PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
July 2025 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	
ABALOPARATIDE Solution for injection 3 mg in 1.5 mL pre-filled pen Eladynos® THERAMEX AUSTRALIA PTY LTD Category 2 (New PBS listing)	Osteoporosis	To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of severe established osteoporosis.	Recommended	The PBAC recommended abaloparatide for the treatment of patients with severe established osteoporosis and very high risk of fracture. The PBAC noted and welcomed input from health care professionals and consumers. The PBAC noted there was a need for alternative anabolic treatment for osteoporosis on the PBS, in particular for patients unable to tolerate or who have a contraindication to romosozumab. The PBAC acknowledged the increasing evidence to suggest that anabolic agents should be used first-line to build new bone, yet some patients do not have access to first-line anabolic treatment due to cardiovascular contraindications. The PBAC accepted that the evidence presented in the submission indicated that abaloparatide is as effective as romosozumab and teriparatide at preventing fractures. The evidence also suggested abaloparatide had similar safety to teriparatide and was not likely to cause the severe cardiovascular events associated with use of romosozumab. The PBAC considered that it would be appropriate for the PBS listings for abaloparatide to allow use in either the first or second-line settings, consistent with the PBS listings for romosozumab. The PBAC advised that the cost of abaloparatide would be acceptable if the overall cost per course of treatment was not higher than that of romosozumab or teriparatide. The PBAC noted that flow-on changes would be required to the restrictions for romosozumab and teriparatide to preclude sequential treatment in patients who had previously been treated with abaloparatide.

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ABIRATERONE ACETATE AND PREDNISOLONE Pack containing 56 tablets abiraterone acetate 500 mg and 56 tablets prednisolone 5 mg Andriga-10 ACTOR PHARMACEUTICALS PTY LTD Category 3 (New PBS listing)	Castration resistant metastatic carcinoma of the prostate (mCRPC)	To request a General Schedule Authority Required (Telephone/Online) listing of a composite pack containing abiraterone acetate and prednisolone for the treatment of patients with mCRPC.	Recommended	The PBAC recommended listing a new composite pack containing abiraterone acetate 500 mg tablets and prednisolone 5 mg tablets (ANDRIGA-10) for the treatment of patients with mCRPC. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness for ANDRIGA-10 would be acceptable if it cost no more than the least costly alternative therapy for mCRPC. The PBAC advised the equi-effective doses of ANDRIGA-10 and the alternative therapies were: • ANDRIGA-10 abiraterone 1000 mg (500 mg tablet x 2) and prednisolone 10 mg (5 mg tablet x 2) is equivalent to abiraterone 1000 mg (500 mg tablet x 2 or 250 mg tablet x 4) and prednisolone 10 mg (5 mg tablet x 2) • Yonsa Mpred abiraterone acetate tablets (fine particle formulation) 500 mg + methylprednisolone 8 mg is equivalent to abiraterone acetate 1000 mg + prednisolone/prednisone 10 mg • enzalutamide 160 mg is equivalent to abiraterone 1000 mg The PBAC recommended the following flow-on changes: • For abiraterone & methylprednisolone: update the caution note to exercise caution in explaining correct dosing directions to the patients when changing between Yonsa Mpred and ANDRIGA-10 or single abiraterone acetate products. • For abiraterone, abiraterone & methylprednisolone, apalutamide, cabazitaxel, darolutamide, enzalutamide, olaparib, talazoparib: add 'abiraterone and prednisolone' to the administrative advice so that it is included in the list of subsidised novel hormonal drugs for prostate cancer.

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ACALABRUTINIB Tablet 100 mg Calquence® ASTRAZENECA PTY LTD Category 2 (Change to existing listing)	Mantle cell lymphoma (MCL)	To request a General Schedule Authority Required (Telephone/Online) listing in combination with bendamustine and rituximab for patients with previously untreated Stage III or IV MCL who are ineligible for stem cell transplantation.	Recommended	The PBAC recommended acalabrutinib (in combination with bendamustine and rituximab, ABR) for the first line treatment of Stage III or IV MCL in patients who are ineligible for stem cell transplantation. The PBAC welcomed the input received via the Consumer Comments facility on the PBS website which outlined the rare and incurable nature of MCL and described the clinical need for more effective treatment options for transplant ineligible patients in the first line setting who have a poor prognosis with existing therapies. The PBAC acknowledged the high need for new treatment options in this setting. Based on the clinical evidence presented in the submission, the PBAC was satisfied that use of acalabrutinib in combination with bendamustine and rituximab was more effective at preventing progression of MCL for some patients than treatment with bendamustine and rituximab alone. The PBAC noted that use of acalabrutinib was also associated with an increased risk of infections and concluded it was less safe than treatment with bendamustine and rituximab alone. The PBAC considered the estimates of the benefits of acalabrutinib in support of the proposed requested price were overly optimistic and that revisions would be required to include more realistic estimates. As such, the PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of acalabrutinib would be acceptable with a price reduction reflecting more realistic estimates of benefits and costs. The PBAC further advised that a risk sharing arrangement that accounts for reduced use of Bruton tyrosine kinase inhibitors in relapsed/refractory MCL would be required. The PBAC indicated that flow-on changes to the existing bendamustine restriction may be required to allow use in combination with acalabrutinib and rituximab.

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AFLIBERCEPT Solution for intravitreal injection 3.6 mg in 90 microlitres (40 mg per mL) pre-filled syringe Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) Afqlir® Enzeevu™ SANDOZ PTY LTD Category 3 (New PBS listing)	Macular oedema secondary to retinal vein occlusion (RVO) Diabetic macular oedema (DMO) Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (AMD)	To request General Schedule Authority Required listings of two aflibercept biosimilars for the treatment of RVO, DMO, and CNV due to AMD under the same conditions as their respective reference biologic.	Recommended	The PBAC recommended the listings of two aflibercept biosimilars (Afqlir® and Enzeev™) and under the same conditions as their reference biologic (Eylea®), for the same indications. The PBAC advised the equi-effective doses to be Afqlir/Enzeevu 2 mg vial/syringe = Eylea 2 mg vial/syringe. The PBAC noted that the submission did not request a lower authority level for the two biosimilar brands, but that it did request the addition of administrative advice reflecting the biosimilar uptake driver that encourages uptake of biosimilar prescribing for treatment-naïve patients. The PBAC considered that the application of that biosimilar uptake driver to Afqlir and Enzeevu would be clinically appropriate and would not impact cost-effectiveness.
APOMORPHINE Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL Movapo® POD STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED Committee secretariat (New PBS listing)	Parkinson disease	To request General Schedule Authority Required (STREAMLINED) and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings of Movapo® POD, administered via an infusion pump with a collar attachment, under the same circumstances as Apomine Solution for Infusion for the treatment of Parkinson's disease.	Recommended	The PBAC recommended the listing of apomorphine (injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL; Movapo POD) under the same circumstances as apomorphine hydrochloride hemihydrate 100 mg/20 mL injection currently listed on the PBS (Apomine Solution for Infusion), for the treatment of Parkinson disease. The PBAC recommended listing Movapo Pod on a cost-minimisation basis to Apomine Solution for Infusion, and advised the equi-effective doses to be 1 mg Movapo POD = 1 mg Apomine Solution for Infusion.

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ARIPIPRAZOLE Powder for injection 300 mg (as monohydrate) with diluent in single dose pre-filled syringe Powder for injection 400 mg (as monohydrate) with diluent in single dose pre-filled syringe Abilify Maintena® LUNDBECK AUSTRALIA PTY LTD Category 4 (New PBS listing)	Schizophrenia	To request General Schedule Authority Required (STREAMLINED) listings of two new forms for the treatment of schizophrenia.	Recommended	The PBAC recommended the General Schedule Authority Required (STREAMLINED) listing of a new pre-filled syringe (PFS) dose form of aripiprazole in both 300 mg and 400 mg (once-monthly) strengths (AOM PFS) for the treatment of schizophrenia, under the same listing circumstances as the currently listed aripiprazole 300 mg and 400 mg vial kit form, on a cost-minimisation basis. The PBAC considered the equi-effective doses as 300 mg AOM PFS and 300 mg AOM vial kit, and 400 mg AOM PFS and 400 mg AOM vial kit. The PBAC considered that the vial kit and PFS should not be considered equivalent for the purposes of substitution.
BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (Standard re-entry Change to existing listing)	Hodgkin lymphoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Written) listing for the first line treatment of advanced Hodgkin lymphoma in combination with chemotherapy.	Recommended	The PBAC recommended the listing of brentuximab vedotin in combination with doxorubicin, vinblastine and dacarbazine (A+AVD) for the first-line treatment of advanced Hodgkin lymphoma. The PBAC welcomed input from clinicians and consumers, who shared their experiences with the side effects of currently available treatments, and their concerns about the long-term toxicity of standard care. The PBAC acknowledged that it was important for more treatment options to be available. The PBAC was satisfied that A+AVD was more effective at preventing lymphoma progression and improving survival for some patients than the current standard of care in Australia (positron emission tomography (PET)-adapted doxorubicin, bleomycin, vinblastine and dacarbazine). The clinical evidence provided in the submission also showed that A+AVD was not as safe as the current standard of care, with patients who received A+AVD in the clinical trial experiencing more serious adverse events, or adverse events leading to dose modification. The PBAC however considered that more alternative treatment options were needed and noted input that A+AVAD has an alternative toxicity profile to currently available treatments that

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				may make it more suitable for some patients. The PBAC considered that the resubmission had addressed the substantive outstanding issues identified at the March 2024 PBAC meeting through its revised economic model and advised that brentuximab vedotin would be cost-effective at the price proposed in the resubmission. The PBAC advised that an Authority Required (Telephone/Online) listing would be appropriate including the existing initial and continuing listings in the relapsed or refractory setting. The PBAC also agreed with the flow-on change: 'The treatment must not exceed a total of 16 cycles for this condition in a lifetime' for patients who had not failed first line PBS-subsidised treatment but could receive the balance of the lifetime maximum of 16 treatment cycles in the relapsed or refractory setting.
BREXPIPRAZOLE Tablet 500 micrograms Rexulti® LUNDBECK AUSTRALIA PTY LTD Category 4 (New PBS listing)	Schizophrenia	To request a General Schedule Authority Required (STREAMLINED) listing of a new strength for the treatment of schizophrenia.	Recommended	The PBAC recommended the General Schedule Authority Required (STREAMLINED) listing of a new form of brexpiprazole, tablet 500 micrograms, for the treatment of schizophrenia under the same circumstances as the current PBS-listed strengths of brexpiprazole tablet.

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BULEVIRTIDE Powder for injection 2 mg Hepcludex® GILEAD SCIENCES PTY LTD Matters arising from the minutes (New PBS listing)	Chronic hepatitis D (CHD)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of CHD. This matter was deferred at the March 2025 PBAC Meeting.	Recommended	The PBAC recommended the listing of bulevirtide for the treatment of CHD in patients positive for hepatitis D virus (HDV) ribonucleic acid (RNA) as detected by polymerase chain reaction (PCR). The PBAC noted that the MSAC supported MBS listing of HDV RNA PCR testing to determine eligibility for treatment with bulevirtide and to monitor the response to treatment. The PBAC recalled that it had previously considered that the evidence indicates that bulevirtide is effective for some patients in terms of achieving a significant reduction in viral load and/or improvement in markers of liver damage compared to the nominated comparator, symptomatic management of CHD, although the longer-term and patient-relevant benefits were highly uncertain. The PBAC reiterated that bulevirtide would be cost-effective with a substantial price reduction to bring the ICER into an acceptable range. The PBAC also maintained its view that the proposed utilisation of bulevirtide was uncertain but the estimates presented in the resubmission appeared to be reasonable.
CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® IPSEN PTY LTD Category 2 (Change to existing listing)	Pancreatic neuroendocrine tumours (pNET) Extra-pancreatic neuroendocrine tumours (epNET)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of unresectable locally advanced or metastatic well- or moderately-differentiated pNET or epNET after prior systemic therapy.	Recommended	The PBAC recommended cabozantinib for the treatment of patients with unresectable or metastatic, well-differentiated epNET or pNET who have progressed on at least one prior systemic therapy other than a somatostatin analogue (SSA). The PBAC welcomed advice from consumers, clinicians and organisations (via the consumer comments and the sponsor hearing) that there is a clinical need for additional treatments for patients with NETs, given these are relatively rare conditions where treatment options are limited. Based on evidence from the CABINET trial, the PBAC was satisfied that cabozantinib improves progression free survival in the 'fourth line' setting when compared to best supportive care. The PBAC was also satisfied that, in the 'third line' setting, cabozantinib is as effective as sunitinib or everolimus for treating pNET; and chemotherapy for treating epNET. The PBAC considered the estimates of benefits in support of the proposed price were not supported by the evidence included in the submission. In particular, the PBAC considered assumptions

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				on overall survival were overly optimistic, and that the proportion of patients that would use cabozantinib in the fourth line setting compared to the third line setting was overestimated. The PBAC's recommendation for listing was based on, among other matters, its assessment that the overall cost-effectiveness of cabozantinib would be acceptable with a price reduction using more realistic estimates. The PBAC also considered that revisions were required to the assumptions across the proposed treatment settings for epNET and pNET informing the overall price. The PBAC advised that flow-on changes would be required to the existing listings for sunitinib and everolimus in pNET to prevent their use in patients who have developed disease progression with cabozantinib. The PBAC also advised that flow-on changes would be required to the existing PBS listings for SSA therapies (octreotide and lanreotide) in non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) to allow concurrent use with cabozantinib.
CALCIPOTRIOL WITH BETAMETHASONE DIPROPIONATE Cream containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g Wynzora® ACTOR PHARMACEUTICALS PTY LTD Category 2 (New PBS listing)	Chronic stable plaque type psoriasis vulgaris	To request a General Schedule Restricted Benefit listing for the treatment of chronic plaque type psoriasis vulgaris in patients who have not adequately responded to potent topical corticosteroid monotherapy.	Recommended	The PBAC recommended the listing of calcipotriol 0.005% with betamethasone (as dipropionate) 0.05% (CAL/BDP) cream, 60 g, as a General Schedule (Restricted Benefit) listing, for the treatment of chronic stable plaque type psoriasis vulgaris in patients who have not adequately responded to potent topical corticosteroid monotherapy, under the same circumstances as CAL/BDP foam and ointment that are listed on the PBS. The PBAC noted CAL/BDP cream provides another option for patients requiring topical CAL/BDP, and considered that CAL/BDP cream had similar efficacy and safety compared to CAL/BDP foam and ointment. The PBAC recommended the listing should cost no more than the lowest cost CAL/BDP formulation listed on the PBS (CAL/BDP ointment), and advised the equi-effective doses are 1 gram CAL/BDP cream to 1 gram CAL/BDP foam and 1 gram CAL/BDP ointment.

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CANNABIDIOL Oral liquid 100 mg per mL, 100 mL Epidyolex® JAZZ PHARMACEUTICALS ANZ PTY LTD Category 3 (Change to existing listing)	Seizures of the Lennox-Gastaut syndrome (LGS)	To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the treatment of seizures associated with LGS. The submission also requested amendments to the clinical criteria, including the requirement for a diagnosis confirmed by an electroencephalogram and a definition of the types of seizures, and to the treatment criteria to allow prescribing by a paediatrician.	Recommended	The PBAC recommended amending the restriction level of cannabidiol for the treatment of seizures associated with LGS 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 LGS. These include easing the requirement for an electroencephalogram (EEG) to confirm diagnosis, removing specific EEG features, seizure frequency and type, and the number of concomitant antiseizure medication. The PBAC further supported allowing prescribing by a paediatrician for both initial and continuing treatment. The PBAC welcomed input from healthcare professionals, a medical organisation, and consumer groups supporting the proposed changes to ensure equitable, affordable, and timely access to cannabidiol. The PBAC noted that actual utilisation of cannabidiol was significantly lower than expected. While the PBAC acknowledged uncertainty regarding the financial implications of the revised PBS restrictions, it considered the changes unlikely to result in a substantial financial impact.
DONANEMAB Solution concentrate for I.V. infusion 350 mg in 20 mL Kisunla® ELI LILLY AUSTRALIA PTY LTD Category 1 (New PBS listing)	Early symptomatic Alzheimer's disease	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing of donanemab for the treatment of patients with early symptomatic Alzheimer's disease.	Not Recommended	The PBAC did not recommend listing donanemab on the PBS for the treatment of patients with mild cognitive impairment due to Alzheimer's disease (AD) or mild AD (referred to collectively as early AD). The PBAC acknowledged there is a high clinical need for effective disease modifying treatments for AD and noted that existing treatments have only modest effectiveness. While clinical trials demonstrated that donanemab can potentially delay the progression of early AD by approximately 6 weeks, the PBAC noted there is a lack of consensus among clinicians that these results would translate into meaningful improvements for patients. The PBAC considered the potential benefits too small and uncertain to justify the burden of this treatment on both patients and the health system. Prior to accessing donanemab, patients would need to undergo specialist diagnostic testing

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				including brain scans or testing of cerebrospinal fluid obtained by lumbar puncture to confirm the presence amyloid plaques and testing for genes that make use of donanemab too unsafe. Additional scans are also required to rule out other health conditions that would make donanemab unsafe. Many patients with mild cognitive impairment would be subject to this initial testing and not gain access to treatment. Patients receiving treatment would need to attend monthly hospital infusions and undergo regular brain scans to monitor for life-threatening side effects, including brain swelling and bleeding. The PBAC concluded that the high burden of treatment on both patients and the health system, combined with the risks and modest clinical impact, makes the drug unsuitable for PBS subsidy. <u>Sponsor's Comment:</u> Lilly wishes to thank all of the healthcare professionals, professional societies, leadership bodies, patient organisations and consumers for their support of the donanemab (Kisunla®) submission. We are disappointed by the PBAC's decision not to recommend the PBS listing of donanemab for the treatment of adult patients with early symptomatic Alzheimer's disease. Lilly is working to fully understand the implications of this outcome and potential next steps.
DURVALUMAB Solution concentrate for I.V. infusion, 120 mg in 2.4 mL, 500 mg in 10mL Imfinzi® ASTRAZENECA PTY LTD Category 2 (Change to existing listing)	Small cell lung cancer (SCLC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of limited-stage SCLC in patients whose disease has not progressed during or following chemoradiation therapy.	Recommended	The PBAC recommended durvalumab for the treatment of limited-stage small cell lung cancer (LS-SCLC) in patients whose disease has not progressed during or following chemoradiation therapy (CRT). The PBAC welcomed comments from healthcare professionals and consumer organisations. The PBAC noted outcomes for patients were typically poor with the current standard of care for LS-SCLC and there was a high clinical need for additional effective treatments. The PBAC was satisfied that treatment with durvalumab provided a moderate overall survival benefit but was associated with immune-mediated adverse events and the inconvenience

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				of prolonged intravenous therapy. The PBAC considered there was some uncertainty about whether the overall survival benefit observed in the clinical trial would be realised in clinical practice. The PBAC considered the benefits claimed by the sponsor in support of the proposed price were overly optimistic, particularly the life years gained and the duration of benefit. The clinical evidence presented in the submission did not allow confidence that these estimated benefits would be realised. The PBAC considered that revisions to the economic model were required to provide confidence in the additional benefits provided by durvalumab and that durvalumab would be cost-effective with a price reduction. The PBAC considered the revised utilisation estimates provided in the pre-PBAC response, which accounted for reduced use of immunotherapy in extensive stage SCLC, would be reasonable with a decrease in durvalumab uptake applied. The PBAC considered that durvalumab should join the existing risk sharing arrangement in place for extensive stage small cell lung cancer with an increase in expenditure caps. The PBAC advised flow-on changes to the listings for durvalumab and atezolizumab for ES-SCLC would be required to limit treatment with immunotherapy to once per lifetime.
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	Prevention of venous thromboembolism (VTE) Treatment of venous thrombosis Prevention of extracorporeal thrombosis during haemodialysis Treatment of acute ST-segment elevation myocardial infarction (STEMI), non-STEMI and unstable angina	To request General Schedule Restricted Benefit listings of a new enoxaparin biosimilar under the same conditions as other enoxaparin brands for the respective forms.	Recommended	The PBAC recommended listing of a new enoxaparin biosimilar (Enoxaject®) on a cost-minimisation basis and under the same circumstances as the existing PBS-listed biosimilar brands of enoxaparin (Clexane® and Exarane®), for the same indications. The PBAC noted that the submission requested the addition of administrative advice reflecting the biosimilar update policy (i.e. encouraging uptake of biosimilar prescribing for treatment-naïve patients). As is the case for Exarane, the PBAC also considered that this administrative advice is clinically appropriate for Enoxaject.

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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 Enoxaject® PHARMACOR PTY LIMITED Category 3 (New PBS listing)				
EPLERENONE Tablet 25 mg Tablet 50 mg Inspra® VIATRIS PTY LTD Category 3 (Change to existing listing)	Heart failure	To request the PBAC consider an amendment to the clinical criteria for eplerenone to align with clinical guidelines for the management of heart failure.	Deferred	The PBAC deferred making a recommendation for the requested amendments to the current PBS restriction for eplerenone (Inspra®) to align with clinical guidelines for the management of heart failure. The PBAC noted the lack of mineralocorticoid receptor antagonist (MRA) medication options on the PBS, and the barriers to subsidised access of eplerenone due to the current PBS restriction. The PBAC noted that the submission had nominated placebo/standard of care as the main comparator but considered that spironolactone was a more appropriate comparator at is the main MRA medication that eplerenone would likely replace in therapy. The PBAC discussed the need for a cost minimisation analysis for an expanded population comparing eplerenone to spironolactone, or for eplerenone as a second line therapy to spironolactone to be explored and therefore deferred making a recommendation at this time to allow for discussions with the sponsor. <u>Sponsor's Comment:</u> The sponsor had no comment.

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ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4 Nepexto® MAXX PHARMA PTY LTD Category 3 (New PBS listing)	Severe active rheumatoid arthritis Severe psoriatic arthritis Ankylosing spondylitis Severe chronic plaque psoriasis Juvenile idiopathic arthritis	To request General Schedule Authority Required and Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new etanercept biosimilar under the same conditions as another biosimilar brand of etanercept in the same form for the treatment of severe active rheumatoid arthritis, severe psoriatic arthritis, ankylosing spondylitis, severe chronic plaque psoriasis, and juvenile idiopathic arthritis.	Recommended	The PBAC recommended the listing of a new etanercept biosimilar (Nepexto®) in the form of Injections 50 mg in 1 mL single use pre-filled syringe (PFS) on a cost-minimisation basis and under the same circumstances as its reference biologic Enbrel® (Injections 50 mg in 1 mL single use PFS). The PBAC advised the equi-effective doses to be Nepexto 50 mg single use PFS = Enbrel 50 mg single use PFS = Brenzys® 50 mg single use PFS. The PBAC noted that the submission requested for the Nepexto listings to be consistent with the biosimilar uptake driver policy, that is, to have an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Nepexto listings encouraging use of a biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Nepexto would be clinically appropriate and would not impact cost-effectiveness.
FUTIBATINIB Tablet 4 mg Lytgobi® TAIHO PHARMA OCEANIA PTY LTD Early re-entry (New PBS listing)	Bile duct cancer (cholangiocarcinoma)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on systemic therapy and have a fibroblast growth factor receptor 2 fusion or rearrangement.	Not recommended	The PBAC did not recommended futibatinib for the treatment of patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on systemic therapy and have a fibroblast growth factor receptor 2 fusion or rearrangement. The PBAC recalled it did not recommend futibatinib at its March 2025 meeting and had advised the outstanding issues related to the cost-effectiveness and financial estimates could be addressed using the early re-entry submission pathway. The PBAC recalled the input it received from organisations when it considered futibatinib at its March 2025 meeting and welcomed further input from organisations to this meeting. The PBAC acknowledged that survival outcomes for patients with advanced or metastatic cholangiocarcinoma are very poor and there is a high clinical need for more effective therapies. The PBAC recalled it previously considered the extent to which futibatinib improved survival was uncertain and that the sponsor had claimed survival benefits in support of its proposed price that were overly optimistic and not adequately supported by the clinal evidence included in the submission.

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				The PBAC considered the early re-entry resubmission did not adequately address the issues it raised when the Committee considered the sponsor's original submission at its March 2025 PBAC meeting. The survival benefits claimed by the sponsor in support of its requested price continued to be highly optimistic. The clinical evidence included in the submission did not allow confidence that the improvement to survival claimed by the sponsor would be realised. Additional studies identified during the evaluation of the submission considered in March 2025 further suggested that the sponsor had overestimated the magnitude of the survival benefits. The PBAC considered that in any resubmission, estimated benefits in support of the proposed price would need to be more realistic. Comparator: Standard of Care (SoC) chemotherapy, represented by FOLFOX Secondary comparator: palliative care (with active symptom control, ASC) The PBAC reaffirmed its previous view that the proposed comparators were reasonable. Clinical claim: Superior effectiveness and safety compared with SoC chemotherapy Secondary Clinical claim: Superior effectiveness and different but manageable safety compared to ASC The PBAC recalled that it had previously accepted the clinical claim of superior comparative effectiveness, and maintained that the magnitude of effect is highly uncertain and likely overestimated. The PBAC recalled it previously accepted the claim of inferior safety compared to ASC, and maintained that the claim of superior safety (vs chemotherapy) was not adequately supported by the data, but theoretically plausible. Economic claim: Cost-utility analysis versus chemotherapy The PBAC noted that the revised economic evaluation had not addressed a number of the Committee's previous concerns. The PBAC considered that the ICER remained underestimated and futibatinib was not cost-effective at the price proposed in the submission.

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				Sponsor's Comment: Taiho remains committed to working with the PBAC to facilitate sustainable patient access to futibatinib in Australia.
GIVOSIRAN Solution for injection 189 mg in 1 mL Givlaari® MEDISON PHARMA AUSTRALIA PTY LIMITED Category 1 (New PBS listing)	Acute hepatic porphyria (AHP)	To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of AHP in adults and adolescents aged 12 years and older.	Deferred	The PBAC deferred making a recommendation for the listing of givosiran for treatment of AHP. The PBAC welcomed input from individuals with lived experience of AHP, health care professionals and organisations. The PBAC noted input that chronic symptoms and acute attacks can include intense and persistent pain, muscle weakness, as well as gastrointestinal, cardiovascular and neurological symptoms. The PBAC acknowledged that there is a high unmet clinical need for people with AHP to access treatments to prevent acute attacks, and that current treatments have been described as ineffective, invasive, difficult to access and associated with serious side effects. The PBAC was satisfied based on the clinical evidence included in the submission that, compared to the current best supportive care, givosiran reduced the rates of acute AHP attacks requiring hospitilisation, urgent healthcare visits or intravenous hemin administration at home. The evidence included in the submission showed that patients treated with givosiran were more likely to experience injection-site reactions, nausea and chronic kidney disease, than those who received best supportive care. Due to these adverse events and because the clinical trial included in the submission was conducted over a short period of time, the PBAC concluded that givosiran was likely to be less safe than best supportive care. The PBAC further noted that the long-term safety risks were poorly understood, especially the potential detrimental effects to kidney and liver function. The PBAC considered that the extent of benefit provided by givosiran was uncertain due to the limited clinical data from a small number of patients, range of disease severity, uncertainty

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				around how givosiran would likely be used and uncertainty around treatment continuation. The PBAC acknowledged challenges obtaining further clinical data due to these factors. The PBAC considered in the context of this rare disease with very substantial impacts on patient quality of life, givosiran would be considered acceptably cost-effective with a price reduction to reduce the cost per patient per year. The PBAC noted this recommendation is in line with other treatments for rare diseases subsidised through the PBS, accounting for clinical need, available evidence, nature of the benefits and size of the patient population. The PBAC considered a financial risk sharing arrangement would be required given the very high cost of givosiran. The PBAC deferred making a recommendation so that additional clinical input on patient numbers, likely circumstances of use, and treatment continuation, could be obtained to inform a risk sharing arrangement. <u>Sponsor's comment</u>: The sponsor had no comment.
GLOFITAMAB Solution concentrate for I.V. infusion 2.5 mg in 2.5 mL Solution concentrate for I.V. infusion 10 mg in 10 mL Columvi® ROCHE PRODUCTS PTY LTD Category 2 (New PBS listing)	Relapsed or refractory diffuse large B-cell lymphoma (RR DLBCL)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of patients with RR DLBCL.	Recommended	The PBAC recommended the listing of glofitamab, for use in combination with gemcitabine and oxaliplatin (Glofit-GemOx), for the treatment of patients with RR DLBCL who have received one or more lines of systemic therapy and are unable to receive autologous stem cell transplant (ASCT) or chimeric antigen receptor T-cell (CAR-T) cell therapy. The PBAC welcomed input from clinicians and consumer organisations. The PBAC noted the input highlighted the need for additional treatment options for people with DLBCL who are not suitable for ASCT and ineligible or can't access CAR-T cell therapy. The PBAC noted consumer comments on the stress associated with living with DLBCL and its impact on individuals' quality of life. Based on the evidence provided in the submission, the PBAC was satisfied that for some patients Glofit-GemOx provides improvements in progression free and overall survival compared to the main alternative therapy – rituximab in combination with gemcitabine plus oxaliplatin.

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				However, the cost of Glofit-GemOx at the requested price was not commensurate with the potential additional benefits. The PBAC considered that some of the benefits claimed by the sponsor in support of its requested price were overly optimistic. On this basis, the PBAC considered that a further price reduction would be needed to ensure that Glofit-GemOx would be acceptably cost-effective. The PBAC considered that some uncertainty remained about the size of the population who are unable to receive ASCT or CAR-T cell therapy and that the risk should be managed through a risk sharing arrangement to mitigate the potential impact to the Commonwealth. The PBAC noted that flow-on changes to the current epcoritamab listing would be required to exclude use after second-line glofitamab.
GUSELKUMAB Solution for I.V. infusion 200 mg in 20 mL vial Injection 100 mg in 1 mL single use pre-filled pen Injection 200 mg in 2 mL single use pre-filled pen, Injection 100 mg in 1 mL single use pre-filled syringe Injection 200 mg in 2 mL single use pre-filled syringe, Tremfya® JANSSEN-CILAG PTY LTD Category 2 (New PBS listing)	Severe Crohn disease (CD)	To request General Schedule Authority Required (Written) listings for subcutaneous injection and a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for I.V. infusion for the treatment of severe CD	Recommended	The PBAC recommended the listings of guselkumab (GUS) for the treatment of adults with severe CD. The PBAC welcomed input from individuals, health professionals and organisations. The PBAC noted the significant quality of life impact severe CD has on patients and the importance of having additional treatment options available, particularly medicines with different mechanisms of action. The PBAC considered that, based on direct evidence, while GUS had similar effectiveness to ustekinumab (UST) for achieving clinical remission and response, it was likely more effective than UST in achieving endoscopic outcomes in the maintenance treatment setting. The PBAC considered the economic model was uninformative, noting it included short-term and long-term benefits for clinical remission that were not supported by the available clinical trial data, and the assumed link between endoscopic remission, longer term clinical remission and quality of life was not adequately supported and quantified. Unable to recommend on a cost-effectiveness basis, the PBAC recommended GUS be cost minimised to UST over 2 years.

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INCOBOTULINUMTOXINA Lyophilised powder for injection 100 units Xeomin® MERZ AUSTRALIA PTY LTD Category 2 (Change to existing listing)	Moderate to severe spasticity of the upper limb Dynamic equinus foot deformity	To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of spasticity of the lower and/or upper limbs associated with cerebral palsy in patients aged 2 years and older.	Recommended	The PBAC recommended the Section 100 Botulinum Toxin Program Authority Required (STREAMLINED) listing of Xeomin® for the treatment of moderate to severe spasticity of the upper limb and dynamic equinus foot deformity due to spasticity, in patients with cerebral palsy aged 2 years and older. The PBAC was satisfied that Xeomin® is as effective and as safe compared to the nominated comparator Botox®. The PBAC considered that while the available clinical data was from paediatric patients, provided fixed contractures had not developed, there would be no clinical reason to expect treatment would not work in adults and noting that, given the nature of the therapy, treatment was unlikely to be continued if no benefit was observed. The PBAC considered that in addition to Botox, clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) was also an alternative therapy. The PBAC recalled it had previously considered Botox and Dysport to be as effective and safe as one another. As such, the PBAC advised that Xeomin would be cost-effective if it were cost-minimised to the lowest cost alternative therapy out of Botox and Dysport. The PBAC considered the equi-effective doses to be Xeomin 1 U = Botox 1 U = Dysport 2.5 U.
INFLIXIMAB Powder for I.V. infusion 100 mg Remsima® CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 3 (New PBS listing)	Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis Severe Crohn disease Complex refractory fistulising Crohn Disease Moderate to severe ulcerative colitis	To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new infliximab biosimilar under the same conditions as other biosimilar brands of infliximab.	Recommended	The PBAC recommended listing of a new infliximab biosimilar (Remsima®) on a cost-minimisation basis and under the same circumstances as the existing PBS-listed biosimilar brands of infliximab 100 mg powder for injection (Inflectra® and Renflexis®), for the same indications. The PBAC advised the equi-effective doses to be 1 mg of Remsima = 1 mg of Remicade (and/or other brands of PBS-listed infliximab). The PBAC noted that the submission requested for the Remsima listings to be consistent with the biosimilar uptake driver policy, that is, to have an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Remsima listings encouraging use of the biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar

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				uptake drivers to Remsima would be clinically appropriate and would not impact cost-effectiveness.
INFLUENZA VACCINE Injection 0.5 mL Injection 0.5 mL Fluad® Flucelvax® SEQIRUS (AUSTRALIA) PTY LTD Category 3 (New NIP listing)	Prevention of influenza	To request National Immunisation Program (NIP) listings of inactivated trivalent influenza vaccines (TIVs), Fluad® (adjuvanted TIV) for patients aged 65 years and older, and Flucelvax® (cell-based TIV) for patients aged 6 months and older, for the prevention of influenza in the same eligible patients as the currently NIP-listed quadrivalent influenza vaccine (QIV) formulations.	Not applicable	This item was withdrawn.
INSULIN DEGLUDEC Solution for injection 100 units per mL Tresiba® Penfill® NOVO NORDISK PHARMACEUTICALS PTY. LIMITED Standard re-entry (New PBS listing)	Type 1 diabetes mellitus (T1DM)	Resubmission to request a General Schedule Restricted Benefit listing for the treatment of T1DM.	Recommended	The PBAC recommended the listing of insulin degludec for the treatment of T1DM on the basis of clinical need for an alternative form of insulin. The PBAC considered that insulin degludec has similar effectiveness to insulin glargine but for a proportion of people living with T1DM there may be practical advantages of this therapy over alternative insulin preparations and additional clinical benefit in reduced nocturnal hypoglycaemia. Whilst the resubmission's cost consequences analysis was not accepted, the PBAC considered that on the basis of equi-effective doses proposed in the pre-PBAC response, the requested price was reasonable.
LENIOLISIB Tablet 70 mg Joenja® PHARMING AUSTRALIA PTY LTD	Activated PI3K delta syndrome (APDS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of symptomatic APDS in adults and adolescents aged 12 years and older .	Recommended	The PBAC recommended the listing of leniolisib for the treatment of symptomatic APDS in adults and adolescents aged 12 years and older. APDS is an ultra-rare severe condition caused by an inborn error of immunity that affects the body's immune system. The PBAC welcomed input from individuals, health care professionals and consumer organisations. The PBAC noted the high unmet clinical need for treatment options

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Category 1 (New PBS listing)				for patients with APDS given the substantial impacts on quality of life for patients and reduced life-expectancy. The PBAC noted evidence provided in the submission that leniolisib improves a range of biological indicators of the immune system that are representative of the underlying disease activity for APDS. The PBAC was therefore satisfied that leniolisib would be likely to improve a range of outcomes for patients including reducing the likelihood and severity of infections, lung disease, swelling of the lymph nodes and risk of lymphoma. 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. However, the PBAC also recognised difficulty obtaining clinical data for this condition due to its rarity. The PBAC considered that the incremental cost-effectiveness was uncertain due to the limited data informing the estimated benefits, but that in the context of this rare and life-limiting disease, leniolisib would be considered acceptably cost-effective with a price reduction that would result in an acceptable cost per patient per year. 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.

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Life Saving Drugs Program (LSDP) medicines for Gaucher disease (type 1) ELIGLUSTAT Capsule containing eliglustat tartrate, 100 mg Cerdelga® IMIGLUCERASE Powder for IV infusion, 400 units Cerezyme® TALIGLUCERASE ALFA Powder for IV infusion, 200 units Elelyso® VELAGLUCERASE ALFA Powder for IV infusion, 400 units Vpriv® Various sponsors Other matters (New PBS listing)	Gaucher disease (type 1) (GD1)	To consider a referral from the LSDP Expert Panel seeking reconsideration of listing medicines for the treatment of GD1.	Deferred	The PBAC deferred making a recommendation on the PBS listing of imiglucerase, velaglucerase alfa, taliglucerase alfa and eliglustat for the treatment of GD1 to allow consultation with clinical and patient groups.

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Life Saving Drugs Program (LSDP) medicines for hereditary tyrosinaemia type 1 NITISINONE Capsule 2 mg Capsule 5 mg Capsule 10 mg Capsule 20 mg Oral suspension 4 mg per mL, 90 mL Orfadin® A.MENARINI AUSTRALIA PTY LIMITED Tablet 2 mg Tablet 5 mg Tablet 10 mg Nityr™ ORPHARMA PTY LTD Other matters (New PBS listing)	Hereditary tyrosinaemia type 1 (HT-1)	To consider a referral from the LSDP Expert Panel seeking reconsideration of listing nitisinone for the treatment of HT-1.	Deferred	The PBAC deferred making a recommendation on the PBS listing of nitisinone for the treatment of HT-1 to allow consultation with clinical and patient groups.
METHADONE Tablet 5 mg Methadone-AFT AFT PHARMACEUTICALS (AU) PTY LTD Category 4 (New PBS listing)	Chronic severe disabling pain	To request a Palliative Care Authority Required (Telephone/Online) listing and a General Schedule Authority Required (STREAMLINED) listing of a new strength under the same conditions as the currently listed strength of methadone tablet for the management of severe disabling pain.	Recommended	The PBAC recommended the listing of methadone 5 mg tablet as a General Schedule (STREAMLINED) and Palliative Care (Telephone/Online) listing under the same circumstances as the currently listed methadone 10 mg tablet for the management of chronic severe disabling pain and severe disabling pain. The PBAC considered that methadone 5 mg tablet be priced with reference to the current PBS-listed methadone 10mg tablets.

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MIRVETUXIMAB SORAVTANSINE Solution for I.V. infusion 100 mg in 20 mL vial Elahere® ABBVIE PTY LTD Category 1 (New PBS listing)	Epithelial ovarian, fallopian tube or primary peritoneal cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of high grade epithelial ovarian, fallopian tube or primary peritoneal cancer in patients who have platinum-resistant disease and high folate receptor alpha (FRα) expression.	Deferred	Deferred The PBAC deferred its consideration of mirvetuximab soravtansine (MIRV) for the treatment of patients with platinum-resistant high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received at least one prior systemic treatment regimen, and have FRα tumour cell expression. The PBAC was of a mind to recommend MIRV, but noted that MIRV was submitted as an integrated codependent application to the Medical Services Advisory Committee (MSAC), which would consider MBS listing of FRα expression testing at its August 2025 meeting. The PBAC also noted that the Therapeutic Goods Administration's initial assessment is expected by September 2025. The PBAC noted and welcomed input from individuals, health care professionals and organisations. The PBAC accepted that there is a clinical need for additional treatments for this population, acknowledging the severe symptoms and impact on patient quality of life. The PBAC also noted that currently available chemotherapy options have significant side effects and are only modestly effective. The clinical evidence presented in the submission satisfied the PBAC that MIRV provides modest improvements to progression free and overall survival in the small group of patients with high FRα tumour cell expression. The PBAC accepted that FRα expression was a necessary criterion for access noting patients without high FRα tumour cell expression may have potentially worse outcomes if treated with MIRV. The cost of MIRV at the requested price was not commensurate with the modest potential benefits. The PBAC considered the benefits estimated in support of the proposed price were uncertain and overestimated. The PBAC considered that MIRV would be cost-effective with a substantial price reduction, to reflect the moderate benefit, and significant uncertainty about the extent of benefits that will be realised. Sponsor comment:

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				AbbVie thanks the PBAC for recognising the unmet need for Australian women with platinum-resistant ovarian cancer and for acknowledging the strong community support for this submission. Our intention is to work with the PBAC and Department towards a mutually acceptable path to listing mirvetuximab soravtansine, enabling equitable access for Australian patients as quickly as possible.
NEMOLIZUMAB Powder for injection containing nemolizumab 30 mg with diluent in pre-filled dual-chamber pen Nemluvio® GALDERMA AUSTRALIA PTY LTD Category 2 (New PBS listing)	Atopic dermatitis	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with severe atopic dermatitis affecting the whole body, face, and/or hands.	Not recommended	The PBAC did not 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 a health care professional. The PBAC noted that while patients have significantly benefited from current treatments for AD, the condition affects patients in different ways. The PBAC acknowledged there is still a need to have alternative treatments with different mechanisms of action on the PBS so patients can choose the treatment option best for their individual circumstances. The PBAC considered the submission's claim that NEMO is similarly effective to dupilumab (DUPI) was not adequately supported by the clinical data comparing NEMO and DUPI at 16 weeks as the data indicated NEMO is not as effective as DUPI. The Committee noted the additional clinical data on improved patient outcomes with an extended induction treatment period out to 24 weeks presented in the Pre-Sub-Committee Response. However, this dosing regimen was not included in the approved Therapeutic Goods Administration (TGA) Product Information. The PBAC considered this dosing regimen would need to be approved by the TGA for any consideration of this as a PBS listing. <u>Sponsor's Comment:</u> Galderma remains committed to working with the PBAC, clinicians and patient groups to make nemolizumab available for Australian patients with severe atopic dermatitis.

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NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Category 2 (Change to existing listing)	Advanced (unresectable) Barcelona Clinic Liver Cancer Stage A, Stage B or Stage C hepatocellular carcinoma (HCC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of advanced (unresectable) HCC.	Not recommended	The PBAC did not recommend the listing of nivolumab in combination with ipilimumab (NIVO+IPI) for the first-line treatment of patients with advanced (unresectable) Barcelona Clinic Liver Cancer (BCLC) Stage A, Stage B or Stage C HCC. The PBAC welcomed input from organisations which supported listing NIVO+IPI on the PBS for HCC. The PBAC acknowledged the impact of HCC on those with this condition and their families. However, the PBAC considered there was a low clinical need for NIVO+IPI as first-line treatment for HCC given it is not recommended as a preferred regimen for HCC in current treatment guidelines and there are alternatives on the PBS (atezolizumab plus bevacizumab, ATEZ+BEV) or recommended to be listed on the PBS (Single Tremelimumab Regular Interval Durvalumab, STRIDE). The clinical evidence included in the submission did not satisfy the PBAC that NIVO+IPI was as effective as the main alternative treatment, ATEZO+BEV, at improving overall survival. The claim that NIVO+IPI was as effective as ATEZO+BEV was based on clinical studies where both were compared to the common alternative sorafenib/lenvatinib. However, the outcomes of the study comparing NIVO+IPI to sorafenib/lenvatinib did not clearly show how much NIVO+IPI improved overall survival compared to sorafenib/lenvatinib. Overall survival for patients varied widely in the comparisons of NIVO+IPI with ATEZO+BEV and point estimate results favoured ATEZO+BEV. The PBAC considered that these results did not sufficiently rule out the possibility that NIVO+IPI would provide worse outcomes for patients than ATEZO+BEV. <u>Sponsor's Comment:</u> The Sponsor is committed to working with the PBAC and the Department of Health, Disability and Ageing to progress these submissions through to PBS listing.

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NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Category 2 (Change to existing listing)	Unresectable or metastatic colorectal cancer (mCRC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of microsatellite instability high or mismatch repair deficient mCRC.	Not recommended	The PBAC did not recommend nivolumab plus ipilimumab for the first line treatment of microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) unresectable mCRC. The PBAC welcomed input from health professionals, individuals, and consumer and medical organisations. The PBAC acknowledged that the likelihood of disease progression remains high for people with mCRC and there is a clinical need for additional therapies. The PBAC also noted the serious side effects of current therapies, particularly chemotherapy. The PBAC considered that the clinical evidence demonstrated that nivolumab plus ipilimumab was more effective than the current standard of care (pembrolizumab) at improving progression free survival. However, the size of benefit was uncertain. The PBAC considered the estimates of clinical benefits in support of the proposed price were overly optimistic and not reliable for assessing how cost-effective nivolumab plus ipilimumab would be compared to pembrolizumab. The PBAC also considered that the financial estimates were uncertain and likely overestimated and would likely require revision. <u>Sponsor's Comment:</u> The Sponsor is committed to working with the PBAC and the Department of Health, Disability and Ageing to progress these submissions through to PBS listing.
NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL	Unresectable advanced and metastatic cancer	To consider a proposal for an expanded listing to facilitate broad access for unresectable advanced and metastatic cancer.	Deferred	The PBAC deferred making a recommendation for an expanded listing of nivolumab and ipilimumab for a multi-indication (broad) listing in unresectable advanced or metastatic cancers. The PBAC considered the most recent proposal from the sponsor had met the majority of its expectations to support a broad listing but considered further discussions were required to finalise the requirements of the Risk Sharing Arrangement (RSA) and financial estimates to ensure the price at which the drugs would be supplied would be cost-effective in all treatment scenarios covered by the listing and the financial risk was acceptably shared between the sponsor and the Commonwealth. The PBAC welcomed the approach of the proposal which would provide clinician discretion to use the medicines in an evidence-

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Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Other matters (Change to existing listing)				based manner and provide access to patient groups with rare cancers where there was evidence of benefit, but for which it was unlikely that a submission for PBS listing for the specific indications would be made. The PBAC noted that, should a broad listing proceed, it would be necessary for the sponsor and clinical community to ensure utilisation of the listing occurred consistent with the intent of the listing. That is, that the medicines would be supplied under the PBS only for indications for which there was evidence to support a reasonable expectation of efficacy and a positive benefit to risk balance for that condition. As such, the PBAC welcomed the sponsor's intention to develop supporting prescriber educational and evidence-based resources to support the listing if it were to be recommended and implemented. The PBAC asked that the sponsor consider the proposed amendments to the financial estimates and RSA structure and provide a revised proposal aligned with these for consideration at the next available opportunity. <u>Sponsor's comment:</u> While disappointed that the PBAC has deferred a decision with regards to this submission to broaden the PBS listing for OPDIVO (nivolumab) and YERVOY (ipilimumab) at the July PBAC meeting, Bristol Myers Squibb Australia (BMSA) remains committed to working with the PBAC to navigate a prompt pathway to approval.

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OCRELIZUMAB Solution for subcutaneous injection 920 mg in 23 mL Ocrevus® ROCHE PRODUCTS PTY LTD Category 4 (New PBS listing)	Relapsing-remitting multiple sclerosis (RRMS)	To request Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings of a new form for the treatment of RRMS.	Recommended	The PBAC recommended the listing of a new form of ocrelizumab (solution for subcutaneous injection 920 mg in 23 mL; ocrelizumab SC) under the same circumstances as the PBS-listed ocrelizumab solution concentrate for intravenous infusion 300 mg in 10 mL (ocrelizumab IV), for the treatment of adult patients with RRMS. The PBAC advised the equi-effective doses to be a single dose of ocrelizumab SC 920 mg in 23 mL to ocrelizumab IV 300 mg in 10 mL, two vials as a single infusion (600 mg), administered every six months.
ODEVIXIBAT Capsule 200 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms Bylvay® IPSEN PTY LTD Matters arising from the minutes (New PBS listing)	Progressive familial intrahepatic cholestasis (PFIC)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of PFIC.	Recommended	The PBAC recommended the PBS listing of odevixibat for the treatment of PFIC. The PBAC recognised that there was a high clinical need for treatments for this rare condition and recalled that it had previously considered that odevixibat was superior compared to the nominated comparator, standard of care. The PBAC considered that the outstanding issues from the March 2025 resubmission had been addressed, including revised restrictions, a reduced price, which resulted in a cost per patient per year that was considered cost-effective, and revised financial estimates. Further, the PBAC considered that a risk sharing arrangement would mitigate financial risks associated with utilisation that is not cost-effective such as dose escalation and in patients who do not respond to treatment.
OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® ASTRAZENECA PTY LTD Category 2 (Change to existing listing)	Unresectable locally advanced (Stage III) non-small cell lung cancer (NSCLC)	To request a General Schedule Authority Required (Telephone/Online) listing of osimertinib as monotherapy for the treatment of patients with unresectable, locally advanced (Stage III) epidermal growth factor receptor (EGFR) mutation positive NSCLC whose disease has not progressed during or following platinum-based chemoradiation therapy.	Recommended	The PBAC recommended the listing of osimertinib for the treatment of locally advanced (Stage III) epidermal growth factor receptor (EGFR) pathogenic variant positive NSCLC that has not progressed during or following platinum-based chemoradiation therapy and cannot be surgically removed. The PBAC welcomed input from an individual and organisations which supported the proposed listing of osimertinib for this population. The PBAC acknowledged the clinical need for treatments for Stage III NSCLC that cannot be surgically removed and noted the lack of targeted treatment currently available for EGFR positive NSCLC. The PBAC noted that it would be preferable for any PBS listing for osimertinib to cover all the

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				EGFR positive NSCLC patient populations. The PBAC also noted comments emphasised the significant financial burden experienced by NSCLC patients. The PBAC considered comments that the cost of osimertinib remained a barrier to treatment and that a PBS listing would ensure equity of access. Based on the evidence included in the submission, the PBAC considered that osimertinib provides an additional clinical benefit for patients over the current standard of care (active surveillance). Results from the key clinical trial showed that patients who received osimertinib had meaningfully improved progression free survival, while the data was too immature to demonstrate any significant improvement in overall survival compared to the current standard of care. The benefits estimated in support of the proposed price were overly optimistic, particularly gains in quality of life and estimated long-term overall survival. The clinical evidence included in the submission, which did not demonstrate improvement in overall survival, did not allow confidence that the benefits claimed in support of the proposed price would be realised. The PBAC considered that osimertinib would be cost-effective with a reduction in price to reflect more realistic estimates of benefits. The PBAC also considered that the financial estimates were uncertain, and likely overestimated, and advised that the inputs used to calculate the eligible patient population required revision.

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PALIPERIDONE I.M. injection (modified release) 25 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 50 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 75 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 100 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 150 mg (as palmitate) in pre-filled syringe Paljuna Monthly JUNO PHARMACEUTICALS PTY LTD Category 3 (New PBS listing)	Schizophrenia	To request General Schedule Authority Required (STREAMLINED) listings of a new generic brand of paliperidone monthly long-acting injection for the maintenance treatment of schizophrenia.	Recommended	The PBAC recommended the General Schedule Authority Required (STREAMLINED) listings for a new generic brand of paliperidone monthly long-acting injection (Paljuna Monthly) in 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg strength pre-filled syringe (PFS) forms, under the same circumstances as the PBS-listed originator brand, Invega Sustenna®, for the treatment of schizophrenia. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Paljuna Monthly would be acceptable if it were cost-minimised to Invega Sustenna. The PBAC advised that Paljuna Monthly and Invega Sustenna should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) at equivalent strengths. The PBAC considered that listing Paljuna Monthly would not result in a net cost to the PBS/RPBS, as it is expected to substitute for Invega Sustenna without increasing overall market utilisation.
PALOPEGTERIPARATIDE Solution for subcutaneous injection 168 micrograms in 0.56 mL pre-filled pen Solution for subcutaneous injection 294 micrograms in 0.98 mL pre-filled pen Solution for subcutaneous injection 420 micrograms in 1.4 mL pre-filled pen Yorvipath® SPECIALISED THERAPEUTICS PHARMA PTY LTD Early re-entry (New PBS listing)	Chronic hypoparathyroidism	Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of chronic hypoparathyroidism.	Not recommended	The PBAC did not recommend palopegteriparatide for the treatment of patients with chronic hypoparathyroidism (HPT) who are inadequately controlled on conventional therapy (i.e. active vitamin D and calcium supplements). The PBAC recalled the input it received from individuals, organisations and health professionals when palopegteriparatide was considered at the March 2025 meeting and welcomed further input from one individual to this meeting. The PBAC acknowledged that there is a clinical need for palopegteriparatide in a proportion of patients with HPT who have difficulty maintaining calcium levels with conventional therapy and for those who develop nephrocalcinosis, kidney stones or kidney impairment. The PBAC noted the burden associated with conventional therapy and acknowledged that the listing of palopegteriparatide would likely improve HPT control and reduce complications in patients who are inadequately controlled on calcium and vitamin D supplements.

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				The PBAC reaffirmed that it was satisfied that palopegteriparatide was effective at treating HPT in patients who were inadequately controlled on conventional therapy and had similar safety to conventional therapy. However, the PBAC noted that the sponsor's resubmission did not adequately address the issues it had raised in March 2025 relating to the economic evaluation. The sponsor continued to claim benefits in support of its proposed price that were overly optimistic. In particular, the PBAC considered the duration of benefit claimed by the sponsor was exceptionally long given the main clinical study assessed patients for 26 weeks. The PBAC considered palopegteriparatide would be cost-effective with a substantial reduction in the price, to reflect more realistic estimates of future benefits. The PBAC considered that the changes to the utilisation estimates were reasonable. The PBAC maintained its previous view that a risk sharing arrangement would be required to mitigate the risk of usage in the first line setting. The previous submission was considered in March 2025. <u>Comparator: Conventional therapy, consisting of active vitamin D and calcium supplements</u> The PBAC reaffirmed its previous view that the proposed comparator was reasonable. <u>Clinical claim: Superior effectiveness and non-inferior safety compared to conventional therapy</u> The PBAC reaffirmed its previous view that palopegteriparatide was superior compared to the nominated comparator of conventional therapy in terms of efficacy and likely comparable in terms of safety. <u>Economic claim: Cost-utility analysis comparing palopegteriparatide with conventional therapy</u>

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				Sponsor's Comment: Specialised Therapeutics (ST) acknowledges the significant input from patient groups, individuals, and 46 healthcare professionals who supported the submissions for Yorvipath. Whilst we appreciate the PBAC have recognised the clinical need for, and superior effectiveness of Yorvipath compared to current treatments, we are disappointed the treatment has not met PBAC's willingness-to-pay expectations. Consequently, it is with regret Yorvipath will not be made available to Australian patients at this time, as further and highly costly submissions to the PBAC are unlikely to be successful given the current impasse on pricing.
PEGUNIGALSIDASE ALFA Solution for I.V. injection 20 mg in 10 mL vial Elfabrio® CHIESI AUSTRALIA PTY LTD Category 2 (New PBS listing)	Fabry disease	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of Fabry disease.	Recommended	The PBAC recommended the listing of pegunigalsidase alfa for the treatment of Fabry Disease (FD), on the basis that it should be available only under Section 100 (Highly Specialised Drugs Program (Public and Private)), and on a cost-minimisation basis to migalastat. The PBAC considered pegunigalsidase alfa provides an alternative therapy for FD to migalastat, which is currently listed on the PBS and other enzyme replacement therapies currently on the Life Saving Drugs Program. It noted consumer comments citing the need for access to effective treatments for FD. The PBAC considered that migalastat was an appropriate comparator, and that pegunigalsidase alfa demonstrates similar effectiveness to migalastat, with a high level of uncertainty, and is as safe as migalastat. The PBAC therefore recommended listing pegunigalsidase alfa on a cost-minimisation basis to migalastat. The PBAC advised the equi-effective doses are pegunigalsidase alfa 78.9 mg every 2 weeks to migalastat 123 mg every other day. The PBAC recommended that the PBS listing for pegunigalsidase alfa should include the clinical criterion 'The treatment must be the sole PBS subsidised therapy for this condition', to prevent concomitant use of FD therapies and that this be flowed on to the current migalastat listing. The PBAC also recommended inclusion of a separate treatment phase to both the pegunigalsidase alfa and migalastat listings

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				to allow patients to switch from using pegunigalsidase alfa to migalastat and vice versa. The PBAC considered it would be appropriate that there be a risk sharing arrangement for pegunigalsidase alfa, and requested that a review of the utilisation of medicines for FD on the PBS be undertaken at a future point in time.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Category 2 (Change to existing listing)	Endometrial cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for pembrolizumab in combination with platinum-based chemotherapy, followed by pembrolizumab monotherapy, for primary advanced or recurrent endometrial cancer, regardless of mismatch repair status.	Not recommended	The PBAC did not recommend pembrolizumab for the treatment of primary advanced or recurrent endometrial cancer. The submission had initially sought listing on the PBS for patients irrespective of whether their endometrial cancer cells had a functioning mismatch repair (MMR) system. However, the submission did not include a comparison of pembrolizumab against the current standard of care for endometrial cancer with proficient MMR (functioning MMR or pMMR). The sponsor subsequently requested the PBAC only consider use for endometrial cancer where mismatch repair is deficient (dMMR) as part of this submission. The PBAC received and welcomed input from organisations. Overall, the PBAC considered there was limited clinical need in the dMMR endometrial cancer setting given alternative treatments (dostarlimab and durvalumab) are subsidised through the PBS. The PBAC acknowledged the potential for pembrolizumab to be beneficial for some patients as an alternative to dostarlimab or durvalumab given it has a shorter maximum treatment duration (two years for pembrolizumab versus three years for dostarlimab or durvalumab). However, the clinical evidence presented in the submission did not satisfy the PBAC that pembrolizumab was as effective as dostarlimab or durvalumab at improving the progression free and overall survival of patients with dMMR endometrial cancer. The comparisons of pembrolizumab with dostarlimab and durvalumab showed that progression free and overall survival for patients who had received pembrolizumab varied widely. Further, point estimates generally favoured dostarlimab and durvalumab. The PBAC considered that these results did not sufficiently rule out the possibility that pembrolizumab would

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				provide worse outcomes for patients than dostarlimab and durvalumab. Sponsor's Comment: MSD is disappointed by the PBAC's decision not to recommend pembrolizumab (KEYTRUDA®) plus chemotherapy for advanced/recurrent (A/R) dMMR endometrial cancer (EC). It is disappointing that the PBAC considered the clinical need for additional treatment options was limited , especially given that MOGA considered the submission to be a "high priority for PBS listing". MSD considers the clinical trial results (NRG-GY018) and analyses presented establish non-inferiority to current treatments, despite patients in the study being prematurely unblinded. Accordingly, international guidelines have universally recommended pembrolizumab as one of the preferred treatment options for 1L dMMR A/R EC alongside dostarlimab and durvalumab. MSD will work with the PBAC to understand if there is a pathway for Australian women with endometrial cancer to have access to pembrolizumab (Keytruda)® in the first-line setting.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Other matters (Change to existing listing)	Unresectable advanced and metastatic cancer	To consider a proposal for an expanded listing to facilitate broad access for unresectable advanced and metastatic cancer.	Not recommended	The PBAC did not recommend the proposal for a multi-indication (broad) listing for pembrolizumab in advanced or metastatic cancers. The PBAC considered the proposal for the broad listing did not establish a reliable basis for the financial estimates, which also raised significant uncertainty in the ability to achieve a cost-effective listing, given the complex pricing and Risk Sharing Arrangement (RSA) structure proposed. The PBAC considered the prices proposed for each of the extended circumstances of use—including the additional indications, extended time on treatment, and retreatment—to be too high, and concluded that a further price discount would be required to ensure cost-effectiveness. The PBAC noted the proposal was restricted to the indications for which pembrolizumab was registered with the Therapeutic Goods Administration and, as such, would not provide access to some patient groups in which there is a significant unmet clinical need, such as rare cancers. The PBAC noted a regulatory

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				and subsequent submission for subsidy was unlikely to be made for these patient groups and recalled it was access for this area of clinical need that was one of the initial driving factors behind the broad listing proposals for PD-L(1) inhibitors. The PBAC considered it was important that any broad listing proposal was paired with consideration of this area of unmet need, either as part of the proposal or in parallel with it. The PBAC acknowledged the collaborative efforts of the sponsor and Department in preparing the proposal and the significant work that had been undertaken to date. The PBAC encouraged the sponsor to continue to work with the Department and to consider whether a revised set of financial estimates and pricing proposal that addressed the issues raised in this consideration could be brought forward for consideration at a future meeting. <u>Sponsor's comment:</u> MSD is disappointed by this decision. MSD partnered closely with clinicians and patient advocacy groups during the development of this submission to ensure it would improve affordable access to immunotherapy for Australian cancer patients. We hope to find clarity on a way forward during upcoming engagements with the PBAC and Department of Health in order to provide an equitable solution for Australian cancer patients.
RESPIRATORY SYNCYTIAL VIRUSYVACCINE Injection (0.5 mL) Abrysvo® PFIZER AUSTRALIA PTY LTD Matters arising from the minutes (New NIP listing)	Respiratory syncytial virus (RSV)	To request National Immunisation Program (NIP) listing for the prevention of lower respiratory tract illness (LRTI) caused by RSV for adults 75 years of age and above, and for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years.	Recommended	The purpose of the July 2025 PBAC consideration was to seek advice on a proposal from the sponsor including a revised price for the proposed NIP listing of RSVpreF (Abrysvo®) for the LRTI caused by RSV for adults 75 years of age and above, and for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years. Consistent with its November 2024 advice, the PBAC recommended that respiratory syncytial virus vaccine (Abrysvo, RSVpreF) be a designated vaccine for the purposes of the *National Health Act 1953* for the prevention of LRTI caused by RSV for adults 75 years of age and above, and for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years.

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				The PBAC recalled that input from individuals and organisations was considered at the time of the November 2024 PBAC consideration. The PBAC agreed that there is a high clinical need for vaccines to reduce the risk of RSV in older adults. The PBAC noted that RSV is a common respiratory infection and although symptoms may be mild, some older adults develop severe disease such as acute bronchitis, pneumonia, or exacerbation of pre-existing conditions including asthma, chronic obstructive pulmonary disease and congestive heart failure. The PBAC considered that the vaccine was effective at preventing LRTI and had an acceptable safety profile. However the evidence provided by the sponsor did not provide certainty about the duration or extent of protection in the requested populations. The PBAC considered the revised information presented by the sponsor, and advised that it would be reasonable to assume the vaccine would provide protection from RSV for three years, as compared with two years which had been supported by the PBAC in November 2024 based on information available at that time. The PBAC noted that the proposal had offered a lower price and revised economic evaluation, however the ICER based on the PBAC's recommended inputs and the proposed price remained unacceptably high. The PBAC did not agree the cost at the price requested would be commensurate with the benefits. On this basis, the PBAC considered that a price reduction would be required to ensure the vaccine is cost-effective in the proposed circumstances of use. The PBAC noted that in addition to the two recommended populations, the Australian Technical Advisory Group on Immunisation (ATAGI) supported a listing for high-risk people aged 60 to 74 years with risk factors as defined by the ATAGI. Consistent with its previous advice, the PBAC considered there is a high clinical need for an effective vaccine for this population. The PBAC noted that this population would be addressed in a future resubmission.

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				The National Immunisation Program (NIP) is the main mechanism through which the Australian Government can fund free vaccines for eligible people, in order to increase immunisation rates and help reduce vaccine-preventable diseases. Vaccines can only be provided for free under the NIP after the PBAC has recommended that the vaccine be a designated vaccine, as required by the *National Health Act 1953*.
RESPIRATORY SYNCYTIAL VIRUS VACCINE Powder and suspension for injection (0.5 mL) Arexvy® GLAXOSMITHKLINE AUSTRALIA PTY LTD Standard re-entry (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	Resubmission to request a National Immunisation Program (NIP) listing for the prevention of lower respiratory tract disease caused by RSV in older adults.	Recommended	The PBAC recommended that respiratory syncytial virus vaccine (Arexvy, RSVPreF3 OA) be a designated vaccine for the purposes of the *National Health Act 1953* for the prevention of lower respiratory tract disease (LRTD) caused by RSV in the two populations requested by the resubmission, which included adults 75 years of age and above, and Aboriginal and Torres Strait Islander peoples aged 60 to 74 years. The PBAC welcomed input from individuals and organisations. The PBAC considered that there is a high clinical need for vaccines to reduce the risk of RSV in older adults. The PBAC considered that Arexvy helped protect against LRTD caused by RSV more than not getting the vaccine and considered it was generally safe and well tolerated although there were some uncertainties around how long Arexvy's protection would last. The PBAC noted the clinical evidence for Arexvy over three seasons, and advised that it would be reasonable to accept vaccine efficacy (VE) over a period of three years for the purposes of the economic evaluation. The PBAC recalled that it recommended another RSV vaccine, Abrysvo, be a designated vaccine at its November 2024 meeting for the same populations (people ≥75 years and Aboriginal and Torres Strait Islander peoples aged 60 to 74 years). The PBAC considered that on balance, based on the available evidence, Arexvy was likely just as safe and just as effective as Abrysvo in preventing LRTD caused by RSV. On this basis, the PBAC advised that Arexvy would be cost-effective at the price that was recommended for RSVPreF (Abrysvo). The PBAC considered, given the comparable effectiveness and safety of the Arexvy

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				and Abrysvo vaccines, that their inclusion on the NIP should not result in any additional net cost to Government. The PBAC noted that in addition to the two recommended populations, the Australian Technical Advisory Group on Immunisation (ATAGI) supported a listing for high risk people aged 60 to 74 years with risk factors as defined by the ATAGI. Consistent with its previous advice, the PBAC considered there is a high clinical need for an effective vaccine for this population. The PBAC noted that this population would be addressed in a future resubmission. The National Immunisation Program (NIP) is the main mechanism through which the Australian Government can fund free vaccines for eligible people, in order to increase immunisation rates and help reduce vaccine-preventable diseases. Vaccines can only be provided for free under the NIP after the PBAC has recommended that the vaccine be a designated vaccine, as required by the *National Health Act 1953*.
Review of PBS-listed medicines for nurse practitioner prescribing Various forms and strengths Various brands Various sponsors	Various	To request the PBAC consider a tranche of PBS-listed medicines which do not include nurse practitioners as authorised prescribers but may be suitable for prescribing by these health professionals.	Recommended	The PBAC considered the final tranche of medicines for the Review of PBS prescribing by nurse practitioners and endorsed midwives (the Review). The PBAC reviewed a list of stakeholder-identified General Schedule oncology and haematology medicines, and Section 100 (S100) Highly Specialised Drugs (HSD) program medicines for which nurse practitioners are not eligible prescribers. The PBAC recommended amendment of most of the identified General Schedule oncology and haematology medicines to allow nurse practitioners to continue existing therapy where patient care is being shared with a medical practitioner. The PBAC recommended that several medicines on the S100 HSD program are suitable for prescribing by nurse practitioners for continuing treatment, where there is agreement from the treating medical specialist. Further, the PBAC was supportive of nurse practitioners prescribing initial or continuing treatment with S100 HSD listed iron chelating medicines (deferasirox,

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				deferiprone, desferrioxamine) where the patient's care is shared with a medical practitioner. The PBAC noted that amendments to the s100 HSD program legislative instrument would be required before these S100 HSD recommendations could be implemented. For consistency with its November 2024 consideration of listings with a nurse-practitioner continuing therapy only (CTO) note, the PBAC recommended removal of the CTO note for the following PBS-listed medicines: estradiol 0.06% (750 microgram/actuation) gel (Estrogel®), progesterone 100 mg capsule (Prometrium®), progesterone 100 mg capsule [30] (&) estradiol 0.06% (750 microgram/actuation) gel (Estrogel Pro®). In making its recommendations, the PBAC reiterated that the intent of the Review is not to expand or vary the scope of practice of nurse practitioners and endorsed midwives as prescribing is limited by a health practitioner's scope of practice, adherence to professional practice standards, and state or territory prescribing regulations.
RIBOCICLIB Tablet 200 mg Kisqali® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 2 (Change to existing listing)	Hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) early breast cancer	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with HR+/HER2- resected, Stage II or III early breast cancer at high risk of recurrence.	Not recommended	The PBAC did not recommend the listing of ribociclib, as combination therapy with adjuvant endocrine therapy (ET), for the treatment of HR+, HER2-, resected early breast cancer (eBC). The PBAC noted the risk of recurrence is lower in the proposed population compared with the HR+, HER2- adjuvant population already funded through the PBS. The PBAC acknowledged the input from patients, clinicians and organisations highlighted the physical and mental impacts of breast cancer, the fear and anxiety of recurrence in the years following cancer treatment and the need for additional therapies. The PBAC also noted the input describing the serious side effects associated with current care; however, the PBAC noted treatment with ribociclib was additive to ET, which would further increase the risk of adverse events. The PBAC noted that whilst the reductions in invasive disease-free survival (iDFS) and distant recurrence-free survival (DRFS) were statistically significant, reflecting the overall low rate of

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				recurrence for node negative/low patients, the reductions were small and smaller than observed for the current listing for the treatment of node positive patients. In the context of the increase in the number adverse events reported with the addition of ribociclib to ET, and that patients treated in the adjuvant setting forego treatment with a CDK4/6 in the metastatic setting, the PBAC considered the overall benefit associated with adding ribociclib to ET in node negative/low patients had not been demonstrated to be clinically meaningful. The PBAC noted the economic model presented in the submission estimated that the clinical benefit in node negative/low patients would be greater than that previously accepted for node positive patients, and considered this result to be implausible. <u>Sponsor's Comment:</u> Novartis believes all Australians with early breast cancer at high risk of recurrence should have equitable access to effective treatment options. The PBAC's decision not to recommend Kisqali leaves some women with HR+/HER2- high-risk early breast cancer without access to a treatment that can reduce their risk of disease recurrence. Novartis will continue to partner with the breast cancer community to advance care through collaboration and innovation.
SELADELPAR Capsule 10 mg Livdelzi® GILEAD SCIENCES PTY LTD Category 2 (New PBS listing)	Primary biliary cholangitis (PBC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of PBC in patients who have had an inadequate response to first line therapy with ursodeoxycholic acid (UDCA) or are intolerant to UDCA.	Deferred	The PBAC deferred making a recommendation for the listing of seladelpar for the treatment of PBC. The PBAC was of a mind to recommend seladelpar, pending advice from the Therapeutic Goods Administration Delegate. The PBAC welcomed input from the Liver Foundation who commented on the significant impact that PBC has on quality of life. The PBAC also noted the input provided during the sponsor hearing, which highlighted the need for alternative treatments for patients who do not respond to first-line treatment with ursodeoxycholic acid (UDCA). The PBAC noted the severity of impairment before effective medication was received, as articulated from the patient perspective presented in the hearing, and the patient's positive experience from the seladelpar trial.

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				The clinical evidence included in the submission did not satisfy the PBAC that seladelpar was more effective than obeticholic acid (OCA) at reducing markers of liver damage and improving cholestasis. The PBAC was satisfied that seladelpar was as effective as OCA for these outcomes and had similar safety. However, the PBAC also noted that patients treated with seladelpar reported improvement in itching symptoms and significantly lower rates of PBC-related pruritus compared to patients treated with OCA. The PBAC acknowledged that pruritus is a significant issue for patients with PBC. The PBAC also considered that seladelpar had similar effectiveness and safety to the near market comparator, elafibranor. The PBAC considered that a price premium for seladelpar over OCA, consistent with what was recommended for elafibranor in March 2025, would be reasonable given the potential reduction in PBC-related pruritus compared to OCA. The PBAC considered that seladelpar should join the risk sharing arrangement for OCA. <u>Sponsor's Comment:</u> The sponsor had no comment.
TACROLIMUS Ointment 1 mg per g, 30 g aZematop® ARROTEX PHARMACEUTICALS PTY LTD Category 2 (New PBS listing)	Atopic dermatitis	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe atopic dermatitis.	Recommended	The PBAC recommended listing of 0.1% tacrolimus (TAC) ointment for the treatment of moderate to severe atopic dermatitis (AD) affecting the body, face and eyelids. The PBAC welcomed input from health care professionals and organisations. The PBAC noted input which highlighted the issues with the currently available TAC compounded products, including drug stability issues, secondary bacterial infections, the significant cost and accessibility issues. The PBAC noted that comments highlighted the need for treatment options for patients who are unable to use topical corticosteroid (TCS) therapies. The PBAC noted that the submission nominated two comparators, 1% pimecrolimus (PIM) cream for the treatment of moderately severe flares on the face and eyelids and vehicle ointment (VO) for flare and maintenance treatment of

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				moderate to severe AD on the body and severe AD on the face and eyelids. For the treatment of moderately severe flares on the face and eyelids, the PBAC considered that 0.1% TAC was likely to have similar efficacy and safety to 1% PIM and, for this use, accepted the sponsor's proposal that 0.1% TAC cost no more than 1% PIM. For flare and maintenance treatment of moderate to severe AD on the body and severe AD on the face and eyelids, the PBAC did not consider VO to be an appropriate comparator. The PBAC considered standard medical management, which would include TCS treatments, to be a more appropriate comparator, noting that broad use of 0.1% TAC is expected and, in a substantial proportion of patients, it is likely that 0.1% TAC would be used as an alternative to moderate to high potency TCS. Noting the issues with the comparative data presented in the submission, the PBAC accepted, based on the results of meta-analyses, that 0.1% TAC was likely to be as effective and safe as standard medical management, including TCS. The PBAC therefore considered that, for this use, 0.1% TAC should cost no more than TCS. The PBAC considered that a weighted price, based on assumed usage across the two treatment settings, should be calculated.
TARLATAMAB Powder for injection 10 mg Imdelltra® AMGEN AUSTRALIA PTY LTD Category 1 (New PBS listing)	Small cell lung cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the third-line plus treatment of extensive-stage small cell lung cancer.	Not applicable	This item was withdrawn.

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TERIPARATIDE Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen Ritosa SUN PHARMA ANZ PTY LTD Category 4 (New PBS listing)	Osteoporosis	To request a General Schedule Authority Required (STREAMLINED) listing under the same conditions as the currently listed brands of teriparatide for the treatment of severe established osteoporosis.	Recommended	The PBAC recommended listing of teriparatide injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen (Ritosa®) under the same circumstances as the currently listed teriparatide injections 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pens (Teriparatide Lupin® and Terrosa®). The PBAC noted that the TGA established bioequivalence between Ritosa and the reference brand Forteo®. The PBAC considered the equi-effective dose of Ritosa 20 µg once daily subcutaneous injection = Terrosa 20 µg once daily subcutaneous injection = Teriparatide Lupin 20 µg once daily subcutaneous injection. The PBAC advised, under Section 101(4AACD) of the *National Health Act 1953*, that brands Ritosa and Terrosa and Teriparatide Lupin of teriparatide injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule).
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 Mounjaro® 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	Type 2 diabetes mellitus (T2DM)	Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of adults with inadequately controlled T2DM.	Deferred	The PBAC deferred making a recommendation on listing tirzepatide (Mounjaro®) on the PBS for the treatment of adult patients with inadequately controlled T2DM. The PBAC agreed that, based on evidence provided by Eli Lilly Australia Pty Ltd, tirzepatide once per week was more effective than semaglutide once per week for managing blood sugar. However, the PBAC remained concerned that the higher price requested by Eli Lilly was more than what the evidence showed it was worth. The PBAC considered the additional costs were overestimated and disproportionate to the modest additional benefits that tirzepatide might deliver over semaglutide. The PBAC was also concerned that if listed on the PBS, there was high likelihood that tirzepatide would be used for purposes other than for the treatment of T2DM. The PBAC did not consider the financial arrangements proposed by the sponsor would adequately manage this risk, and the impact on costs to the Commonwealth.

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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® KwikPen® ELI LILLY AUSTRALIA PTY LTD Standard re-entry (New PBS listing)				The PBAC deferred its decision so that it could have further discussions with the sponsor about listing tirzepatide on the PBS at a price consistent with expected benefits and with arrangements that would appropriately share financial risk. <u>Sponsor's comment:</u> Lilly is disappointed with the PBAC's deferral of the decision on the listing of tirzepatide for adults with inadequately controlled T2DM, noting this marks the third submission over a span of more than two years. Lilly does, however, appreciate the opportunity to continue discussions with PBAC. We thank all of the healthcare professionals, professional societies, leadership bodies, patient organisations, and consumers for their ongoing support and advocacy and are aware of the importance of this listing for the diabetes community. Lilly acknowledges the differing perceptions of value between the parties and remains committed to working with PBAC to swiftly determine if there is a viable path forward — one that reflects a fair price and appropriate risk-sharing.
TRIGLYCERIDES, MEDIUM CHAIN Oil 500 mL (MCT Oil) MCT Oil NUTRICIA AUSTRALIA PTY LIMITED (Other matters)	Chylous ascites Chylothorax Fat malabsorption Hyperlipoproteinaemia type 1 Intractable childhood epilepsy Cerebrospinal fluid glucose transporter defect Long chain fatty acid oxidation disorders	To request an increase in the maximum quantity of MCT Oil for all PBS-listed indications.	Recommended	The PBAC recommended removing the Administrative Advice 'No increase in the maximum quantity or number of units may be authorised' and 'No increase in the maximum number of repeats may be authorised' from the PBS listing of MCT Oil to enable patients requiring a larger quantity to receive prescriptions adequate for 1 months' supply per dispensing. The PBAC advised that increasing the maximum quantity in the listing may result in increased wastage for patients not requiring the larger quantities, but allowing prescribers to request an increased quantity for situations where patients require larger amounts for 1 months' supply will support patient access and reduce administrative burden while reducing the risk of wastage. The PBAC recommended that the removal of the Administrative Advice be flowed-on to the listing of Liquigen® (medium chain triglycerides oral liquid, 250 mL bottle).

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TRIGLYCERIDES - MEDIUM CHAIN, FORMULA Oral powder 400 g (Monogen) Monogen® NUTRICIA AUSTRALIA PTY LIMITED (Other matters)	Dietary management of conditions requiring a source of medium chain triglycerides Hyperlipoproteinaemia type 1 Long chain fatty acid oxidation disorders Chylous ascites Chylothorax	To request an increase in the maximum quantity of Monogen for all PBS-listed indications.	Recommended	The PBAC recommended removing the Administrative Advice 'No increase in the maximum quantity or number of units may be authorised' and 'No increase in the maximum number of repeats may be authorised' from the PBS listing of Monogen to enable patients requiring a larger quantity to receive prescriptions adequate for 1 months' supply per dispensing. The PBAC also recommended simplifying the listings for Monogen by combining the existing listings into a single, new item code. The PBAC advised that the current maximum quantity for Monogen would be sufficient for most patients, however there may be some patients who would require increased quantities. The PBAC advised that allowing prescribers to request an increased quantity for situations where patients require larger amounts for 1 months' supply will enable patients to access an increased quantity where required while reducing the risk of wastage. The PBAC recommended that the removal of the same Administrative Advices be flowed-on to the other listings for triglycerides medium chain formula (Peptamen® Junior, Lipistart®, Nutrini® Peptisorb).
TRIGLYCERIDES – MEDIUM CHAIN Oil 500 mL MCT Oil NUTRICIA AUSTRALIA PTY LIMITED Category 4 (Change to existing listing)	Chylous ascites Chylothorax Fat malabsorption Hyperlipoproteinaemia type 1 Intractable childhood epilepsy Cerebrospinal fluid glucose transporter defect Long chain fatty acid oxidation disorders	To request an increase in the maximum quantity of MCT Oil for all PBS-listed indications.	Not applicable	This item was withdrawn.

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VANZACAFTOR WITH TEZACAFTOR AND WITH DEUTIVACAFTOR Pack containing 84 tablets vanzacaftor 4 mg with tezacaftor 20 mg and with deutivacaftor 50 mg Pack containing 56 tablet vanzacaftor 10 mg with tezacaftor 50 mg and with deutivacaftor 125 mg Alyftrek® VERTEX PHARMACEUTICALS PTY LTD Category 2 (New PBS listing)	Cystic fibrosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of cystic fibrosis in patients who are aged 6 years and older and who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.	Deferred	The PBAC deferred making a recommendation for vanzacaftor, tezacaftor and deutivacaftor (VNZ/TEZ/D-IVA) for the treatment of cystic fibrosis in patients aged 6 years and older who have at least one mutation in the CFTR gene that is responsive to VNZ/TEZ/D-IVA based on clinical and/or in vitro assay data. The PBAC was of a mind to recommend VNZ/TEZ/D-IVA on receipt of the Therapeutic Goods Administration Delegate's Overview which was not available at the time of PBAC consideration. The PBAC welcomed input from clinicians and consumers. The PBAC acknowledged there was strong support for the listing of this medicine. The PBAC noted consumer comments that VNZ/TEZ/D-IVA would provide a once daily treatment option for patients with responsive mutations. Additionally, the PBAC noted VNZ/TEZ/D-IVA would provide access to a CFTR modulator for a small number of patients (<10) who have mutations that do not respond to elexacaftor, tezacaftor and ivacaftor (ELX/TEZ/IVA). The PBAC considered VNZ/TEZ/D-IVA was as effective and safe as ELX/TEZ/IVA. The PBAC noted the submission requested listing at a similar cost to ELX/TEZ/IVA and considered this was reasonable. The PBAC considered that VNZ/TEZ/D-IVA could be included in the risk sharing arrangement currently in place for CFTR modulators with no increase in expenditure caps. <u>Sponsor's comment:</u> The sponsor had no comment.

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VELMANASE ALPHA Powder for I.V. infusion 10 mg Lamzede® CHIESI AUSTRALIA PTY LTD Category 1 (New PBS listing)	Alpha- mannosidosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing as an enzyme replacement therapy for the treatment of non-neurological manifestations in patients with alpha-mannosidosis.	Deferred	The PBAC deferred making a recommendation for the listing of velmanase alfa for the treatment of non-neurological symptoms of alpha-mannosidosis (AM) to seek further information from the sponsor about the benefits of treatment and associated cost-effectiveness and to further develop the eligibility criteria for a PBS listing. The PBAC acknowledged that AM is an extremely rare and devastating genetic condition arising from issues with the alpha-mannosidase enzyme, leading to excess oligosaccharides (complex sugar molecules) throughout the body, with multi-systemic effects on patients. The Committee noted no effective pharmacological treatments for this disease are currently available in Australia. The PBAC noted that some patients receive haematopoietic stem cell transplant (HSCT), which comes with a high mortality risk and is therefore generally reserved for patients where the benefits are expected to outweigh the high risk. The PBAC noted that the current number of patients in Australia known to have AM is very low, noting that one child is born with the condition every 3-4 years. The PBAC noted that some of these patients will be considered for HSCT or might not be suitable for treatment with velmanase alfa. Whilst the PBAC accepted velmanase alfa is effective for reducing the level of oligosaccharides in the blood, the available data showed an uncertain association with the clinical and more patient-relevant outcomes studied in the trial, including walking distance, stair-climbing ability and lung capacity. However, the PBAC acknowledged reliable clinical data was difficult to obtain, given the rarity of disease and as most patients with AM are children. Therefore, the PBAC considered it would be helpful to receive additional information clarifying the clinical and patient-relevant benefits of treatment with velmanase alfa. The PBAC considered the uncertainty in the clinical information made the economic model presented in the submission difficult to interpret. Further, the PBAC considered

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				that the velmanase alfa was not cost-effective at the price proposed. In recognition of the rarity of the condition and the high need for effective therapies, the Committee considered velmanase alfa would be acceptably cost-effective with a price reduction that would result in an acceptable cost per patient per year, in line with other treatments for rare diseases funded on the PBS, accounting for clinical need, available evidence, range of the benefits and size of the patient population. Sponsor's comment: We thank the PBAC for acknowledging the unmet need in ultra-rare diseases and taking a flexible, patient-centered approach to the assessment of velmanase alfa (Lamzede®). Chiesi Australia is committed to working with the Department of Health on a path forward that ensures patients, and their families are no longer left waiting.
VORASIDENIB Tablet 10 mg Tablet 40 mg Voranigo® SERVIER LABORATORIES (AUST.) PTY. LTD. Category 1 (New PBS listing)	Astrocytoma or oligodendroglioma	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of isocitrate dehydrogenase-mutant astrocytoma or oligodendroglioma.	Not recommended	The PBAC did not recommend the listing of vorasidenib for the treatment of isocitrate dehydrogenase (IDH)-mutant astrocytoma or oligodendroglioma. The PBAC welcomed input from individuals, health care professionals and organisations. The PBAC acknowledged the high unmet clinical need for effective treatments for IDH-mutant astrocytoma or oligodendroglioma, noting that there are currently no other effective treatments available for patients not in immediate need of chemotherapy/radiotherapy. The PBAC 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 the that clinical evidence showed vorasidenib was more effective than active surveillance in terms

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				of radiographic progression (observable changes in medical imaging). The PBAC acknowledged that delaying the need for chemotherapy and radiotherapy is a treatment effect that is likely to have a meaningful impact on patient quality of life. The PBAC noted that, due to the slow progression of the disease, it was not possible to demonstrate a difference in overall survival or patient quality of life between vorasidenib and standard treatment within the trial. The PBAC noted that limitations of the clinical evidence made it uncertain whether benefits claimed in support of the proposed price would be realised. The PBAC considered the estimates of benefits in support of the proposed price were overly optimistic – particularly the estimated quality of life gains and the duration of progression free and overall survival. The PBAC considered the duration of treatment may be substantially longer than was assumed in the submission and a risk sharing arrangement would be required to address the potential for use beyond progression. The PBAC considered these issues could be resolved in a resubmission using the early re-entry pathway. <u>Sponsor's comments:</u> Servier is disappointed that the PBAC did not recommend the listing of vorasidenib for the treatment of isocitrate dehydrogenase (IDH)-mutant astrocytoma or oligodendroglioma. However, Servier is pleased that the PBAC has acknowledged the high unmet clinical need for effective treatments for IDH-mutant astrocytoma or oligodendroglioma and that treatment with vorasidenib is likely to have a meaningful impact on patient quality of life by delaying the need for chemotherapy and radiotherapy. Servier thanks the IDH-mutant astrocytoma and oligodendroglioma clinical and patient community for their valuable input to help inform the PBAC's decision making. Servier is committed to working with the Department to facilitate equitable patient access to vorasidenib as soon as possible.

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CARMELLOSE WITH GLYCEROL AND HYALURONIC ACID Eye drops containing carmellose sodium 5 mg with glycerol 9 mg and sodium hyaluronate 1 mg per mL Optive Fusion® ABBVIE PTY LTD	Severe dry eye syndrome	To request the PBAC review its May 2023 recommendation that has not yet been accepted by the applicant.	The PBAC rescinded the May 2023 recommendation for this drug.
GALCANEZUMAB Injection 120 mg in 1 mL pre-filled pen Emgality® ELI LILLY AUSTRALIA PTY LTD	Treatment-resistant high frequency episodic migraine	To request the PBAC review its March 2022 recommendation that has not yet been accepted by the applicant.	The PBAC extended the March 2022 recommendation for this drug for a further 12 months.
HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR Eye drops containing sodium hyaluronate 1.5 mg per mL with polyethylene glycol 400, propylene glycol and hydroxypropyl guar, 10 mL Systane® Hydration ALCON LABORATORIES (AUSTRALIA) PTY LTD	Severe dry eye syndrome	To request the PBAC review its May 2023 recommendation that has not yet been accepted by the applicant.	The PBAC rescinded the May 2023 recommendation for this drug.
MIRIKIZUMAB Solution concentrate for I.V. infusion 300 mg in 15 mL Solution for injection 100 mg in 1 mL pre-filled pen Omvoh® ELI LILLY AUSTRALIA PTY LTD	Ulcerative colitis	To request the PBAC review its July 2023 recommendation that has not yet been accepted by the applicant.	The PBAC extended the July 2023 recommendation for this drug for a further 12 months.

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MOBOCERTINIB Capsule 400 mg Exkivity® TAKEDA PHARMACEUTICALS AUSTRALIA PTY LTD	Non-small cell lung cancer	To request the PBAC review its July 2023 recommendation that has not yet been accepted by the applicant.	The PBAC rescinded the July 2023 recommendation for this drug.
SECUKINUMAB Solution for injection 300 mg in 2 mL pre-filled pen Solution for injection 300 mg in 2 mL pre-filled syringe Cosentyx® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED	Non-radiographic axial spondyloarthritis Severe active psoriatic arthritis Severe psoriatic arthritis Ankylosing spondylitis Active ankylosing spondylitis Severe chronic plaque psoriasis	To request the PBAC review its March 2022 recommendation that has not yet been accepted by the applicant.	The PBAC extended the March 2022 recommendation for this drug for a further 12 months.
SOMAPACITAN Injection 5 mg in 1.5 mL pre-filled pen Injection 10 mg in 1.5 mL pre-filled pen Injection 15 mg in 1.5 mL pre-filled pen Sogroya® NOVO NORDISK PHARMACEUTICALS PTY LIMITED	Paediatric patients with growth hormone deficiency	To request the PBAC review its July 2023 recommendation that has not yet been accepted by the applicant.	The PBAC extended the July 2023 recommendation for this drug for a further 12 months.
SOMAPACITAN Injection 10 mg in 1.5 mL pre-filled pen Sogroya® NOVO NORDISK PHARMACEUTICALS PTY LIMITED	Adult-onset growth hormone deficiency	To request the PBAC review its March 2022 recommendation that has not yet been accepted by the applicant.	The PBAC extended the March 2022 recommendation for this drug for a further 12 months.

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Transition of existing quadrivalent influenza formulations to trivalent formulations Injection (0.5 mL) Various brands Various sponsors (Other matters)	Prevention of influenza	To request advice from the PBAC on varying the National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1) to transition existing quadrivalent influenza vaccine formulations to trivalent formulations.	The PBAC noted that, in accordance with the World Health Organisation's recommendations, companies supplying influenza vaccines for the National Immunisation Program are transitioning their existing quadrivalent formulations to trivalent formulations. The PBAC also noted advice from the Australian Technical Advisory Group on Immunisation that studies comparing egg-based quadrivalent vaccines with trivalent vaccines have shown no significant difference in safety and reactogenicity outcomes. The PBAC recommended new brands containing trivalent formulations of influenza vaccines be designated vaccines. The PBAC also recommended specific changes to circumstances for currently designated trivalent influenza vaccines. The PBAC's recommendations for the trivalent formulations were on a cost-minimisation basis to the existing quadrivalent formulations.

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Adalimumab Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen Humira® ABBVIE PTY LTD Other matters (Change to existing listing)	paediatric chronic plaque psoriasis (CPP) paediatric enthesitis/spondylitis related juvenile idiopathic arthritis (ERA)	To request the PBAC's advice: 1. on amending the authority requirements for adalimumab for first continuing treatment of paediatric CPP. 2. on amending the authority requirements for adalimumab for initial and first continuing treatment of paediatric ERA. 3. regarding inclusion of a Grandfather listing for juvenile idiopathic arthritis (JIA), to accommodate paediatric patients currently received adalimumab via the sponsor's compassionate access program, who would otherwise meet the amended eligibility criteria for JIA (as recommended by the PBAC in December 2024).	The PBAC recommended the inclusion of a Grandfather listing for the amended JIA population (recommended in December 2024). The PBAC recommended amending the authority requirements for adalimumab for the treatment of paediatric ERA (recommended in December 2024) to align with the current authority requirements for adalimumab for the treatment of JIA (paediatric patients). The PBAC did not recommend amending the authority requirements for adalimumab for the treatment of CPP. The PBAC noted the requests from clinical stakeholders to amend the various authority requirements. The PBAC noted that the request from the sponsor for Humira® for a Grandfather listing would allow eligible children with JIA currently receiving treatment via the sponsor compassionate access program to transition to PBS subsidised therapy.

Version 4
Amendment:
1. SELADELPAR (Livdelzi®) – Added PBAC outcome

Previous Amendments:
1. MIRVETUXIMAB SORAVTANSINE (Elahere®) – Added PBAC outcome
2. VANZACAFTOR WITH TEZACAFTOR AND WITH DEUTIVACAFTOR (Alyftrek®) – Added PBAC outcome

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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.

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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.