provided in the submission demonstrating that canakinumab reduces the frequency of febrile attacks and reduces systemic inflammation, which is expected to reduce kidney deterioration and failure. The clinical evidence presented in the submission did not allow confidence about the extent to which the benefits claimed in support to the proposed price would be realised in practice. However, the PBAC also recognised the difficulty in obtaining clinical data for this condition due to its rarity. The PBAC considered the value for money of canakinumab at the price requested by the sponsor was uncertain due to the limited clinical data, but that in the context of this rare and life-limiting disease, canakinumab would be considered acceptably cost-effective with a price reduction. The PBAC noted this recommendation is in line with other treatments for rare diseases funded on the PBS and takes into account clinical need, available evidence, nature of the benefits, and the size of the patient population. The PBAC considered that a risk-sharing arrangement should be put in place to reduce the financial risk of the cost of the drug to the PBS being higher than expected.
CANNABIDIOL Oral liquid 100 mg per mL, 100 mL Epidyolex® JAZZ PHARMACEUTICALS ANZ PTY	Severe myoclonic epilepsy in infancy (Dravet syndrome)	To request a change to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the treatment of Dravet	Recommended	The PBAC recommended amending the authority requirements for cannabidiol for the treatment of seizures associated with Dravet syndrome (DS) from Authority Required (Telephone/online PBS Authorities system) to Authority Required (STREAMLINED). The PBAC also recommended amendments to the current PBS criteria for cannabidiol to improve access for patients with DS, including

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LTD Category 3 (Change to existing listing) PBS General Schedule		syndrome. The submission also requested amendments to the treatment criteria to allow prescribing by a paediatrician without the need for consultation with a neurologist, and continuation of therapy by a general practitioner with a paediatrician. Authority Required (STREAMLINED)		allowing prescribing by paediatricians for both initial and continuing treatment. The PBAC advised that changes to the cannabidiol listing should flow on to fenfluramine and stiripentol. The PBAC noted and welcomed input from neurologists, Epilepsy Action Australia, the Epilepsy Foundation and Pharmaceutical Society of Australia. The PBAC noted that all inputs described that the recommended amendments to the restriction would improve access to cannabidiol and enhance the efficiency of the prescribing process. The PBAC noted that there was a small population that benefits from this treatment and advised that the estimated nil net financial impact to the PBS/RPBS was appropriate.
CICLOSPORIN Eye drops containing ciclosporin 1 mg per mL, 2 mL Vevye® AFT PHARMACEUTICALS (AU) PTY LTD Category 4 (New PBS Listing) PBS General Schedule	Dry eye disease with keratitis	To request listing of a new form of ciclosporin eye drops for the treatment of dry eye disease with keratitis in adult patients whose condition has not been adequately controlled by monotherapy with an artificial tears substitute. Authority Required (Telephone/Online)	Recommended	The PBAC recommended the General Schedule Authority Required (telephone/electronic) listing of ciclosporin eye drops (Vevye) for the treatment of chronic severe dry eye disease with keratitis in adult patients whose condition has not been adequately controlled with an artificial tears substitute. The PBAC's recommendation for listing was based on, among other matters, its assessment that Vevye should not cost any more than the currently PBS-listed ciclosporin eye drops. The PBAC advised that Vevye should join the existing risk sharing arrangement (RSA) for ciclosporin eye drops and that there should be no increase to the expenditure caps.

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DUPILUMAB Injection 300 mg in 2 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled pen Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD Category 2 (Change to existing listing) PBS General Schedule	Chronic obstructive pulmonary disease (COPD)	To request listing of dupilumab for use as add-on maintenance treatment for uncontrolled COPD in adult patients with raised blood eosinophils and on a stable combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA). Authority Required (Telephone/Online)	Recommended	The PBAC recommended the listing of dupilumab as an add-on maintenance treatment for adults with uncontrolled chronic obstructive pulmonary disease (COPD) and type 2 inflammation (defined by the submission as blood eosinophil ≥ 300 cells/µL). In making this recommendation, the PBAC accepted that there was a persistent clinical need for treatment options in patients who continue to experience exacerbations while receiving treatment with triple inhaled therapy. The PBAC acknowledged the support for this listing from individuals who would like access to dupilumab, health care professionals and organisations. The PBAC noted comments describing the significant impact COPD had on the daily lives of patients, impacting their ability to work and socialise, which led to a decline in mental health. The PBAC noted the input highlighted the importance of additional treatment options to help manage impact of the disease on patients, reduce reliance on oral corticosteroids, and ultimately improve long-term health outcomes. The PBAC considered that a price reduction was required for dupilumab to be considered cost-effective and that further revisions to the estimated costs were required. The PBAC considered that with these revisions, a risk sharing arrangement would address remaining uncertainty about the cost. The PBAC advised that if listed, the arrangement should include mepolizumab which the PBAC also considered at the March 2026 meeting for the treatment of the same population. The PBAC noted that flow-on changes to all PBS-subsidised biological medicines listed for nasal polyps, uncontrolled severe allergic asthma, and uncontrolled severe asthma will

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				be required to prevent use of more than one biologic at a time for these indications including uncontrolled COPD.
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 Category 2 (Change to existing listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Gastric cancer (GC) or gastro-oesophageal junction cancer (GOJC)	To request listing of durvalumab for the perioperative treatment (i.e., before and after surgery) of adult patients with GC or GOJC who are eligible for neoadjuvant FLOT (fluorouracil, leucovorin, oxaliplatin, docetaxel) chemotherapy. Authority Required (Telephone/Online)	Recommended	The PBAC recommended the listing of durvalumab for use both before and after surgery in patients with gastric or gastroesophageal junction cancers (GC/GOJC) who are eligible for the chemotherapy combination of fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) before surgery. The PBAC acknowledged that these cancers are challenging to treat and have significant impacts on quality of life despite currently available treatment options. The PBAC was satisfied that addition of durvalumab to existing treatment before and after surgery reduces the risk of the cancer returning and helps patients with GC/GOJC live longer when compared with current standard treatments. The PBAC considered durvalumab would be cost effective with a price reduction to reflect evidence of benefit, cost of other medicines it had recommended for use before and after surgery, uncertainty about subsequent immunotherapy, and the changing landscape with respect to PBS listings for immunotherapy. The PBAC considered that with some minor adjustments to the economic modelling, the estimated cost to the government was reasonable.
EDARAVONE Solution concentrate for I.V. infusion 30 mg in 20 mL Radicava®	Amyotrophic lateral sclerosis (ALS)	To request a change to the existing listing of edaravone for the initial treatment of ALS, to allow initiation of treatment outside public or private hospital settings.	Recommended	This item was considered out of session. The recommendation was made between the November 2025 and March 2026 PBAC meetings. Full outcome available at: www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/recommendations-made-out-of-session-by-the-pbac-between-meet

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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
TEVA PHARMA AUSRALIA PTY LTD Category 3 (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)		Authority Required (Telephone/Online)		
EFGARTIGIMOD ALFA Injection 1000 mg in 5 mL pre-filled syringe Vyvgart® ARGENX AUSTRALIA PTY. LTD. Category 4 (New PBS listing) PBS General Schedule	Generalised myasthenia gravis (gMG)	To request listing of a pre-filled syringe form of efgartigimod alfa for the initial and continuing treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive. Authority Required (Telephone/Online)	Recommended	The PBAC recommended efgartigimod alfa (EFG) 1000 mg / 5.0 mL pre filled syringe (PFS), for the treatment of adult patients with generalised myasthenia gravis (gMG) who are anti acetylcholine receptor (AChR) antibody positive. The PBAC welcomed input from a health care professional and organisation that highlighted the significant and ongoing burden of symptoms that people with gMG experience. The PBAC recommended EFG PFS as a section 100 (Highly Specialised Drug) Authority Required (Written/Online) listing. The PBAC considered that a claim of non inferior effectiveness and non inferior comparative safety of EFG PFS versus EFG SC and EFG IV was reasonable, and noted that there was no data to establish clinical superiority and a higher price of EFG PFS over other therapies recommended for gMG at the March 2025 and November 2025 PBAC meetings (ravulizumab, rozanolixizumab and zilucoplan). The PBAC recommended EFG PFS on the basis that it be priced as per the other gMG medicines recommended (and noting that 1 vial EFG PFS should be priced equivalent to 1 vial EFG SC or 2.4 vials of EFG IV). The PBAC advised that EFG PFS should also enter into the Risk Sharing Arrangement for these previously recommended gMG medicines.

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EFGARTIGIMOD ALFA Solution for subcutaneous injection 1000 mg in 5.6 Injection 1000 mg in 5 mL pre-filled syringe Vyvgart® ARGENX AUSTRALIA PTY. LTD. Category 1 (Change to existing listing) PBS General Schedule	Chronic inflammatory demyelinating polyneuropathy (CIDP)	To request listing of efgartigimod alfa for the treatment of adult patients with progressive or relapsing active CIDP who have had an inadequate response to immunoglobulin (Ig) alone or in combination with another therapeutic treatment, or are refractory to Ig, or have an intolerance or contraindication to Ig. Authority Required (Written or Telephone/Online)	Not Recommended	The PBAC did not recommend efgartigimod alfa (Vyvgart®) for the treatment of active chronic inflammatory demyelinating polyneuropathy (CIDP) in patients whose symptoms continue despite treatment with blood products such as immunoglobulin and for those who cannot tolerate immunoglobulin. CIDP is a chronic autoimmune nerve disorder. The PBAC acknowledged the consumer input received and considered that there is a high unmet need for additional treatment options for people with CIDP. However, the PBAC was not satisfied that the available evidence clearly demonstrated which patients should receive efgartigimod in clinical practice, nor how patients would be safely switched from immunoglobulin treatment to efgartigimod alfa. As the clinical benefits compared with immunoglobulin treatment were uncertain, the PBAC considered that the economic analysis and high estimated cost to the public did not provide enough certainty or information for decision making. Sponsor's comment: Given the PBAC's acknowledgement of the high unmet need in this patient population, argenx is disappointed with the decision not to recommend efgartigimod alfa (Vyvgart®) for the treatment of CIDP. argenx thanks consumers for their input highlighting the significant patient and carer burden, as well as the need for new treatment options in CIDP. The company remains committed to working with the PBAC to ensure the clinical value of efgartigimod in CIDP is fully recognised, and to providing CIDP patients with sustainable

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				access to innovative treatments that help them live healthier and more productive lives, while also reducing the demand on Australia's constrained immunoglobulin supply.
ENOXAPARIN 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 pre-filled syringe 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 pre-filled syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe Clexane® Safety-Lock Clexane® Forte Safety-Lock SANOFI-AVENTIS AUSTRALIA PTY LTD	Prevention and treatment of thrombo-embolic disorders Haemodialysis	To request listing of Clexane with a new safety system, consistent with the existing PBS listings for Clexane Safety-Lock and Clexane Forte Safety-Lock. Restricted Benefit	Not applicable	This item was withdrawn.

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(Other matters) PBS General Schedule				
ENZALUTAMIDE Capsule 40 mg Xtandi® ASTELLAS PHARMA AUSTRALIA PTY LTD Standard re-entry (Change to existing listing) PBS General Schedule	Non-metastatic hormone sensitive prostate cancer (nmHSPC)	Resubmission to request listing of enzalutamide for use with concurrent androgen deprivation therapy in patients with nmHSPC with biochemical recurrence at high-risk for metastasis. Authority Required (Telephone/Online)	Recommended	The PBAC recommended the listing of enzalutamide (Xtandi®), for use in combination with androgen deprivation therapy (ADT), for the treatment of patients who have non-metastatic hormone sensitive prostate cancer (m0HSPC) with high-risk biochemical recurrence (BCR). Patients with high-risk biochemical recurrence have a rapid increase in prostate-specific antigen following initial treatment indicating a greater risk of metastases and death from prostate cancer. The PBAC considered that for patients with m0HSPC enzalutamide plus ADT resulted in improved survival compared to the current treatment of ADT alone. The PBAC considered that the resubmission had largely addressed the key concerns it raised in relation to the previous November 2024 submission and accepted that enzalutamide was cost-effective at the price proposed in the resubmission. However, the PBAC considered that there remained some uncertainty in the estimated number of patients that would use enzalutamide. The PBAC advised that enzalutamide for the treatment of m0HSPC should join the current arrangement in place to manage financial risk of PBS-listed treatments for metastatic hormone sensitive prostate cancer (mHSPC) risk sharing arrangement (RSA) with an increase to the expenditure limits.
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE Sachets containing oral powder 40 g,	Phenylketonuria (PKU)	To request listing of PKU GMPro Delight for the dietary management of PKU in children (from 3 years of age) and adults.	Recommended	The PBAC recommended listing glycomacropeptide formula with long chain polyunsaturated fatty acids docosahexaenoic acid and low in phenylalanine (PKU GMPro Delight®) sachets containing oral powder 40 g for the dietary management of phenylketonuria (PKU) under the same circumstances as

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30 (PKU GMPro Delight) PKU GMPro® Delight NUTRICIA AUSTRALIA PTY LIMITED Category 3 (New PBS listing) PBS General Schedule		Restricted Benefit		glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine (PKU Sphere20®) sachets containing oral powder 35 g for the same indication. The PBAC considered that PKU GMPro Delight should be cost-minimised to the comparator accepted by the NPWP (i.e. PKU Sphere20) at an equivalent price per gram of protein equivalent.
INCOBOTULINUMTOXINA Lyophilised powder for injection 100 units Xeomin® MERZ AUSTRALIA PTY LTD Category 2 (Change to existing listing) PBS Section 100 (Botulinum Toxin Program)	Moderate to severe spasticity of the lower limb in adults following an acute event	To request listing of incobotulinumtoxinA (Xeomin®) for the treatment of moderate to severe spasticity of the lower limb in adults following an acute event. Authority Required (STREAMLINED)	Recommended	The PBAC recommended the listing of incobotulinumtoxinA (Xeomin®) for the treatment of moderate to severe spasticity of the lower limb in adults following stroke, traumatic brain injury, or spinal cord injury. The PBAC noted that the submission did not provide any trials comparing Xeomin directly to Botox and instead, compared Xeomin to Botox using one trial comparing Botox to placebo and two trials comparing Xeomin to placebo. While the PBAC noted there were some uncertainties with the clinical evidence, it considered that overall, Xeomin was likely as effective as botulinum toxin type A (Botox®). The PBAC's recommendation was on the basis that it should be available only under special arrangements under Section 100 (Botulinum Toxin Program) and its assessment that Xeomin® would be cost-effective if it cost no more than the least costly of either Botox or clostridium botulinum type A toxin-haemagglutinin complex (Dysport®). The PBAC advised the equi-effective doses to be Xeomin 1 U = Botox 1 U = Dysport 3.75 U.

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INOTUZUMAB OZOGAMICIN Powder for I.V. infusion 1 mg Besponsa® PFIZER AUSTRALIA PTY LTD Category 3 (Other matters) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Acute lymphoblastic leukaemia (ALL)	To seek PBAC advice on the termination of the Risk Sharing Arrangement (RSA) component of the Deed of agreement for inotuzumab ozogamicin for the treatment of ALL. Authority Required	Advice Provided	The PBAC advised that the Risk Sharing Arrangement (RSA) for inotuzumab ozogamicin for the treatment of acute lymphoblastic leukaemia can be removed. In forming this view, the PBAC noted that utilisation of inotuzumab ozogamicin has remained low and relatively stable over time and that no new clinical uncertainties or changes to the PBS restriction had been identified for inotuzumab ozogamicin since listing. The PBAC considered that the original rationale for including inotuzumab ozogamicin in a shared RSA with blinatumomab, which was to manage uncertain financial estimates and a high incremental cost-effectiveness ratio, had diminished over time.
LANREOTIDE Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe Lacreo SUN PHARMA ANZ PTY LTD Category 4 (New PBS listing) PBS Section 100	Acromegaly Functional carcinoid tumour Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)	To request listing of a new brand of lanreotide for the treatment of three conditions: 1. Patients with acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy or in patients who are dopamine agonist treatment refractory; 2: Patients with symptoms of carcinoid syndrome associated with carcinoid tumours; and 3: Adult patients with unresectable locally	Recommended	The PBAC recommended lanreotide LACREO 60 mg/0.2 mL injection 0.2 mL syringe, LACREO 90 mg/0.3 mL injection 0.3 mL syringe and LACREO 120 mg/0.5 mL injection 0.5 mL syringe for the treatment of acromegaly, functional carcinoid tumour and non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET). The PBAC advised the equi-effective doses to be 1 mg LACREO equals 1 mg Somatuline Autogel. The PBAC noted and welcomed input from an organisation that outlined the physical, psychological and daily burden for patients living with acromegaly, functional carcinoid tumour and GEP-NET. Input from this organisation noted the benefits of lanreotide (LACREO) included reduced treatment and financial burden and improvement in overall quality of life. The PBAC advised that lanreotide LACREO, Mytolac and Somatuline Autogel will be considered equivalent for the purposes of substitution, and flow on changes to other brands will be noted.

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(Highly Specialised Drugs Program)		advanced or metastatic GEP-NETs. Authority Required (STREAMLINED)		
LONCASTUXIMAB TESIRINE Powder for I.V. infusion 10 mg Zynlonta® SWEDISH ORPHAN BIOVITRUM PTY LTD Category 1 (New PBS listing) PBS Section 100 (Efficient Funding Of Chemotherapy)	Diffuse large B-cell lymphoma (DLBCL)	To request listing of loncastuximab tesirine for the treatment of adult patients with relapsed or refractory DLBCL who have received two or more prior lines of therapy. Authority Required (Telephone/Online) for initial treatment Authority Required (STREAMLINED) for continuing treatment	Not Recommended	The PBAC did not recommend loncastuximab tesirine for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who have received two or more prior lines of therapy. The PBAC welcomed input from health care professionals and organisations. The PBAC acknowledged the need for therapies for patients unsuitable for, or relapsing after, CAR-T or bispecific therapies. The PBAC also noted some access and equity considerations, including the potential for delivery in regional cancer centres. The PBAC considered that limitations in the submission evidence did not allow confidence about the extent to which loncastuximab tesirine was more effective than chemoimmunotherapy. However, the PBAC accepted that it was likely reasonable, if uncertain, that loncastuximab tesirine would improve overall survival (the length of time patients remain alive) compared to chemoimmunotherapy. The PBAC considered it was reasonable to accept that the safety of loncastuximab tesirine was similar to chemoimmunotherapy. The PBAC considered that the claims made by the sponsor on the benefits of loncastuximab tesirine to justify its requested price were too optimistic given the uncertain benefits from the clinical data. The PBAC considered that in, addition to the

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				changes to the assessment of costs associated with loncastuximab tesirine proposed by its Sub-Committees, an additional price reduction to the price reduction proposed by the sponsor before the PBAC meeting would be required to achieve cost-effectiveness. The Committee indicated that a financial arrangement with the sponsor would be appropriate to manage any risk that the cost to the PBS of listing loncastuximab tesirine is higher than expected. The PBAC advised that these matters could be addressed in an early re-entry submission. Sponsor's comment: The sponsor had no comment.
MEPOLIZUMAB Injection 100 mg in 1 mL single dose pre-filled pen Nucala® GLAXOSMITHKLINE AUSTRALIA PTY LTD Category 2 (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Chronic obstructive pulmonary disease (COPD)	To request listing of mepolizumab for use in combination with an inhaled corticosteroid (ICS), a long-acting beta-agonist (LABA), and a long-acting muscarinic antagonist (LAMA) for the treatment of adult patients with COPD characterised by an eosinophilic phenotype who continue to experience exacerbations. Authority Required (Written)	Recommended	The PBAC recommended the listing of mepolizumab as an add-on maintenance treatment for adults with uncontrolled chronic obstructive pulmonary disease (COPD) and type 2 inflammation (blood eosinophil ≥ 300 cells/µL). In making this recommendation, the PBAC accepted that there was a persistent clinical need for treatment options in patients who continue to experience exacerbations while receiving treatment with triple inhaled therapy. The PBAC acknowledged the support for this listing from individuals who would like access to mepolizumab, health care professionals and organisations. The PBAC noted that comments highlighted that COPD exacerbations (i.e. sudden worsening of symptoms) significantly limited daily functioning, contributed to a reduced quality of life, and increased the likelihood of future exacerbations. Comments also highlighted the importance of additional treatment options to help manage the significant disease burden, reduce reliance on oral corticosteroids, and ultimately

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				improve long-term outcomes. Overall, the PBAC considered that the submission's claim that mepolizumab was more effective compared to triple inhaled therapy alone was reasonable but that the evidence did not allow certainty about the extent to which the additional benefit would be realised. The PBAC considered that a price reduction was required for mepolizumab to be considered cost-effective and that further revisions to the estimated number of patients that would use mepolizumab were required. The PBAC considered that with these revisions, the remaining uncertainties related to the estimated costs of listing mepolizumab could be managed through an arrangement to manage financial risk. The PBAC advised that if listed, the arrangement should also include dupilumab, which the PBAC also considered at the March 2026 meeting for the treatment of the same population. The PBAC noted that flow-on changes to all PBS-subsidised biological medicines listed for nasal polyps, uncontrolled severe allergic asthma, and uncontrolled severe asthma will be required to prevent use of more than one biologic at a time for these indications including uncontrolled COPD.
MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE Injection (0.5mL) Bexsero®	Prevention of invasive meningococcal disease (IMD) caused by Neisseria meningitidis group B strains	To request the PBAC consider a proposal to expand the current National Immunisation Program (NIP) listing of Bexsero for use in broader infant and adolescent populations to prevent IMD caused by	Advice Provided	The PBAC considered that there was not enough evidence provided to change its previous advice on expanding the population who are eligible for Bexsero immunisation against disease caused by Meningococcal B strains on the National Immunisation Program to include all infants under 2 years old and adolescents through catch-up programs. The PBAC accepted that the clinical need for Bexsero remains well established, the vaccine was effective and the safety profile

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GLAXOSMITHKLINE AUSTRALIA PTY LTD (Change to existing NIP listing)		Neisseria meningitidis group B.		was acceptable. The PBAC noted that there may be potential public health benefits associated with routine Bexsero vaccination, however these were outside the remit of PBAC's standard decision-making criteria and did not justify potential additional costs to Australian taxpayers. The PBAC advised that a price reduction would be required to achieve acceptable cost-effectiveness for Bexsero.
NEMOLIZUMAB Powder for injection containing nemolizumab 30 mg with diluent in pre-filled dual-chamber pen Nemluvio® GALDERMA AUSTRALIA PTY LTD Standard re-entry (New PBS listing) PBS General Schedule	Atopic dermatitis	Resubmission to request listing of nemolizumab for the treatment of moderate to severe atopic dermatitis in patients aged 12 years and older who are eligible for systemic therapy. Authority Required (Telephone/Online)	Recommended	The PBAC recommend the listing of nemolizumab (NEMO) for the treatment of patients with severe atopic dermatitis (AD) affecting the whole body, face, and/or hands. The PBAC welcomed input from organisations and an individual which supported the resubmission. The PBAC recalled it previously did not recommend listing NEMO as it considered the previous submission's claim that NEMO is similarly effective to dupilumab (DUPI) was not adequately supported by the clinical data comparing NEMO and DUPI. The PBAC noted that the resubmission presented additional information which included patients who underwent a longer period (to Week 24) of treatment with NEMO following an inadequate response after treatment with NEMO for 16 weeks. The PBAC considered that based on this new information, NEMO was likely as effective as DUPI. The PBAC's recommendation was based on, among other matters, its assessment that the cost of NEMO should be no more than the least costly of either DUPI or upadacitinib. The PBAC advised that NEMO should join the current risk sharing arrangement for severe AD with no increase to the expenditure caps.
NIVOLUMAB Solution for subcutaneous injection 600 mg in 5 mL	Malignant melanoma Non-Small Cell Lung Cancer (NSCLC) Renal Cell Carcinoma (RCC)	To request listing of a new strength and form of nivolumab for the existing PBS-listed indications, except where nivolumab is	Recommended	The PBAC recommended the listing of nivolumab solution for subcutaneous injection 600 mg in 5 mL for use across the existing PBS listed indications for nivolumab, except where nivolumab is administered 3-weekly or where nivolumab is used in combination with ipilimumab. The PBAC agreed that

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Opdivo® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Category 4 (New PBS listing) PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy Program)	Squamous Cell Carcinoma of the Head and Neck (SCCHN) Urothelial Carcinoma (UC) Oesophageal / Gastro-oesophageal cancers(OC/GC)	administered every three weeks in combination with ipilimumab. Authority Required (Telephone/Online) Authority Required (STREAMLINED)		nivolumab subcutaneous injection should be included in the existing multi-indication (broad) listing for the treatment of immunotherapy-sensitive advanced or metastatic cancers, and that a dual Section 100 (Efficient Funding of Chemotherapy – Related Benefits) and Section 85 (General Schedule) listing was appropriate. The PBAC considered evidence from a head-to-head clinical trial and supporting pharmacokinetic studies and concluded that subcutaneous nivolumab was non-inferior to intravenous nivolumab in terms of effectiveness and safety. The PBAC accepted that subcutaneous nivolumab offers a less invasive mode of administration and may reduce treatment time and infusion chair utilisation, without increasing system burden. The PBAC recommended listing on a cost-minimisation basis, accepting that 600 mg every two weeks or 1200 mg every four weeks of subcutaneous nivolumab is equi-effective to 240 mg every two weeks or 480 mg every four weeks of intravenous nivolumab, respectively. The PBAC noted that the estimated financial impact to the PBS was a net cost saving, with modest savings over time. The PBAC considered that the proposed prescribing instructions differentiating use to flat dosing regimens were appropriate and would support alignment with the existing broad listing arrangements. The PBAC considered that it would be appropriate for NIVO SC to join the existing risk-sharing arrangements in place for NIVO IV without any changes to caps.

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OBINUTUZUMAB Solution for I.V. infusion 1000 mg in 40 mL Gazyva® ROCHE PRODUCTS PTY LTD Category 2 (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Lupus nephritis	To request listing of obinutuzumab for the treatment of adult patients with a confirmed diagnosis of active class III or IV lupus nephritis with or without class V who are receiving standard therapy with mycophenolate and corticosteroids. Authority Required (Telephone/Online)	Recommended	The PBAC recommended obinutuzumab for the treatment of patients with active class III or IV lupus nephritis with or without class V (based in ISN/RPS 2003 classification) who are receiving standard therapy with mycophenolate mofetil (MMF) and corticosteroids. The PBAC welcomed input from health care professionals and consumer and medical organisations highlighting the high clinical need for effective therapies for lupus nephritis. The PBAC acknowledged the impact of lupus nephritis on young women, First Nations people and individuals of Asian and African ancestry. The PBAC noted that lupus nephritis is not only more prevalent in First Nations people but is also associated with a significantly higher disease burden characterised by more severe disease, increased morbidity and higher mortality rates compared to people who are not of First Nations descent. The input outlined that obinutuzumab is associated with reductions in corticosteroid doses and described the clinical meaningfulness of the potential for reductions in corticosteroid related side effects and harms. The PBAC accepted that obinutuzumab was more effective than standard therapy at improving kidney function, such as improved rates of complete kidney recovery when compared with standard therapy alone. However, the REGENCY clinical trial showed that obinutuzumab had higher rates of side effects, including infections and reactions related to administering infusions. In support of its requested price, the sponsor claimed that obinutuzumab would substantially reduce rates of kidney

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				dialysis, transplants and deaths. However, the PBAC considered some of the assumptions of continued benefit beyond the trial duration for these outcomes were overly optimistic. As such, the PBAC advised obinutuzumab would be represent value for money with a price reduction reflecting more realistic estimates of some of the long term benefits and costs. The PBAC considered that revisions were also required to the submission's financial estimates around the prevalence and assumptions about the number of patients who would start using obinutuzumab. The PBAC considered there was a significant risk that people would use obinutuzumab for a longer duration than estimated by the sponsor. The PBAC therefore advised that a risk sharing arrangement with the sponsor would be required to mitigate this risk. The PBAC advised that the listing would necessitate a change to another PBS listing for anifrolumab, a medicine that treats systemic lupus erythematosus, to prevent combination use of anifrolumab with obinutuzumab.
OMALIZUMAB Injection 75 mg in 0.5 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Omlyclo® CELLTRION HEALTHCARE AUSTRALIA PTY LTD	Uncontrolled severe asthma Uncontrolled severe allergic asthma Severe chronic spontaneous urticaria	To request listing of two new forms of the Omlyclo biosimilar brand of omalizumab that mirror the originator brand's current listings with the same strengths and forms. Authority Required	Recommended	The PBAC recommended the listing of omalizumab 75mg and 150mg (Omlyclo®) in the pre-filled pen (PFP) form on the PBS for use in specialist settings for uncontrolled severe asthma and severe chronic spontaneous urticaria. These new PFP pen forms for the 75mg and 150mg strength can be used in the same situations as the existing Omlyclo pre-filled syringe (PFS) forms. The PBAC noted that Omlyclo is a biosimilar to the originator Xolair® and allowed substitution of the brands for one another. However, since current PBS listing of omalizumab for uncontrolled severe allergic asthma in children aged 6 to 12 years is for PFS only, the PBAC decided

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Category 4 (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)				it would not be appropriate to link the PFP to PFS products for this age group and indication. The PBAC considered that the listing of these new Omlyclo forms would not increase the cost to the Australian public as it is expected to replace existing Xolair or Omlyclo pre-filled syringe use.
ODEVIXIBAT Capsule 200 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms Bylvay® IPSEN PTY LTD Category 1 (Change to existing listing) PBS General Schedule	Alagille syndrome (ALGS)	To request listing of odevixibat for the treatment of cholestatic pruritis in ALGS in patients aged 6 months and older. Authority Required	Not Recommended	The PBAC did not recommend odevixibat for the treatment of cholestatic pruritus (severe itching caused by bile build up) in Alagille syndrome (ALGS) in patients aged six months and older. The PBAC noted that ALGS is a rare condition with severe impacts on quality of life, including sleep, comfort, and wellbeing. The PBAC acknowledged the input from consumers, healthcare professionals and organisations describing the substantial burden of cholestatic pruritus in ALGS in this vulnerable population, noting that persistent and severe pruritus may significantly impair sleep, schooling, development, family functioning and mental health. The PBAC considered that there is a clear need for better treatments for this condition. The PBAC considered that there was evidence showing that odevixibat can reduce itching more than current treatments for some patients with ALGS. However, the PBAC noted that no evidence was presented to support any benefit for odevixibat in slowing ALGS progression, helping patients with ALGS to keep their own liver for longer, or improving overall survival. Additionally, the long-term benefits remain uncertain.

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				The PBAC considered that the economic model used to estimate value for money was not reliable due to unsupported assumptions, and the PBAC could not be confident that the benefits justify the requested price. Further, the estimates of the total cost to government were uncertain due to unsupported assumptions about how many people would be eligible for, and receive, treatment. Sponsor's comment: The sponsor had no comment.
PEGCETACOPLAN Solution for subcutaneous infusion 1,080 mg in 20 mL Empaveli® SWEDISH ORPHAN BIOVITRUM PTY LTD Category 2 (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Complement 3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN)	To request listing of pegcetacoplan for the treatment of patients aged 12 years and older with C3G or primary IC-MPGN. Authority Required (Written)	Not Recommended	The PBAC did not recommend listing pegcetacoplan for treatment of complement 3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN). The PBAC welcomed input from individuals, health professionals and organisations. The PBAC considered that there is a high clinical need for treatments for C3G and primary IC-MPGN, which are rare conditions that impact predominantly young people and cause decline in kidney function. The PBAC acknowledged that existing treatments provide only modest improvements in maintaining kidney function. The PBAC acknowledged the impact of C3G and primary IC-MPGN on individuals who are often young adults, working, and raising or starting families. The PBAC noted the impact of chronic kidney disease, relapses and the burden of treatment on their ability to participate in daily activities and their mental health. The PBAC reviewed the clinical evidence comparing the effectiveness and safety of pegcetacoplan with the current standard of care for both people with native kidneys and with

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				C3G/IC-MPGN recurrence following kidney transplantation. The PBAC considered it is possible that pegcetacoplan provides a clinical benefit for some patients in terms of slowing progression to end-stage kidney disease. However, the PBAC noted the clinical benefit was only supported by evidence of improvement in indirect measures of health benefit - reduction in proteinuria (unusually high levels of protein in urine), and slower decline in eGFR (estimated glomerular filtration rate; a test that measures how well your kidneys are filtering waste from your blood) compared to placebo. The clinical evidence also showed that pegcetacoplan was less safe than standard of care, with increased risk of infection. The PBAC considered that the estimated benefits relating to avoiding long-term dialysis and transplant were improbable and highly uncertain due to the limited clinical data, reliance on indirect measures of health benefit, and unsupported assumptions. The PBAC considered that the cost-effectiveness of pegcetacoplan had not been established. In the context of a substantial price reduction for pegcetacoplan, and noting the clinical need and available evidence, the PBAC considered the cost-effectiveness may be able to be assessed using a cost per responder approach. The PBAC considered that a cost per responder approach should provide interpretation, and quantification where possible, of the clinically meaningful benefits that are expected to result from reduced proteinuria and potential reduction in decline in eGFR response, for example, avoiding or delaying dialysis and transplants. The PBAC advised that these matters could be addressed in an early re-entry submission.

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PEGVALIASE Injection 2.5 mg in 0.5 mL pre-filled syringe Injection 10 mg in 0.5 mL pre-filled syringe Injection 20 mg in 1 mL pre-filled syringe Palynziq® BIOMARIN PHARMACEUTICAL AUSTRALIA PTY LTD Standard re-entry (New PBS listing) PBS General Schedule	Phenylketonuria (PKU)	To request listing of pegvaliase for the treatment of patients aged 16 years and older with PKU who have inadequate blood phenylalanine control (baseline blood phenylalanine level above 600 micromole per L) despite prior management with available treatment options (including a phenylalanine restricted diet and sapropterin). An inadequate response to a trial of sapropterin is defined as failure to achieve a 30 per cent or greater reduction in blood phenylalanine from baseline following initial treatment with sapropterin. The submission also seeks PBAC consideration for extending eligibility to patients aged 16 years and older with PKU who have a protein tolerance of less than 15 grams per day, even if sapropterin responsive. Authority Required (Telephone/Online)	Deferred	The PBAC deferred making a recommendation for listing pegvaliase for the treatment of patients with phenylketonuria (PKU) who have inadequate blood phenylalanine (Phe) control despite prior management with available treatment options including a Phe-restricted diet and sapropterin. The PBAC welcomed input from individuals, clinicians and groups. The PBAC acknowledged the challenges of living with PKU including the severe and lifelong burden of dietary restrictions. The PBAC also noted the cognitive impacts of high Phe levels including difficulty concentrating, reduced mental clarity, anxiety and fatigue. The PBAC acknowledged that the existing treatment, sapropterin, does not work adequately in all patients in terms of reducing blood Phe levels and improving dietary restrictions. As such, the PBAC recognised the high unmet clinical need for effective treatments in the proposed patient population. The PBAC accepted that pegvaliase is more effective than a Phe-restricted diet alone at reducing blood Phe levels. However, the PBAC considered the evidence presented in the submission did not allow confidence about the extent to which pegvaliase would provide benefits compared to a Phe-restricted diet alone. This was because of limitations in the quality of clinical evidence and methodological concerns with available studies. The PBAC acknowledged reliable clinical data were difficult to obtain given the rarity of disease. The PBAC noted that pegvaliase was associated with higher rates of hypersensitivity and skin reactions compared with a Phe-restricted diet alone.

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				However, the PBAC considered it was unclear whether the sponsor's proposed pricing structure and risk sharing arrangement (RSA) proposal would achieve a cost-effective price and adequately manage the financial risk to the Commonwealth. The deferral was to allow further consultation with the sponsor and the Department regarding how best to implement the intent of the sponsor's requested pricing and RSA proposal. Sponsor's comment: BioMarin welcomes the PBAC's acknowledgment of the significant unmet clinical need faced by people living with PKU who are unable to achieve adequate blood Phe control despite existing treatment options. We look forward to working collaboratively with the PBAC and the Department to explore a path forward for these patients.
RESPIRATORY SYNCYTIAL VIRUS VACCINE Powder and suspension for injection (0.5 mL) Arexvy® GLAXOSMITHKLINE AUSTRALIA PTY LT Standard re-entry (Change to existing NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	Resubmission to request a change to the National Immunisation Program (NIP) listing of Arexvy to extend eligibility to individuals aged 60 to 74 years who are at high risk of lower respiratory tract disease caused by RSV. The resubmission also requests that the PBAC reconsider the parameters upon which the cost-effectiveness of Arexvy was previously recommended for	Recommended	The PBAC recommended a change to the previously recommended National Immunisation Program (NIP) listing for respiratory syncytial virus vaccine (RSVPreF3 OA, Arexvy®). The submission requested NIP listing for adults aged 60-74 years with at least one condition associated with increased risk of severe respiratory syncytial virus vaccine (RSV) disease as described in the Australian Immunisation Handbook (AIH). The PBAC welcomed input from health care professionals and organisations, which supported the proposed listing, especially for patients aged 60-74 years with underlying medical conditions. The PBAC considered that there is a high clinical need for vaccines to reduce the risk of RSV in older

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		older adults aged 75 years and older and First Nations adults aged 60 to 74 years based on updated clinical and epidemiological evidence.		adults. Noting (i) the varying risk profiles for severe RSV among the subgroups within the proposed population, (ii) that it was likely that more than half of the population aged 60-74 years would meet the criteria for increased risk, and (iii) the potential for improved outcomes at the population level with a broader listing, the PBAC recommended expanding the eligible population to include all people aged 60-74 years. As the PBAC previously recommended RSVPreF3 OA for all adults aged 75 years and above, the revised NIP listing would allow a single dose of vaccine for all people aged 60 years and above. Consistent with its previous advice in July 2025, the PBAC considered that the vaccine was superior to no vaccine in terms of effectiveness with an acceptable safety profile. However, some of the claims made by the sponsor to support its requested price were, in the PBAC's view, not adequately supported by the clinical evidence. The PBAC advised the cost of the vaccine would be acceptable with a price reduction reflecting more realistic estimates of benefits and costs. The PBAC acknowledged the sponsor may be unwilling to proceed with a recommendation for the eligible population to include all people aged 60-74 years, based on comments in the pre-PBAC response. The PBAC noted the sponsor's proposal to further restrict eligibility to people aged 65-74 years at increased risk of severe RSV. The PBAC did not consider there was a sound clinical basis to restrict the population at increased risk to those aged above 65 years. However, it accepted that the population with the highest

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				clinical need was those with increased risk. The PBAC therefore recommended, in the event that a listing for all people aged 60-74 years was unable to be progressed, restricting the eligible population to those aged 60-74 years at increased risk of severe RSV disease (as defined by ATAGI). The resubmission also requested further consideration of the PBAC's July 2025 positive recommendation for RSVPreF3 OA, which had recommended NIP listing of PSVPreF3 for those at least 75 years and First Nations adults 60-74 years. The resubmission sought a higher price based on more favourable estimates of benefits than those accepted by the PBAC in December 2025. The PBAC advised that the resubmission evidence did not adequately justify these revisions and therefore did not support any changes.
RETIFANLIMAB Solution concentrate for I.V. infusion 500 mg in 20 mL Zynyz® SPECIALISED THERAPEUTICS ALIM PTY LTD Matters outstanding (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Squamous cell anal carcinoma (SCAC)	To request listing of retifanlimab for use in combination with carboplatin and paclitaxel for the treatment of inoperable locally recurrent or metastatic SCAC not previously treated with systemic chemotherapy. This item was deferred at the November 2025 PBAC meeting. Authority Required (STREAMLINED)	Recommended	The PBAC recommended the listing of retifanlimab when used together with chemotherapy (carboplatin and paclitaxel), to treat people with cancer of the lining of the anus, specifically those with squamous cell anal cancer (SCAC) that cannot be removed by surgery, has spread, and has not been previously treated with chemotherapy. The PBAC recalled input from health professionals and organisations in relation to the November 2025 submission, noting the severity of disease and need for new treatments for this rare cancer. The PBAC recalled it previously accepted that retifanlimab was more effective than chemotherapy alone at delaying cancer progression. The PBAC recalled it had previously deferred making a decision on the PBS listing of retifanlimab as it was unknown at the time if the Therapeutic Goods Administration (TGA) would approve its registration. After receiving confirmation that the TGA was likely to approve retifanlimab, the PBAC

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				recommended that retifanlimab be listed at a lower price commensurate with the benefit it provides over chemotherapy. The PBAC considered that the lower price should be determined based on the economic model with updated inputs provided by the sponsor prior to the PBAC meeting.
RETIFANLIMAB Solution concentrate for I.V. infusion 500 mg in 20 mL Zynyz® SPECIALISED THERAPEUTICS ALIM PTY LTD Matters outstanding (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Merkel cell carcinoma (MCC)	To request listing of retifanlimab for the treatment of metastatic or recurrent, locally advanced MCC not amenable to curative surgery or radiation. This item was deferred at the November 2025 PBAC meeting. Authority Required (STREAMLINED)	Recommended	The PBAC recommended the listing of retifanlimab for the treatment of Merkel cell carcinoma (MCC, a type of skin cancer) which has spread to another part of the body or recurred and cannot be cured by surgery or radiation. The PBAC recalled input from individuals, health care professionals and organisations from its November 2025 consideration, and noted there is an unmet clinical need for treatments of MCC. The PBAC recalled it previously did not accept the sponsor's claim that retifanlimab is more safe and effective than avelumab for the treatment of MCC but accepted that retifanlimab is as safe and effective as avelumab for MCC. The PBAC recalled it previously deferred making a decision on the PBS listing of retifanlimab as it was unknown at the time if the Therapeutic Goods Administration (TGA) would approve the registration of retifanlimab. After receiving confirmation that the TGA was likely to approve retifanlimab, the PBAC recommended listing retifanlimab at a cost no higher than that of a course of treatment of avelumab. The PBAC expected that the overall financial cost would increase slightly once retifanlimab was available on the PBS, as retifanlimab would provide access to a small number of extra patients with locally advanced MCC. The PBAC

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				considered that retifanlimab should be included in the existing risk sharing arrangement for MCC. The PBAC considered that 500 mg of retifanlimab every 4 weeks would be equivalent to 800 mg of avelumab every 2 weeks, based on the flat dosing regimens recommended in their respective product information. The PBAC noted that flow on changes to the avelumab PBS listing would be required to include the clinical criterion 'Patient must be untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at initiation therapy for this condition'.
RILUZOLE Oral suspension 50 mg per 10 mL, 300 mL Teglutik® ASTERI PHARMA PTY LTD Category 4 (Change to existing listing) PBS General Schedule	Amyotrophic lateral sclerosis	To request that riluzole oral liquid be considered as an exempt item under section 84AH of the National Health Act 1953. Where a pharmaceutical item is determined to be an exempt item, that pharmaceutical item is excluded from fifteen year Anniversary Price, first new brand and price disclosure reductions. Exempt items are not exempt from five and ten year Anniversary Price reductions. Authority Required (Telephone/Online)	Advice Provided	The PBAC advised that riluzole oral suspension 50 mg per 10 mL, 300 mL (Teglutik®) can be considered as an exempt item under section 84AH of the National Health Act 1953 on the basis that the oral suspension form of riluzole is the only suitable option for patients for whom the PBS-listed tablet form is unsuitable due to difficulties in swallowing. The PBAC considered that no other PBS listed product is bioequivalent, biosimilar or 'a' flagged to riluzole oral suspension, and noted there were no alternative brands of the riluzole oral suspension.
RISPERIDONE Subcutaneous injection (modified	Schizophrenia	To request listing of a new subcutaneous form of risperidone with multiple	Recommended	The PBAC recommended the listing of a long acting (modified release (MR)) subcutaneous (SC) injectable form of risperidone for the treatment of adult patients with

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release) 50 mg in 0.14 mL pre-filled syringe Subcutaneous injection (modified release) 75 mg in 0.21 mL pre-filled syringe Subcutaneous injection (modified release) 100 mg in 0.28 mL pre-filled syringe Subcutaneous injection (modified release) 125 mg in 0.35 mL pre-filled syringe Uzedy® TEVA PHARMA AUSTRALIA PTY LTD Category 2 (New PBS listing) PBS General Schedule		strengths for the treatment of adult patients with schizophrenia. Authority Required (STREAMLINED)		schizophrenia. The PBAC welcomed input from health care professionals and a joint letter from organisations. The PBAC agreed that the introduction of MRSC risperidone may support more consistent use of antipsychotic therapy for patients with schizophrenia. The PBAC considered that MRSC risperidone had similar safety and effectiveness to paliperidone 1 monthly (PP1M) long acting injection (LAI) and aripiprazole 1 monthly (A1M) LAI. The PBAC also considered MRSC risperidone had similar safety and effectiveness to risperidone 2 weekly intramuscular LAI, and risperidone 4 weekly intramuscular LAI. The PBAC considered MRSC risperidone 75 mg administered once monthly to be equi-effective to PP1M 37.5 mg once monthly and A1M 352 mg once monthly. The PBAC advised that the cost of MRSC would be acceptable if the overall cost was not higher than the lowest cost LAI antipsychotic therapy of aripiprazole, paliperidone, or risperidone.
ROMIDEPSIN Injection set including 1 vial powder for injection 10 mg and 2 mL solvent ROMIDEPSIN-REACH REACH PHARMACEUTICALS PTY LTD Category 2 (New PBS listing)	Relapsed or refractory peripheral T-cell lymphoma	To request listing of romidepsin for the treatment of adults patients with peripheral T-cell lymphoma who have received at least one prior systemic therapy. Authority Required (Telephone/Online)	Recommended	The PBAC recommended the listing of romidepsin for the treatment of patients with peripheral T-cell lymphoma whose disease has returned or did not respond to chemotherapy. The PBAC noted there was a high clinical need for additional therapies for this patient population and that the input from individuals, health care professionals and organisations highlighted this need. The PBAC considered it likely that romidepsin will provide similar health outcomes to pralatrexate in the proposed patient population. The PBAC considered that the price of romidepsin would be

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PBS Section 100 (Efficient Funding of Chemotherapy Program)				acceptable if it cost no more than pralatrexate, assuming the same duration of treatment. The PBAC considered that 3 doses of romidepsin at 14 mg/m2 every 28-day cycle for 3.5 months (3.80 cycles) would be equivalent to 6 doses of pralatrexate at 30 mg/m2 every 49-day cycle for 3.5 months (2.17 cycles). The PBAC noted that flow on changes to the existing pralatrexate listings would be required to prevent use of romidepsin and pralatrexate in combination for this condition.
RUXOLITINIB Tablet 5 mg Tablet 10 mg Tablet 15 mg Tablet 20 mg Jakavi® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 4 (Change to existing listing) PBS General Schedule	Myelofibrosis Graft versus host disease Polycythemia vera	To request a change to all existing listings of ruxolitinib for all indications to allow prescribing by nurse practitioners. Authority Required	Recommended	The PBAC recommended the addition of nurse practitioners (NPs) as authorised prescribers for ruxolitinib on Pharmaceutical Benefits Scheme (PBS), in the continuing treatment phase of all current indications. The PBAC noted and welcomed input from a health care professional. The PBAC acknowledged the key role of nurse practitioners in patient care. In its consideration, the PBAC recalled its July 2025 review of General Schedule oncology and haematology medicines, and whether these should be eligible for NP prescribing. Ruxolitinib was not considered at this meeting as it had not been identified for review by stakeholders. For oncological or haematological conditions in general, the PBAC considered that the clinical work up required for a diagnosis and differential diagnosis may be complex and likely require that a patient's care be overseen by an oncologist or haematologist. As such, the PBAC was of a view that limiting NP prescribing to continuing therapy with a specific medicine was more suitable, rather than allowing NP prescribing in both initiation and continuing settings. It considered that NPs sharing

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				patient care with a medical practitioner would assist in mitigating potential risks. In its current decision, the PBAC advised that listing for ruxolitinib should follow precedent for other NP prescribing items for other haematological drugs. The PBAC considered that its decision would be no additional cost to the PBS.
SARS-CoV-2 mRNA Injection (0.5mL) Spikevax® MODERNA AUSTRALIA PTY LTD Category 2 (New NIP listing)	Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2	To request a National Immunisation Program (NIP) listing for the prevention of coronavirus disease 2019 (COVID-19) in individuals aged 18 years and older who have specific medical conditions that increase their risk of severe COVID-19.	Not Applicable	The PBAC recommendation cannot be made public until the TGA outcome is known.
SELPERCATINIB Capsule 40 mg Capsule 80 mg Retevmo® ELI LILLY AUSTRALIA PTY LTD Category 1 (Change to existing listing) PBS General Schedule	Medullary thyroid cancer (MTC)	To request listing of selpercatinib for the treatment of patients with advanced or metastatic MTC with a rearranged during transfection (RET) mutation. Authority Required (STREAMLINED)	Recommended	The PBAC recommended the listing of selpercatinib (Retevmo®) on the PBS, for the treatment of patients with locally advanced or metastatic medullary thyroid cancer (MTC), a rare type of thyroid cancer, that has a confirmed RET gene variant and cannot be surgically removed. The PBAC finalised its advice for selpercatinib out of session, following notification that, at its April 2026 meeting, the Medical Services Advisory Committee (MSAC) supported public funding of the related genetic testing to detect RET variants. The PBAC welcomed input from individuals, health care professionals and organisations which described the debilitating impacts of progressive MTC, limited funded treatment options, and potential benefits associated with

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				selpercatinib. The PBAC considered that because selpercatinib could be taken by mouth, it would help support access for rural and regional patients. The PBAC considered there was a high clinical need for patients with progressive MTC that cannot be surgically removed. However, the PBAC considered that the need for patients with indolent (slow growing) MTC was low and the benefits of treating these patients with selpercatinib was uncertain. The PBAC noted there was evidence that selpercatinib delayed the time before cancer worsened compared with current treatments. While it appeared that selpercatinib may help people with MTC to live longer (overall survival), the size of this benefit was highly uncertain. The PBAC considered that the price proposed for selpercatinib was unacceptably high, and value for money was unclear because it was uncertain how long patients would stay on treatment and what the long-term benefits would be. The PBAC considered that the price for selpercatinib the treatment of MTC would be acceptable at the same price it is currently listed on the PBS for lung cancer. The PBAC considered changes to the estimated number of treated patients were required and noted there was likely to be an additional small population of patients diagnosed with locally advanced or metastatic MTC in the last few years who may be appropriate for treatment with selpercatinib once it is listed on the PBS. The PBAC recommended an arrangement should be in place to manage the financial risk to PBS associated with potential use of selpercatinib in patients with slow growing disease.

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				As part of its recommendation, the PBAC nominated selpercatinib to proceed through Pricing Pathway A, reflecting the clinical need and anticipated benefit.
TACROLIMUS Ointment 1 mg per g, 30 g aZematop® ARROTEX PHARMACEUTICALS PTY LTD Matters arising from the minutes (New PBS listing) PBS General Schedule	Atopic dermatitis	To request the PBAC review the revised proposed price, the restrictions, and the previously estimated utilisation of tacrolimus for the treatment of moderate to severe atopic dermatitis. This item was previously recommended by the PBAC at its July 2025 meeting.	Recommended	The PBAC recommended the listing of 0.1% tacrolimus ointment for the treatment of flare-ups in to moderate to severe atopic dermatitis (AD) affecting the body, face and eyelids in patients whose condition is not adequately controlled with topical corticosteroids. The PBAC recalled that it had previously recommended 0.1% tacrolimus for a broader population as an alternative to topical corticosteroids. The PBAC considered that the proposed restriction, with some changes, would better limit use of 0.1% tacrolimus for flares to use after treatment with topical corticosteroids. The PBAC advised that the cost of 0.1% tacrolimus would be acceptable if the overall cost was similar to 1% pimecrolimus. The PBAC considered that 0.1% tacrolimus may be used in patients who may not have trialled topical corticosteroids first and recommended a risk sharing arrangement (RSA) to manage this risk.
TAFAMIDIS Capsule 61 mg Vyndamax® PFIZER AUSTRALIA PTY LTD Category 3 (Other matters)	Transthyretin amyloid cardiomyopathy (ATTR-CM)	To request revision of the previously estimated utilisation of tafamidis for the treatment of ATTR-CM, specifically, an increase to the subsidisation caps for the current Risk Sharing Arrangement (RSA). Authority Required (Written or Telephone/Online) for initial treatment	Not Recommended	The PBAC did not recommend changes to the risk sharing arrangement (RSA) for tafamidis for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM). The PBAC agreed that a change to the RSA expenditure caps may be appropriate, but not to the degree proposed. The PBAC considered that the revised financial estimates and prevalence data presented in the submission were uncertain. The PBAC recognised that newer diagnostic techniques (i.e. bone scanning) have increased ATTR-CM diagnosis, and expanded the population treated with tafamidis above the existing patient estimates. The PBAC raised concerns that the expanded population may differ from the population that

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PBS General Schedule		Authority Required (Telephone/Online) for continuing treatment		was originally recommended for PBS listing, especially with different diagnostic criteria and the use of SGLT2 inhibitors in heart failure with preserved ejection fraction (HFpEF). The PBAC advised that a submission was required that provides evidence supporting equivalence between diagnosis of ATTR-CM using the clinical trial (ATTRACT) criteria and bone scanning, and that the magnitude of benefit is the same across the whole population. Sponsor's comment: The sponsor had no comment.
TAFASITAMAB Powder for I.V. infusion 200 mg Minjuvi® SPECIALISED THERAPEUTICS ALIM PTY LTD Matters outstanding (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Relapsed and/or refractory follicular lymphoma (FL)	To request listing of tafasitamab for use in combination with lenalidomide and rituximab for the treatment of patients with relapsed and/or refractory FL. This item was deferred at the November 2025 PBAC meeting. Authority Required (Telephone/Online)	Recommended	The PBAC recommended the PBS listing of tafasitamab for use in combination with lenalidomide and rituximab for the treatment of patients with relapsed or refractory follicular lymphoma (FL). In November 2025, the PBAC was of a mind to recommend tafasitamab but deferred its decision as the Therapeutics Goods Administration had not yet approved the medicine. At its March 2026 meeting, the PBAC made its recommendation noting that the TGA has since supported the registration of tafasitamab in Australia. The PBAC noted previous input from health care professionals and organisations. It acknowledged the unmet needs for patients with FL, particularly those who are not fit for or unable to access stem cell transplantation. While there were no head-to-head trials, the PBAC noted it has previously accepted that tafasitamab was more effective than rituximab-based chemotherapy at improving progression-free survival (the length of time that patients lived without their cancer progressing after treatment). However, the evidence in the submission did not allow

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				confidence about the extent to which these outcomes would be realised in Australia. The tafasitamab trial included treatment with lenalidomide and rituximab in place of rituximab-based chemotherapy in the tafasitamab and control arms of the study. Rituximab-based chemotherapy is standard of care in Australian clinical practice. Also, the trial results did not clearly show that tafasitamab was better at improving overall survival (length of time that patients remained alive after starting treatment). The PBAC considered that tafasitamab (with lenalidomide and rituximab) was less safe than rituximab-based chemotherapy. The PBAC considered that the benefits claimed by the sponsor to justify its requested price were too optimistic, particularly its estimates of the increase in survival. The PBAC considered that a reduced price that reflected more realistic estimates of benefits would be acceptable. The PBAC considered the overall cost to the public to be overestimated and advised that adjustments were required in estimating a more accurate cost. The PBAC considered a risk-sharing arrangement was required to address any residual uncertainty regarding the estimated patient numbers. The PBAC noted that listing tafasitamab for use in combination with lenalidomide and rituximab would require a Section 100 Highly Specialised Drug Program Authority Required (Telephone/Online) listing of lenalidomide to enable use in combination with tafasitamab.

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TARLATAMAB Powder for injection 1 mg Powder for injection 10 mg Imdelltra® AMGEN AUSTRALIA PTY LIMITED Category 1 (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Extensive-stage small cell lung cancer (ES-SCLC)	To request listing of tarlatamab for second-line and subsequent treatment of adult patients with ES-SCLC whose disease has progressed on or after platinum-based chemotherapy. Authority Required (STREAMLINED)	Not Recommended	The PBAC did not recommend tarlatamab for the treatment of extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after first line treatment of platinum-based chemotherapy. The PBAC noted there is a high clinical need for patients in this therapeutical area, as ES-SCLC is a rapidly progressive disease and there are limited effective treatments in the second- and later-line settings. The PBAC noted and welcomed comments from health care professionals, individuals who would like access to tarlatamab, and medical/consumer organisations. The PBAC noted comments highlighting that there was a high clinical need for effective therapies for ES-SCLC, noting that patients currently have few effective treatment options, with only modest clinical benefit, and typically face rapidly progressive disease, substantial symptom burden, and short survival. The PBAC noted that the trial evidence suggested that tarlatamab was associated with benefits in terms of progression free survival (PFS) and overall survival (OS) compared to standard of care (SOC) chemotherapy. However, the PBAC noted significant safety concerns, including the high risk of immune effector cell-associated neurotoxicity syndrome (ICANs) and cytokine release syndrome (CRS), which were likely to have to a large impact in clinical practice. The PBAC noted key uncertainties related to the economic model and considered that the OS projections were overly optimistic. The PBAC considered that changes to the model assumptions and a substantial price reduction were required to achieve a cost-effective listing that reflected more realistic estimates of benefits and costs. The PBAC considered that a risk sharing arrangement was required to mitigate the risk

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				that people would access the subsidy outside the proposed criteria. The PBAC advised that the remaining issues could be addressed in an early re-entry submission.
TECLISTAMAB Solution for subcutaneous injection 30 mg in 3 mL Solution for subcutaneous injection 153 mg in 1.7 mL Tecvayli® JANSSEN-CILAG PTY LTD Category 2 (New PBS listing) PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy Program)	Relapsed or refractory multiple myeloma (RRMM)	To request listing of teclistamab for the treatment of adult patients with RRMM who have received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Authority Required (Telephone/Online)	Recommended	The PBAC recommended that teclistamab be listed on the PBS for the treatment of patients with relapsed or refractory multiple myeloma (RRMM) who have received at least 3 prior lines of therapy. The PBAC considered that the use of teclistamab would result in similar outcomes (both in terms of efficacy and safety) as elranatamab, which is currently PBS listed for the treatment of RRMM in the same population requested for teclistamab. The PBAC welcomed the input from individuals, health care professionals and organisations. The PBAC noted that the input highlighted the continued need for new and effective therapies for patients with RRMM. The PBAC noted the positive responses to treatment for patients who have accessed teclistamab via clinical trials and the substantial improvements that treatment offered to their quality of life. The PBAC considered that the requested restrictions, which aligned with the elranatamab restrictions, were appropriate. The PBAC advised that a flow on change to the elranatamab restrictions would be required to allow switching between teclistamab and elranatamab in the absence of disease progression (e.g. in case of intolerance to one drug). The PBAC also considered that the price of teclistamab should equal that of elranatamab and, as such, the listing of teclistamab on the PBS should have little to no impact on overall costs for the PBS. The PBAC advised that teclistamab should join the arrangement currently in place for elranatamab to manage financial risks with no increase in the existing spending limits.

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TILDRAKIZUMAB Injection 100 mg in 1 mL single dose pre-filled syringe Ilumya® SUN PHARMA ANZ PTY LTD Category 3 (Change to existing listing) PBS General Schedule	Severe chronic plaque psoriasis	To request a change to the existing listings for tildrakizumab for the continuing treatment of severe chronic plaque psoriasis, to allow the maintenance dose to be increased from 100 mg to 200 mg per administration, administered every 12 weeks. Authority Required	Recommended	The PBAC recommended tildrakizumab 200 mg (100 mg/mL injection, 2 x 1 mL syringe) for the treatment of severe chronic plaque psoriasis. The PBAC considered that tildrakizumab 200 mg would result in the same outcomes (i.e. efficacy and safety) compared with tildrakizumab 100 mg. The PBAC noted and welcomed input from the Australasian College of Dermatologists, who advocated for increasing the maintenance dose to 200 mg to provide an opportunity to improve outcomes in patient with severe disease or obesity. The PBAC considered that treating doctors, at their discretion, may escalate the dose of tildrakizumab to 200 mg in any patient who has responded adequately to the most recent course of tildrakizumab 100 mg, noting that the magnitude of any improved outcomes may be modest.
TIRZEPATIDE Solution for injection 2.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 5 mg in 0.5 mL vial/pre filled pen Solution for injection 7.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 10 mg in 0.5 mL vial/pre-filled pen Solution for injection 12.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 15 mg in 0.5 mL vial/pre-filled pen	Type 2 diabetes mellitus (T2DM)	Resubmission to request listing of tirzepatide for the treatment of adults with inadequately controlled T2DM. This item was deferred at the July 2025 PBAC meeting. Authority Required (Telephone/Online)	Recommended	The PBAC recommended the listing of tirzepatide (Mounjaro®) for the treatment of adults with inadequately controlled type 2 diabetes mellitus. The PBAC recalled input from individuals, health care professionals and organisations in relation to the July 2025 submission, noting benefits of tirzepatide use including improved daily blood glucose readings, improved HbA1c results and weight loss and noting the high cost of tirzepatide making it difficult for some people to access. The PBAC acknowledged the clinical need for additional effective treatment options for people with type 2 diabetes mellitus, noting that a proportion of patients do not achieve adequate glycaemic control with currently PBS-listed therapies. The PBAC noted that tirzepatide is currently available through the private market and considered that PBS listing would improve equity of access, particularly for patients for whom cost may be a barrier.

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Injection 4.17 milligrams per mL (2.5 mg per dose) in multi-dose pre-filled pen, 4 dose Injection 8.33 milligrams per mL (5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 12.5 milligrams per mL (7.5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 16.67 milligrams per mL (10 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 20.83 milligrams per mL (12.5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 25 milligrams per mL (15 mg per dose) in multi-dose pre-filled pen, 4 doses Mounjaro® Mounjaro® KwikPen® ELI LILLY AUSTRALIA PTY LTD Matters outstanding				The PBAC noted that it had previously considered tirzepatide at its July 2023, November 2024 and July 2025 meetings, and that the current submission included revisions in response to the PBAC deferring making a recommendation for tirzepatide at its July 2025 meeting. These revisions included changes to the proposed pricing, updated estimates of the number of patients that would use tirzepatide and a revised approach to managing financial risks. The PBAC considered tirzepatide 10 mg and 15 mg strengths to be cost-effective, and tirzepatide 5 mg would be cost-effective with a reduced price. The PBAC accepted the sponsor's revised estimates of the number of patients that would use tirzepatide, considering these to be reasonable for the purposes of the submission, while acknowledging ongoing uncertainties related to changes in the market dynamics and supply constraints. The PBAC accepted the supply of tirzepatide under normal PBS arrangements and considered this appropriate to support equitable access through community pharmacy. The PBAC requested that arrangements for managing financial risks be progressed separately between the sponsor and the Department.

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(New PBS listing) PBS General Schedule				
TOFERSEN Solution for intrathecal injection 100 mg in 15 mL Qalsody® BIOGEN AUSTRALIA PTY LTD Early Re-entry (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Amyotrophic lateral sclerosis (ALS)	Resubmission to request listing of tofersen for the treatment of ALS associated with a mutation in the superoxide dismutase 1 gene in patients who have not experienced respiratory failure.	Recommended	The PBAC recommended listing tofersen (Qalsody®) on the PBS for the treatment of patients with amyotrophic lateral sclerosis (ALS) who have a superoxide dimutase 1 (SOD1) gene pathogenic variant. The PBAC recalled receiving input from individuals, health care professionals and organisations in November 2025 with the original submission. It noted the high unmet need for targeted treatments for this rare subtype of ALS. The PBAC acknowledged the progressive nature of the disease and that any slowing of disease progression or retention of functional capacities was a crucial factor in improving patient quality of life. The PBAC recalled that in November 2025 it had considered that, although not demonstrated statistically in the trial, based on biomarkers (plasma neurofilament light chain, an indicator of neurological disease progression), tofersen was likely more effective than best supportive care at slowing the progression of SOD1-ALS and increasing overall survival. However, the PBAC noted that the effect of tofersen in preventing loss of physical function would likely be modest. The PBAC considered that given the progressive nature of SOD1-ALS, stabilisation of disease would still be beneficial for patients, their families and their carers. The PBAC also previously noted that tofersen was less safe than best supportive care, with side effects mainly associated with its administration via lumbar puncture. The PBAC considered that the cost requested by the sponsor in the resubmission was acceptable. The PBAC also considered that the estimates of eligible patients and

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				associated costs presented in the resubmission were reasonable with minor changes. The PBAC considered that the risk sharing arrangement proposed by the sponsor would mitigate the risk associated with the uncertain long-term benefits of tofersen and the uncertain duration of therapy. The PBAC advised that the listing would require changes to the restrictions for the PBS-listed medicine edaravone to prevent combined use of edaravone and tofersen.
TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® ASTRAZENECA PTY LTD Category 2 (Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy Program)	Breast cancer	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)	Not Recommended	The PBAC did not recommend listing trastuzumab deruxtecan (Enhertu®) on the PBS 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 (mBC) who have received at least one prior line of endocrine therapy (ET) in the metastatic setting and are no longer suitable for further ET. The PBAC welcomed input from health professionals and organisations, which highlighted the burden of metastatic breast cancer and its treatment on patients and noted the value of choice in deciding the order of treatments for mBC. The PBAC accepted that trastuzumab deruxtecan was more effective than chemotherapy in improving the length of time that patients lived without their cancer getting worse in patients with HER2-low mBC, but considered that the evidence included in the submission did not allow confidence about the extent of benefit for patients with HER2-ultralow mBC because of the small number of these patients in the trial and uncertainty in the testing to identify HER2-ultralow mBC. The PBAC noted that trastuzumab deruxtecan caused a clear increase in harms compared with chemotherapy including life-threatening adverse events, and did not appear

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				to extend life expectancy. The claimed benefits of trastuzumab deruxtecan were, in the PBAC's view, uncertain and overestimated. The PBAC advised that trastuzumab deruxtecan was not cost effective at the price requested when more realistic estimates of benefits and costs were considered.
UPADACITINIB Tablet 15 mg Tablet 30 mg Tablet 45 mg Rinvoq® ABBVIE PTY LTD Category 2 (Change to existing listing) PBS General Schedule	Fistulising Crohn's disease (FCD)	To request listing of upadacitinib for the treatment of adult patients with complex refractory FCD who have an externally draining enterocutaneous or rectovaginal fistula. Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment	Recommended	The PBAC recommended listing upadacitinib (Rinvoq®) on the PBS for the treatment of complex refractory fistulising Crohn's disease (FCD). The PBAC welcomed the input from health professionals and organisations that supported the listing and acknowledged fistulising disease is a severe and debilitating complication of Crohn's disease that has a profound impact on patients and there remains a clinical need for new and effective therapies to help patients manage their condition, as many patients do not respond to or lose response to current treatments. The PBAC considered the clinical evidence presented was uncertain as the evidence base was largely based on small groups of patients with FCD from larger Crohn's disease trials. However, the PBAC acknowledged the treatments it had previously recommended for FCD were supported by similarly uncertain evidence. On balance, the PBAC was satisfied that upadacitinib was likely to be as effective and safe as the other PBS listed therapies for FCD, including infliximab, adalimumab and ustekinumab. The PBAC advised the cost of upadacitinib would be acceptable if the overall cost per patient was not higher than the least costly PBS listed therapy for FCD, and the listing would likely be cost neutral or result in a small cost saving to the PBS if listed on that basis. The PBAC advised the restrictions should align with the other

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				PBS listed therapies for FCD including aligning with its recommendation for the broader inflammatory bowel diseases restriction changes made at the same meeting. The PBAC recommended an additional listing for the 30 mg form of upadacitinib for induction therapy in FCD, severe Crohn's disease and ulcerative colitis for patients with severe renal impairment (as the standard 45 mg initial dose is not appropriate for these patients).
USTEKINUMAB Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Ardelya® SANDOZ PTY LTD Category 3 (New PBS listing) PBS General Schedule	Severe chronic plaque psoriasis Severe psoriatic arthritis	To request listing of a new ustekinumab biosimilar for the treatment of severe chronic plaque psoriasis and severe psoriatic arthritis that mirrors the originator brand's current listings. Authority Required	Recommended	The PBAC recommended listing of a new ustekinumab biosimilar (Ardelya®) in 45 mg and 90 mg pre-filled syringe (PFS) forms for the treatment of adult patients with severe chronic plaque psoriasis and severe psoriatic arthritis on a cost-minimisation basis and under the same conditions as its reference biologic (Stelara®). The PBAC advised the equi-effective doses to be 1 mg Ardelya = 1 mg Stelara. The PBAC noted the sponsor's request that the authority levels for Ardelya should be consistent with those for Steqeyma (the first ustekinumab biosimilar to be listed on the PBS), which aligns with the biosimilar uptake driver policy. The PBAC also noted that the submission requested the addition of administrative advice reflecting the biosimilar uptake driver that encourages biosimilar prescribing for treatment-naïve patients (which already exists in the listings). The PBAC considered that the application of both biosimilar uptake drivers to Ardelya would be clinically appropriate.
VORASIDENIB Tablet 10 mg Tablet 40 mg Voranigo®	Astrocytoma or oligodendroglioma	Resubmission to request listing of vorasidenib for the treatment of patients with isocitrate dehydrogenase-mutant astrocytoma or oligodendroglioma who have residual or recurrent disease	Recommended	The PBAC recommended the listing of vorasidenib for the treatment of isocitrate dehydrogenase-mutant (IDH) astrocytoma or oligodendroglioma. The PBAC welcomed the strong support from individuals, health care professionals and organisations for this resubmission. The PBAC maintained its previous view that there is a high unmet clinical need for effective treatments for astrocytoma and

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SERVIER LABORATORIES (AUST.) PTY. LTD. Early Re-entry (New PBS listing) PBS General Schedule		after at least one prior surgery.		oligodendroglioma, noting that there are currently no other effective treatments available for patients not in immediate need of chemotherapy/radiotherapy. The PBAC recalled it had noted that as the disease progresses patients experience headaches, nausea/vomiting, seizures, drowsiness, visual disturbance, speech/language problems, sensory loss, motor deficits and changes in cognitive and/or functional ability. These symptoms have a significant impact on quality of life, including inability to work, drive, remain independent, and anxiety is associated with surveillance only, knowing that the condition will inevitably progress. The PBAC also acknowledged that chemotherapy/radiotherapy is associated with substantial toxicity and worsening of neurological deficits. The PBAC accepted vorasidenib was superior to active surveillance in terms of radiological progression (observable changes in medical imagining) and acknowledged that delaying the need for chemotherapy and radiation therapy and the reduction in epileptic seizures are clinically meaningful outcomes that are likely to positively impact on patient quality of life (QoL). The PBAC considered the additional trial data, revised estimates of benefits and revised estimates of costs provided in the resubmission addressed most of the Committee's previous concerns with the July 2025 submission. The PBAC considered vorasidenib would be acceptably cost-effective at the reduced price proposed in the resubmission and the revised financial estimates were considered reasonable. The PBAC advised that amendments to the sponsor's

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				proposed approach to managing financial risk were required to address the uncertainty of how long patients may stay on treatment, including the possibility that patients may remain on treatment after disease progression. The PBAC advised that the use of vorasidenib should be reviewed once listed on the PBS to confirm whether patient numbers reflect the estimates of use provided in the resubmission.
ADALIMUMAB ETRASIMOD GOLIMUMAB INFLIXIMAB OZANIMOD TOFACITINIB UPADACITINIB USTEKINUMAB VEDOLIZUMAB Various forms Various brands Various sponsors Other matters (Change to existing listing) PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Severe Crohn disease Moderate to severe ulcerative colitis Complex refractory fistulising Crohn disease Moderate to severe chronic pouchitis	To seek PBAC advice on matters relating to the administration of PBS listings for inflammatory bowel diseases.	Recommended	The PBAC recommended a series of amendments to align restrictions, improve consistency across indications and reduce administrative complexity across the PBS listings for inflammatory bowel disease (IBD) medicines, specifically the following PBS indications: Severe Crohn disease, Moderate to Severe Ulcerative Colitis, Fistulising Crohn Disease, Moderate to Severe Chronic Pouchitis. The changes include simplifying item codes; adjusting authority requirements; allowing greater flexibility around prior therapy requirements, dosing and assessment timeframes; and enabling patients who commenced treatment outside the PBS to transition to PBS subsidised therapy where eligibility can be demonstrated. While noting potential shifts in utilisation, the PBAC considered the overall financial impact to be minimal and highlighted that the amendments will address longstanding issues for prescribers. Overall, the PBAC considered the recommended changes to be highly positive and likely to be well received by clinicians and patients.

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ADALIMUMAB INFLIXIMAB Injection 20 mg in 0.2 mL pre-filled syringe Injection 20 mg in 0.4 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 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen Powder for I.V. infusion 100 mg Humira® Amgevita® Hadlima® Hyrimoz® Yuflyma® Abrilada® Inflectra® Ixifi® Remicade®	Crohn disease Ulcerative colitis	To seek PBAC advice on the appropriateness of the current prior-therapy requirements specified in the PBS listings for adalimumab and infliximab for the treatment of paediatric patients with Crohn disease and ulcerative colitis, and to seek advice on matters relating to the administration of these PBS listings.	Advice Provided	The PBAC recommended that the PBS listings for adalimumab and infliximab intravenous infusion for paediatric patients with severe, and moderate to severe Crohn disease respectively, be amended to allow children with high-risk disease (at high-risk of complicated disease) to receive subsidised treatment without first having to trial conventional therapies. This recommendation was on the basis that the PBAC was satisfied that there was sufficient evidence, including support from European clinical guidelines, that first line therapy with adalimumab or infliximab results in improved outcomes in children with high-risk Crohn disease compared to initial treatment with conventional therapies. The PBAC advised that the current PBS prior therapy requirements for infliximab and adalimumab are broadly aligned with clinical guidelines for paediatric patients with Crohn disease (not at high-risk of complicated disease) and ulcerative colitis and that that no change to the prior therapy requirements for these patient groups were required at this time. The PBAC acknowledged and welcomed joint input from stakeholder groups Crohn's and Colitis Australia and the Gastroenterological Society of Australia, outlining recommendations to revise PBS listings for adalimumab and infliximab to follow current evidence-based protocols for the treatment of children with Crohn disease and ulcerative colitis. The PBAC acknowledged the consumer input provided by the stakeholder, including statements from families of young people with IBD with these diseases sharing their experiences with short and long-term symptoms and

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Remsima® Renflexis® ABBVIE PTY LTD ARROTEX PHARMACEUTICALS PTY LTD ARROW PHARMA PTY LTD SANDOZ PTY LTD CELLTRION HEALTHCARE AUSTRALIA PTY LTD PFIZER AUSTRALIA PTY LTD PFIZER AUSTRALIA PTY LTD JANSSEN-CILAG PTY LTD CELLTRION HEALTHCARE AUSTRALIA PTY LTD ORGANON PHARMA PTY LTD (Change to existing listing)				complications from standard treatments, as well as the negative mental and physical effects on the young person and their families. The PBAC noted long term effects on growth, development and education in paediatric patients with delayed access to effective treatment. The PBAC noted that the cost of treatment with adalimumab and infliximab intravenous infusion is higher than standard medicines. The PBAC advised that first-line treatment for paediatric patients with CD at high-risk for complicated disease with adalimumab and infliximab intravenous infusion would be cost-effective at the current price.
Nurse Practitioner Prescribing under the Section 100 Highly Specialised Drugs Program and bulevirtide Various forms and strengths Various brands Various sponsors	Various	To request the PBAC's review of the suitability of medicines within the listings presented for designated Registered Nurse prescribing.	Advice Provided	The PBAC recommended that in implementing the PBAC's July 2022 recommendation for NP prescribing of erythropoietin stimulating agents and July 2025 recommendation for NP prescribing of iron chelating agents, it was appropriate that non-specialist medical practitioners be provided with prescribing rights for these medicines on an equivalent basis with authorised NPs – i.e., that non-specialist medical practitioners be able to prescribe initial and continuing treatment with these medicines without a requirement to obtain agreement from the treating specialist. The PBAC recommended that its July 2025 recommendation

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Other matters (Change to existing listing)				for the listing of bulevirtide for the treatment of chronic hepatitis D infection should be amended to listing as a s100 HSD Community Access benefit only. The recommended restriction wording will remain unchanged.
RACGP letter regarding PBAC recommendations for preservative-free (PF) ocular lubricants Various forms Various brands Various sponsors (Other matters)	Severe dry eye	For the Pharmaceutical Benefits Advisory Committee (PBAC) to note the correspondence from the Royal Australian College of General Practitioners (RACGP) to the Department of Health, Disability and Aging, expressing opposition to the November 2025 PBAC recommendation to restrict Pharmaceutical Benefits Scheme (PBS) subsidy of preservative-free (PF) ocular lubricants to prescribing by eye specialists and optometrists and to remove general practitioners (GPs) as authorised prescribers of PF ocular lubricants and advise of any next steps resulting from this correspondence.	Advice provided	The PBAC considered correspondence from the Royal Australian College of General Practitioners (RACGP) which did not support the PBAC's recommendation from November 2025 to restrict PBS prescribing of preservative free (PF) ocular lubricants to ophthalmologists and optometrists. The PBAC recalled that its November 2025 recommendation was consistent with previous clinical advice that ophthalmologists and optometrists are the most appropriate practitioners to diagnose severe dry eye disease and determine the need for PF ocular lubricants. The PBAC noted the RACGP's advice that general practitioners (GPs) often provide care for patients with severe dry eye disease, particularly in regional, rural and remote areas where access to specialists may be limited. The RACGP considered that restricting prescribing only to specialists could negatively impact for access these patients. The PBAC rescinded its November 2025 recommendation to change prescribing arrangements and instead supported progressing Option 1 from the Utilisation analysis and financial estimates for potential changes to the restrictions for PBS listings of ocular lubricants in patients with severe dry eye (the Report): Option 1: Changing the restriction level for PF ocular lubricants to align with preservative containing (PC) ocular lubricants, with an accompanying price reduction. The report modelled low, medium and high constraint scenarios to maintain overall budget neutrality relative to the projected growth in expenditure on PBS-listed ocular lubricants.

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				The PBAC noted the ongoing price divergence between PF and preservative containing (PC) ocular lubricants, which has emerged despite the original cost minimisation intent and increasing utilisation of PF products. The PBAC recommended that the Department seek to negotiate a reduction in the price of PF ocular lubricants to support the low budget neutrality constraint option from the Report. Subject to agreement of an acceptable price reduction, the PBAC recommended that the restriction level for PF ocular lubricant PBS listings be amended from Authority Required (Streamlined) to Restricted Benefit to align with PC ocular lubricants. The PBAC further advised that, should negotiations not result in an acceptable price reduction, the Committee would be of a mind to recommend a change to the authority requirements for PF ocular lubricants from Authority Required (Streamlined) to Authority Required (Telephone/Online) to support management of PBS utilisation and expenditure.
Review of designated Registered Nurse prescribing Various forms and strengths Various brands Various sponsors Other matters	Various conditions	To request the PBAC's review of the suitability of medicines within the listings presented for designated Registered Nurse prescribing.	Noted	The Pharmaceutical Benefits Advisory Committee (PBAC) considered how the Pharmaceutical Benefits Scheme (PBS) could safely support prescribing by designated registered nurse (RN) prescribers. The PBAC advised that proposed medicine lists presented for consideration should be grouped by pharmacological class or by anatomical therapeutic chemical classification (ATC code) to facilitate consistent decision making. The PBAC noted a revised timeline for review of PBS listings for designated (RN) prescribing and agreed to provide advice at subsequent meetings.

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CABOZANTINIB Tablet 20 mg Tablet 40 mg Cabometyx® IPSEN PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Clear cell variant renal cell carcinoma	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC extended its March 2024 recommendation for this drug for a further 12 months.
HUMAN MENOPAUSAL GONADOTROPHIN Injection 600 I.U. in 0.96 mL pre-filled multi-dose pen Injection 1200 I.U. in 1.92 mL pre-filled multi-dose pen Menopur® 600 Menopur® 1200 FERRING PHARMACEUTICALS PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)	In Vitro fertilisation	To request the PBAC review its July 2022 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC extended its July 2022 recommendation for this drug for a further 12 months.
INFLUENZA VACCINE Injection 0.5 mL Flublok® Quadrivalent	Prevention of influenza	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC rescinded its March 2024 recommendation.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
SANOFI-AVENTIS AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)			
LEBRIKIZUMAB Injection 250 mg in 2 mL single use autoinjector Ebglyss® ELI LILLY AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Atopic dermatitis	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC rescinded its March 2024 recommendation.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (Australia) PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Gastroesophageal cancers	To request the PBAC review its May 2022 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC extended its May 2022 recommendation for this drug for a further 12 months.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
PNEUMOCOCCAL CONJUGATE VACCINE, 15-VALENT ADSORBED 0.5 mL pre-filled syringe Vaxneuvance® MERCK SHARP & DOHME (Australia) PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Prevention of pneumococcal disease	To request the PBAC review its March 2023 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC rescinded its March 2023 recommendation.
PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 15-VALENT ADSORBED 0.5 mL pre-filled syringe To be determined MERCK SHARP & DOHME (Australia) PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Prevention of pneumococcal disease	To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC rescinded its November 2021 recommendation.
PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 20-VALENT ADSORBED 0.5 mL pre-filled syringe	Prevention of pneumococcal disease	To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC rescinded its November 2022 recommendation.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Prevenar 20® PFIZER AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)			
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 (Review of positive PBAC recommendations not accepted by applicants)	Hyperkalaemia in patients with chronic kidney disease	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC extended its March 2024 recommendation for this drug for a further 12 months.
TOFACITINIB Tablet (modified release) 11 mg Xeljanz® XR PFIZER AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Rheumatoid arthritis Psoriatic arthritis	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC extended its March 2024 recommendation for this drug for a further 12 months.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TRIENTINE Tablet 150 mg (as tetrahydrochloride) Cuprior® ORPHALAN (Review of positive PBAC recommendations not accepted by applicants)	Wilson disease	To request the PBAC review its May 2022 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC rescinded its May 2022 recommendation.
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 (Review of positive PBAC recommendations not accepted by applicants)	Psoriatic arthritis Chronic plaque psoriasis Crohn disease Ulcerative colitis Complex refractory fistulising Crohn disease	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.	In March 2026, the PBAC extended its March 2024 recommendation for this drug for a further 12 months.
USTEKINUMAB Injection 45 mg in 0.5 mL Injection 45 mg in 0.5 mL single use pre-	Psoriatic arthritis Chronic plaque psoriasis Crohn disease	To request the PBAC review its March 2024 recommendation that	In March 2026, the PBAC extended its March 2024 recommendation for this drug for a further 12 months.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
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 (Review of positive PBAC recommendations not accepted by applicants)	Ulcerative colitis Complex refractory fistulising Crohn disease	has not yet been accepted by the applicant.	

Version 2:

1. ASCIMINIB (Scemblix®)(Category 2) – Added
2. BUROSUMAB (Crysvita ®) – Updated to remove spelling error
3. CANNABIDIOL (Epidyolex®) – Updated to remove spelling error
4. ENOXAPARIN (Clexane® Safety-Lock, Clexane® Forte Safety-Lock)(Other matters) – Added
5. EDARAVONE (Radicava®) – Added
6. EFGARTIGIMOD ALFA (Vyvgart®) – Updated to remove spelling error
7. INOTUZUMAB OZOGOMICIN (Besponsa®) – Updated to remove spelling error
8. OMALIZUMAB (Omlyclo®) – Updated to remove spelling error
9. PEGVALIASE (Palynziq®) – Updated to remove spelling error
10. TRASTUZUMAB DERUXTECAN (Enhertu®) – Added
11. PEMBROLIZUMAB (Keytruda®) – Amended PBAC outcome

Version 3:

1. RILUZOLE (Teglutik®) (Category 4) – Added

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2026 PBAC MEETING

Submission category types

Category 1	A request for PBS or NIP listing of one or more of the following: • A first in class medicine or vaccine, and/or a medicine or vaccine for a new population. OR • A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC. OR • A drug or designated vaccine with a TGA Provisional determination related to the proposed population.
Category 2	A request for PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication and do not meet the criteria for a Category 1 submission.
Category 3	Requests to change existing listings that do not change the population or cost effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission.
Category 4	A request for one or more of the following: • Listing of a new pharmaceutical item of a listed medicine. • Consideration as an exempt item (Exempt item as per subsection 84AH of the *National Health Act 1953*). • Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing. • A change/new manner of administration of a listed medicine. • A change to the maximum quantity and/or number of repeats of a listed medicine. • A change or addition to the prescriber type(s) of a listed medicine.
Committee Secretariat	Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following: • New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk • Pharmaceutical benefits that can no longer be supplied early • New brand of glucose indicator pharmaceutical item.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2026 PBAC MEETING

Resubmission pathways

There are four different resubmission pathways available to applicants following a 'not recommended' PBAC outcome. Resubmission pathways are not available for submissions that receive a positive recommendation from the PBAC. The resubmission pathways are classified into the following categories:	
Standard re-entry	The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where: • an applicant chooses not to accept the PBAC nominated resubmission pathway; or • an Early Re-entry or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or • an applicant decides to lodge later than the allowable timelines for the other pathways.
Early re-entry pathway	An Early Re-entry Pathway may be nominated by the PBAC where the PBAC considers that the remaining issues could be easily resolved and the medicine or vaccine does not represent High Added Therapeutic Value (HATV) for the proposed population. Applicants who accept this pathway are eligible for PBAC consideration at the immediate next meeting.
Early resolution pathway	For medicines or vaccines deemed by the PBAC to represent HATV AND where the PBAC considers that the remaining issues could be easily resolved, including when: • new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and • a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission. Applicants who accept this pathway are eligible for PBAC consideration out-of-session (before the main meeting), unless the department, in consultation with the PBAC Chair, identifies an unexpected issue such that the resubmission needs consideration at the next main PBAC meeting.
Facilitated resolution pathway	A Facilitated Resolution Pathway may be nominated by the PBAC where the PBAC considers the issues for resolution could be explored through a workshop AND where the medicine or vaccine meets the HATV criteria. Applicants who accept this pathway are eligible for a solution-focussed workshop with one or more members of the PBAC. The workshop agenda will be based on the issues for resolution outlined in the PBAC Minutes. This can be further clarified during the post-PBAC meeting with the Chair.