PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
November 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	
21-VALENT PNEUMOCOCCAL CONJUGATE VACCINE Injection, 0.5 mL Capvaxive® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Category 2 (New NIP listing)	Prevention of pneumococcal disease in adults	To request a National Immunisation Program (NIP) listing for the prevention of pneumococcal disease for: adults who are currently eligible to receive the 13-valent pneumococcal conjugate vaccine under the NIP (adults under 70 with specified medical risk conditions, Aboriginal and Torres Strait Islander adults over 50 years of age, and all adults over 70 years of age) and Aboriginal and Torres Strait Islander people aged 25 to 49.	Recommended	The PBAC recommended that 21-valent pneumococcal conjugate vaccine (21vPCV, Capvaxive) be a designated vaccine for the purposes of the *National Health Act 1953*, for the prevention of pneumococcal disease in individuals with an at-risk condition aged ≥ 18 years, non-Indigenous adults aged ≥ 65 years and Aboriginal and Torres Strait Islander adults aged ≥ 25 years. The PBAC welcomed advice from the Australian Technical Advisory Group on Immunisation (ATAGI). Consistent with ATAGI advice, the submission proposed that 21vPCV be listed on the NIP as a single dose for all groups. The PBAC noted this would simplify the adult pneumococcal schedule. In comparison, the current schedule recommends 13-valent pneumococcal conjugate vaccine (13vPCV) followed by booster doses of 23-valent pneumococcal conjugate vaccine (23vPPV) in the Medically at Risk (MaR) and Aboriginal and Torres Strait Islander populations. The PBAC recommended reducing the age threshold for non-indigenous adults to 65 years (from 70 years), as proposed by the ATAGI. The PBAC noted that adults with chronic liver disease (CLD) and chronic obstructive pulmonary disease (COPD) are at increased risk of pneumococcal disease. It therefore recommended expanding the eligibility of the adult MaR population to include people with CLD or COPD. The PBAC noted that there were no clinical outcomes data for 21vPCV, and that there was the potential for coverage of 21vPCV to change over time. As such, the PBAC advised that more conservative assumptions should be applied when assessing the benefits the sponsor claimed in support of its proposed price. Additionally, the PBAC advised a price reduction would be required for 21vPCV to be considered cost effective, to reflect more realistic estimates of benefits and costs.

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AFLIBERCEPT Solution for intravitreal injection 2 mg in 50 microlitres (40 mg per mL) Solution for intravitreal injection 2 mg in 50 microlitres (40 mg per mL) pre-filled syringe Eydenzelt® CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 3 (New PBS listing)	Subfoveal choroidal neovascularisation (CNV) due to pathologic myopia (PM)	To request listing of a new aflibercept biosimilar for the treatment of CNV due to PM that mirrors the originator brand's current listing. Authority Required	Recommended	The PBAC recommended the listing of a new aflibercept biosimilar (Eydenzelt®) for the treatment of subfoveal choroidal neovascularisation (CNV) due to pathologic myopia (PM) on a cost-minimisation basis and under the same conditions as its reference biologic (Eylea®). The PBAC advised the equi-effective doses to be 1 mg Eydenzelt = 1 mg Eylea. The PBAC noted that initial treatment should remain Authority Required (Written/Online) and continuing treatment should be Authority Required (Streamlined) (in other words, the same restriction levels as Eylea). The PBAC also noted that the submission requested the addition of administrative advice reflecting the biosimilar uptake driver that encourages biosimilar prescribing for treatment-naïve patients. The PBAC considered that the application of that biosimilar uptake driver to Eydenzelt would be clinically appropriate.
BELANTAMAB MAFODOTIN Powder for injection 70 mg (50 mg per ml) Powder for injection 100 mg (50 mg per ml) Blenrep® GLAXOSMITHKLINE AUSTRALIA PTY LTD Category 1 (New PBS listing)	Relapsed and/or refractory multiple myeloma (MM)	To request listings of belantamab mafodotin for use in combination with bortezomib and dexamethasone for initial and continuing treatment of relapsed and/or refractory MM after one prior line of therapy. Authority Required (Telephone/Online) listing for initial treatment Authority Required (STREAMLINED) listing for continuing treatment	Not Recommended	The PBAC did not recommend listing belantamab mafodotin on the PBS for use in combination with bortezomib and dexamethasone (BmBd) for the treatment of multiple myeloma which has returned or is not responding to treatment, specifically relapsed and/or refractory multiple myeloma (RRMM) after one prior line of therapy. The PBAC welcomed the input from individuals, health professionals and organisations which supported the submission. The PBAC noted that input highlighted the need for additional lines of treatment to increase survival time. The submission sought conditions that would restrict BmBd to use in patients who have previously received only one prior line of therapy. The PBAC noted that this did not align with the clinical trial or with how clinicians would like to use multiple myeloma therapies. A large proportion of patients in the trial had received more than one prior line of therapy before receiving BmBd. At the multiple myeloma stakeholder meeting, clinicians emphasised that the categorisation of medicines by line of therapy reduced clinical discretion and may delay access to the optimal regimen. Clinicians agreed that the current line of therapy

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				nomenclature was no longer appropriate and that treatment sequencing could be improved if determined by prior drug exposure rather than lines of therapy. The PBAC therefore considered that BmBd should be listed for the treatment of RRMM more broadly to allow clinician and patient discretion about when and how it can be used. The PBAC accepted that BmBd was more effective at improving progression free and overall survival rates than the current standard of care, daratumumab in combination with bortezomib and dexamethasone. However, the PBAC also noted that belantamab mafodotin was associated side effects involving the eyes, including blurred vision, dry eye and visual impairment which affected patients ability to read and to drive. The PBAC considered that the claims made by the Sponsor to justify its requested price were too optimistic and did not adequately account for the costs and quality of life impacts associated with severe side effects affecting the eyes. The PBAC also considered that the estimation of how many patients will use this drug would need to be revised to account for use across the wider population of patients whose cancer has returned or is resistant to treatment. The PBAC considered that the measurement of sustained minimal residual disease (MRD) negativity could improve treatment decisions in patients with RRMM such as when to stop treatment and help to minimise side effects. The PBAC noted that the technology to measure MRD would need to be funded on the Medicare Benefits Schedule (MBS). Sponsor comment: GSK is disappointed by the decision not to recommend belantamab mafodotin (Blenrep®), in combination with bortezomib and dexamethasone (BVd). Equitable access to BVd for relapsed and/or refractory multiple myeloma (RRMM) is a priority for GSK, noting that the current PBS listings of drugs for RRMM create challenges in practice for

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				the optimal sequencing of RRMM treatments. GSK will work with the PBAC to ensure such barriers to optimal care are resolved in a future resubmission.
BIMEKIZUMAB Injection 320 mg in 2 mL single use pre-filled pen Bimzelx® UCB AUSTRALIA PROPRIETARY LIMITED Category 4 (New PBS listing)	Severe chronic plaque psoriasis (CPP)	To request a listing of a new strength of bimekizumab for the treatment of severe CPP. Authority Required	Recommended	The PBAC recommended the listing of bimekizumab 320 mg/2 mL prefilled pen for the treatment of severe chronic plaque psoriasis (CPP) under the same circumstances as bimekizumab 160 mg/1 mL prefilled pens. The PBAC welcomed input from medical organisations and noted that availability of bimekizumab 320 mg/2 mL was likely have a positive impact on improving adherence and reducing needle anxiety. The PBAC advised the equi-effective doses were one bimekizumab 320 mg/2 mL pre-filled pen and two bimekizumab 160 mg/1 mL pre-filled pens.
CALCIPOTRIOL WITH BETAMETHASONE Gel containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g Actobet® ACTOR PHARMACEUTICALS PTY LTD Category 4 (New PBS listing)	Chronic stable plaque type psoriasis vulgaris	To request listing of a new form of calcipotriol with betamethasone for the treatment of chronic stable plaque type psoriasis vulgaris. Restricted Benefit	Recommended	The PBAC recommended the listing of calcipotriol + betamethasone gel (Actobet) on the PBS. The PBAC recognised that there was a clinical need for a new form of topical calcipotriol + betamethasone treatment for the management of chronic stable plaque type psoriasis vulgaris of the scalp and body. The PBAC considered the equi-effective doses to be 1 mg Actobet = 1 mg calcipotriol + betamethasone ointment. The PBAC considered Actobet to have equivalent Psoriasis Area and Severity Index (PASI) % reductions compared to previously listed calcipotriol + betamethasone gel formulations.

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CETRORELIX Solution for injection 250 micrograms (as acetate) in 1 mL single use pre filled syringe Femvi® SUN PHARMA ANZ PTY LTD Category 4 (New PBS listing)	Assisted Reproductive Technology (ART)	To request a listing of a new form of cetrorelix for use in ART. Authority Required (STREAMLINED)	Recommended	The PBAC recommended the listing of cetrorelix solution for injection 250 micrograms (as acetate) in 1 mL single use pre-filled syringe, (Femvi®), on the basis that it should be available only under the same special arrangements as the currently listed cetrorelix (Cetrotide®) 250 microgram powder for reconstitution injection and inert substance diluent (1 mL syringe) for use in assisted reproductive technology to prevent premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation. The PBAC recommended the special arrangements of listing be under the Section 100 (IVF) schedule, Authority Required (Streamlined). This recommendation was on the basis of a cost minimisation with the equi-effective dose of Femvi 250 microgram SC = Cetrotide 250 microgram SC. The PBAC also recommended that the two forms of cetrorelix be considered interchangeable (a-flagged) with an administrative note added to the two listings regarding the different presentations of the medicines (PFS compared to powder for reconstitution and inert substance diluent).
DELGOCITINIB Cream 20 mg per g, 60 g Anzupgo® LEO PHARMA PTY LTD Category 2 (New PBS listing)	Chronic hand eczema (CHE)	To request listing of delgocitinib for the treatment of moderate to severe CHE where topical corticosteroids failed to achieve an adequate response or are medically inappropriate. Authority Required (Written)	Recommended	The PBAC recommended listing delgocitinib (Anzupgo®) on the PBS for the treatment of moderate to severe chronic hand eczema (CHE) for patients who cannot use or have not had an adequate response to multiple rounds of treatment with topical corticosteroids (TCS). The PBAC welcomed input from individuals, health professionals and organisations, who described CHE as a relentless condition causing both pain and physical distress that interferes with a range of daily tasks. The PBAC considered the management of CHE in practice was complex, and some patients would use multiple TCS, compounded topical treatments (e.g. tacrolimus), emollients, phototherapy, systemic agents and avoid irritants to attempt to manage their condition. The PBAC acknowledged that a gap in treatment options existed for peoples who have tried or cannot use TCS but were unsuitable or ineligible for subsequent therapies including systemic immunosuppressant drugs, or targeted therapies like dupilumab or upadacitinib. The PBAC acknowledged the need for new and

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				effective treatment options, especially given the side effects of prolonged medium to high potency TCS use, known safety issues with systemic immunosuppressant agents, and limits on accessing targeted therapies. The PBAC considered that the make-up of the nominated comparator of 'standard of care', defined in the submission as consisting of emollients and avoidance of known irritants, did not reflect the treatments likely to be replaced in practice, and that at least a proportion of patients would be receiving TCS. However, noting that clinical evidence against TCS was unlikely to become available, the PBAC accepted the comparison versus SoC. The PBAC considered the sponsor's approach to justifying its requested price unreliable as the economic model was based on multiple cycles of delgocitinib treatment, whereas there was only clinical evidence for one treatment cycle, and several inputs were based on insufficient data. The PBAC advised a simpler approach that assessed the benefits and costs over a single 16-week cycle of delgocitinib treatment would be adequate to determine an appropriate treatment cost per patient. The PBAC noted that there was a risk that more people would access subsidy for delgocitinib than the submission estimated, and that delgocitinib could be used on other body areas besides the hands. However, the PBAC considered that applying restrictions the prescribable amount and number of repeats would limit use outside of the proposed criteria. The PBAC noted that flow-on restriction changes would be required for dupilumab and upadacitinib, for use in patients aged 12 years or older, to allow use following treatment with delgocitinib after confirmation of a diagnosis of chronic, severe atopic dermatitis of the hand.

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DENOSUMAB Injection 60 mg in 1 mL pre-filled syringe Injection 120 mg in 1.7 mL Stoboclo® Osenvelt® CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 3 (New PBS listing)	Osteoporosis Giant cell tumour of bone Bone metastases	To request listings of two new denosumab biosimilars that mirror their respective originator brand's current listings. Authority Required (STREAMLINED)	Recommended	The PBAC recommended the listing of two new denosumab biosimilars (Stoboclo® [Injection 60 mg in 1 mL pre-filled syringe] and Osenvelt® [Injection 120 mg in 1.7 mL]) on a cost-minimisation basis and under the same conditions as their reference biologics (Prolia® and Xgeva® respectively) for the same indications. The PBAC advised the equi-effective doses to be 1 mg Stoboclo = 1 mg Prolia and 1 mg Osenvelt = 1 mg Xgeva. The PBAC noted that lowering the authority level for the two new biosimilars won't apply as all existing listings of denosumab (including for the reference brands) are already streamlined authority. The PBAC also noted that for the existing biosimilar brands of denosumab, there is already administrative advice reflecting the biosimilar uptake policy that encourages biosimilar prescribing for treatment-naïve patients. The PBAC considered this administrative advice is clinically appropriate for Stoboclo and Osenvelt.
DESMOPRESSIN Nasal spray (pump pack) containing desmopressin acetate 10 micrograms per actuation, 50 actuations, 5 mL Desmomed MEDSURGE HEALTHCARE PTY LTD Committee Secretariat (New PBS listing)	Cranial diabetes insipidus Primary nocturnal enuresis	To request listing of a new desmopressin acetate 10 microgram per actuation nasal spray with a different pack size that mirrors the originator brand's current PBS listings. Authority Required (STREAMLINED)	Recommended	The PBAC recommended listing a new brand of desmopressin nasal spray (Desmomed) with a new pack size (50 actuations, 5 mL) for the treatment of cranial diabetes insipidus and primary nocturnal enuresis, under the same restrictions as the currently PBS-listed reference brand, Minirin® nasal spray (60 actuations, 6 mL). The PBAC advised that Desmomed be cost-minimised to Minirin nasal spray on a per actuation (dose) basis. The PBAC noted the TGA's establishment of bioequivalence between Desmomed and Minirin nasal spray. The PBAC noted the ongoing shortage of Minirin nasal spray and the scheduled cessation of approval to supply Desmopressin Nasal Spray USP (Apotex) under Section 19A, effective 31 October 2025. In the absence of alternative PBS-listed products, the PBAC considered there to be a clinical need for an additional brand to support continued patient access. The PBAC advised that Desmomed and Minirin nasal spray should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) under Section 101 (4AACD) of the National Health Act.

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DURVALUMAB Solution concentrate for I.V infusion, 120 mg in 2.4 mL Solution concentrate for I.V. infusion, 500 mg in 10 mL Imfinzi® ASTRAZENECA PTY LTD Category 2 (Change to existing listing)	Muscle invasive bladder cancer (MIBC)	To request listing of durvalumab for the perioperative treatment (i.e. before and after surgery) of patients with MIBC who are planning to undergo radical cystectomy and are eligible for cisplatin-based neoadjuvant chemotherapy (i.e. eligible for cisplatin-based chemotherapy given prior to surgery). Authority Required (STREAMLINED)	Recommended	The PBAC recommended the listing of durvalumab for use before and after surgery in patients with muscle-invasive bladder cancer (MIBC) who are planning to have their bladder removed and are eligible for cisplatin-based chemotherapy before surgery. The PBAC acknowledged that MIBC is a challenging condition to treat with significant impacts on quality of life despite the current treatment options available. The PBAC was satisfied that, on balance, use of durvalumab before and after surgery improves the risk of the cancer returning and helps patients with MIBC live longer when compared with current standard of care. Based on the evidence included in the submission, the PBAC estimated that for every 100 patients who received durvalumab before and after surgery, 10 additional patients would remain cancer free at 3 years and 7 additional patients would remain alive at 5 years. However, the size of this benefit is uncertain due to differences across the clinical trials used to assess the effectiveness of durvalumab. Furthermore, the PBAC noted that the uncertainty was also from differences between treatments in the clinical trials and real-world clinical practice in Australia. The PBAC considered that with some revision to the estimated costs of treatment, together with a price reduction, durvalumab would be acceptably cost-effective. The PBAC considered that the estimated cost to the government was reasonable once minor adjustments were made to address an overestimation of the number of patients who would use this medicine. The PBAC recommended that durvalumab should be included in the existing risk sharing arrangement (RSA) in place for adjuvant nivolumab in patients at high risk of recurrence. The RSA would also be adjusted with an increase in the number of patient to include all eligible patients who are receiving surgery. The PBAC noted that there will also be changes to the restrictions for

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				nivolumab for urothelial carcinoma to restrict the use of immunotherapy to only once-per-lifetime and to simplify the approval process for initial and continuation treatments.
EFGARTIGIMOD ALFA Solution for subcutaneous injection 1000 mg in 5.6 mL Vyvgart® ARGENX AUSTRALIA PTY. LTD. Category 4 (New PBS listing)	Generalised myasthenia gravis (gMG)	To request a subcutaneous injection form of efgartigimod alfa for initial and continuing treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive. Authority Required	Recommended	The PBAC recommended efgartigimod alfa, 1 000 mg for subcutaneous injection (EFG SC), for the treatment of generalised myasthenia gravis (gMG) as a Section 100 (Highly Specialised Drugs) Authority Required (Written/Online) listing, as per the four gMG medicines recommended at its March 2025 meeting (efgartigimod alfa for infusion (EFG IV), zilucoplan, ravulizumab and rozanolixizumab). The PBAC advised that the equi-effective dose of 1 vial of subcutaneous EFG SC (1 000 mg) was equivalent to 2.4 vials of EFG IV (961 mg) was appropriate, and that the clinical claim of non-inferior effectiveness and non-inferior safety between the 2 forms was reasonable. The PBAC's recommendation was on the basis that the subcutaneous form be priced as per the other gMG medicines recommended at the March 2025 PBAC meeting, which comprised of a cost-comparison to intravenous immunoglobulin (IVIg) with a price premium administration benefit over IVIg. For the cost comparison, an annual dose of EFG SC 18,880 mg was considered equal to 541.1 g per year of IVIg. The PBAC advised that the efgartigimod alfa subcutaneous form should also enter the risk-sharing arrangement for the gMG medicines recommended in March 2025. The PBAC welcomed input from healthcare professionals, individuals and medical organisations and noted the effect of EFG SC in improving access to medicines for gMG, fewer side effects, and a marked increase in quality of life. It noted that people living with gMG in Australia face a significant and ongoing burden due to fluctuating symptoms, intrusive treatments, and treatment-related side effects.

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ENCORAFENIB BINIMETINIB Capsule 75 mg Tablet 15 mg Tablet 45 mg Braftovi® Mektovi® PIERRE FABRE AUSTRALIA PTY LTD Category 2 (New PBS listing)	Non-small cell lung cancer (NSCLC)	To request listing of encorafenib for use in combination with binimetinib for the treatment of adult patients with advanced or metastatic NSCLC with a BRAF V600E mutation who have not received prior systemic treatment in the metastatic setting. Authority Required (STREAMLINED)	Recommended	The PBAC recommended listing encorafenib and binimetinib (E+B; Braftovi® and Mektovi®) on the PBS for the treatment of adult patients with BRAF V600E mutation positive metastatic non-small cell lung cancer. The PBAC welcomed input from individuals, health professionals and organisations and acknowledged the high impact of the condition on patients and their families. Consumers supported more treatment options for people with this rare form of lung cancer. Since each patient tolerates treatments differently, the PBAC acknowledged the need for alternative treatments that have different side effect profiles. The PBAC was satisfied that E+B would provide similar health outcomes to the existing PBS-subsidised treatment, dabrafenib plus trametinib. The PBAC also considered that E+B may be better tolerated by some patients and result in fewer fevers than D+T. The PBAC advised that E+B would be cost-effective with a similar treatment cost to D+T. The PBAC considered that 450 mg/day of encorafenib and 90 mg/day of binimetinib would be equivalent to 300 mg/day of dabrafenib 300 mg/day and 2 mg/day of trametinib. The Committee also noted that the new 45 mg strength of binimetinib should also be listed for the treatment of melanoma, at the same price per mg as the 15 mg tablet, as this would reduce the number of tablets patients need to take. The PBAC noted that the addition of E+B to the PBS would result in changes to the restriction criteria for atezolizumab, cemiplimab, nivolumab, ipilimumab and pembrolizumab, allowing for sequential use of E+B if the condition progresses after these therapies. The PBAC noted that changes would also be required to the current D+T listing to prevent treatment switching between E+B and D+T for the same condition, except in the cases where the patient experiences intolerance or toxicity.

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ESTRADIOL WITH PROGESTERONE Capsule containing estradiol 1mg (as hemihydrate) with progesterone 100mg Bijuva® THERAMEX AUSTRALIA PTY LTD Category 2 (New PBS listing)	Vasomotor symptoms in post menopausal women	To request listing of estradiol with progesterone for the treatment of moderate to severe vasomotor symptoms in post-menopausal women. Restricted Benefit	Recommended	The PBAC recommended the listing of estradiol with progesterone (Bijuva) on the Pharmaceutical Benefits Scheme (PBS). Bijuva is an oral menopausal hormone therapy (MHT) for the treatment of moderate to severe vasomotor symptoms in postmenopausal women. The PBAC welcomed input from individuals, health care professionals and organisations. Stakeholders highlighted the impact of menopause symptoms on daily life. They also highlighted the need for more treatment options, especially for those who cannot use patches or gels. The PBAC acknowledged that it was important to have a diverse range of menopausal hormone therapy options available on the PBS. The PBAC noted that there is currently no oral fixed dose combination product containing estradiol and progesterone (or a similar progestogen hormone) for continuous menopausal hormone therapy listed on the PBS. The PBAC also acknowledged that while Bijuva could be purchased privately, the current cost was a barrier to access for some people. The PBAC noted that estradiol and progesterone (or a progestogen) are available separately on the PBS and can be used for menopausal hormone therapy. Additionally, there are PBS-listed products that combine topical (applied to the skin) estradiol and oral progesterone or a topical progestogen. One example of such products is Estrogel Pro. These products can also be used as continuous menopausal hormone therapy. The PBAC accepted the sponsor's claim that Bijuva had similar effectiveness to Estrogel Pro but did not accept the sponsor's claim that it would have similar safety. The PBAC noted evidence that oral estradiol increases risk of venous thromboembolism to a greater extent than transdermal estradiol. The sponsor had requested a price that was higher than other PBS listed menopause hormone therapies. It estimated that listing Bijuva would result in a cost saving through substitution with Estrogel Pro. The PBAC considered that cost saving was likely overestimated. This was because

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				Bijuva would likely be used as a substitute for less expensive menopausal hormone treatment therapies. Such therapies include patches, and separate oral estradiol and oral progesterone products that are prescribed together. The PBAC recommended Bijuva to be listed at a price no higher than the sum of the individual prices of estradiol valerate 1 mg tablet (28 days) and progesterone 100 mg capsule (25 days out of a 28-day cycle), based on equivalent doses.
FEDRATINIB Capsule 100 mg Inrebic® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Standard re-entry (New PBS listing)	Myelofibrosis (MF)	Resubmission to request listing of fedratinib for the treatment of patients with intermediate/high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis, or post-essential thrombocythaemia myelofibrosis. Authority Required (Telephone/Online)	Recommended	The PBAC recommended listing of fedratinib on the PBS for the treatment of patients with intermediate/high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis, or post-essential thrombocythaemia myelofibrosis. The PBAC was satisfied that fedratinib is as effective as ruxolitinib at reducing spleen volume, although it caused more gastrointestinal issues (such as diarrhoea, nausea or vomiting) and ongoing thiamine supplementation and monitoring was required with fedratinib due to the risk of Wernicke's encephalopathy. The PBAC welcomed input from individuals and consumer organisations. The PBAC noted the consumer support for having an additional treatment option that is not limited to a specific line of therapy and/or intermediate myelofibrosis subtype. The PBAC considered that the fedratinib mean daily dose of 349.96 mg/day is equal to ruxolitinib mean daily dose of 26.2 mg/day. The PBAC considered that nurse practitioners should be permitted to prescribe fedratinib for continuing existing treatment, where the patient's care is shared with a medical practitioner. The PBAC considered this should

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				flow on to the listings for momelotinib and ruxolitinib for the intermediate-1, intermediate-2 and high-risk myelofibrosis populations.
FENFLURAMINE Oral solution 2.2 mg (as hydrochloride) per mL, 360 mL Fintepla® UCB AUSTRALIA PROPRIETARY LIMITED Category 2 (Change to existing listing)	Lennox-Gastaut Syndrome (LGS)	To request listing of fenfluramine as add-on therapy for patients with LGS who are not adequately controlled with at least two other anti-epileptic drugs. Authority Required (Telephone/Online)	Recommended	The PBAC recommended listing fenfluramine (Fintepla®) on the Pharmaceutical Benefits Scheme (PBS) for the treatment of seizures in people with Lennox-Gastaut Syndrome who have not adequately responded to at least two other anti-seizure medications (ASMs). The PBAC welcomed input from individuals, healthcare professionals and organisations highlighting the devastating impact of Lennox-Gastaut Syndrome. Lennox-Gastaut Syndrome is a lifelong, rare and serious form of epilepsy that usually begins in childhood. It causes seizures that are often hard to control and can lead to injury and developmental delay. The PBAC acknowledged the significant caregiver burden for parents, families and carers. It also acknowledged that existing treatments, including anti-seizure medicines and cannabidiol, do not work well for everyone. The PBAC accepted there was a need for more treatment options. It noted that fenfluramine has a different mechanism of action to current treatment options on the PBS. The PBAC considered that while available clinical evidence was uncertain, on balance, fenfluramine was as effective as cannabidiol. It also noted that fenfluramine is associated with side effects including appetite suppression and weight loss. The PBAC noted these risks may be particularly concerning

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				for people with Lennox-Gastaut Syndrome, who may have feeding difficulties and be underweight. Furthermore, the PBAC was concerned that fenfluramine was known to cause serious cardiac (heart) issues and cardiac events have been reported in post-marketing surveillance for fenfluramine in treating Dravet syndrome and Lennox-Gastaut Syndrome. The PBAC considered the long-term risk of serious cardiac issues remained uncertain. Overall, the PBAC considered fenfluramine was likely to be less safe than cannabidiol in treating Lennox-Gastaut Syndrome. The PBAC considered the cost of fenfluramine per patient should reflect how effective and safe it is compared to cannabidiol. The PBAC considered fenfluramine should have similar restrictions to those it recommended for cannabidiol at its July 2025 meeting. It recommended subsidy for people who have not responded to at least two other anti-seizure medicines, with the additional requirement of cardiac monitoring. Despite a number of outstanding uncertainties, on balance, the PBAC considered the additional cost of listing fenfluramine on the PBS for Lennox-Gastaut Syndrome was likely to be small. The PBAC considered it appropriate to include fenfluramine in the risk sharing arrangements in place for cannabidiol for Lennox-Gastaut Syndrome with no change in the expenditure caps.
FEZOLINETANT Tablet 45 mg Veoza® ASTELLAS PHARMA AUSTRALIA PTY LTD Standard re-entry (New PBS listing)	Moderate to severe menopause-related vasomotor symptoms (VMS)	Resubmission to request listing of fezolinetant for the treatment of moderate to severe menopause-related VMS for whom menopausal hormone therapy is not suitable. Authority Required (STREAMLINED)	Recommended	The PBAC recommended fezolinetant (Veoza®) for the treatment of moderate to severe menopause-related vasomotor symptoms (VMS, also known as hot flushes) in people who are contraindicated to menopausal hormone therapy (MHT), have experienced side-effects necessitating withdrawal, or have had an inadequate response to MHT. The PBAC welcomed input from individuals, healthcare professionals and organisations in support of fezolinetant. The PBAC considered that there is a clinical need for non-hormonal treatments in patients who cannot take MHT.

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				The PBAC previously considered fezolinetant at its March 2025 meeting and did not recommend listing on the PBS at that time. The PBAC considered that it was not appropriate for fezolinetant to be used by people who could take MHT to treat menopause-related VMS as proposed by the sponsor, and noted there was increasing concerns that fezolinetant could cause liver damage in some patients. In this resubmission, the sponsor proposed revised clinical criteria that more clearly defined who could access fezolinetant on the PBS. The PBAC considered these proposed criteria were clinically appropriate, and accepted the proposed comparison with 'no treatment'. The PBAC recalled that evidence had shown that fezolinetant was more effective than no treatment at reducing the frequency of VMS episodes (hot flushes). Due to evidence of the risk of liver damage and the lack of long-term data, the PBAC considered fezolinetant less safe than no treatment. The PBAC considered that it was uncertain that the benefits claimed by the sponsor to support its requested price would be realised in practice. Additionally, it was still uncertain about how many people would access subsidy for fezolinetant – particularly, outside of the more narrow group of patients to be treated and concerns about liver toxicity. The PBAC recommended reduction in the price for fezolinetant. The PBAC also advised that a risk sharing arrangement with the sponsor would be required to mitigate risk associated with use outside the proposed restriction criteria. The PBAC considered that regular monitoring of liver function is important to mitigate risk of liver damage, and that this requirement should be included in the restriction.
FUTIBATINIB Tablet 4 mg	Bile duct cancer (cholangiocarcinoma)	Resubmission to request listing of futibatinib for the treatment of patients with locally advanced or metastatic cholangiocarcinoma	Deferred	The PBAC deferred making a recommendation for PBS listing of futibatinib for the treatment of patients with locally advanced or metastatic cholangiocarcinoma (a type of cancer in the bile duct) which has grown or spread despite being treated previously and has a specific genetic change;

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Lytgobi® TAIHO PHARMA OCEANIA PTY LTD Matters arising from the minutes (New PBS listing)		who have previously progressed on systemic therapy and have a fibroblast growth factor receptor 2 fusion or rearrangement. Authority Required (STREAMLINED)		the fibroblast growth factor receptor 2 (FGFR2) genetic variant in tumour tissue. The PBAC recalled the input it received from organisations when it considered futibatinib at previous PBAC meetings in March 2025 and July 2025 and noted that there is a clinical need for more effective therapies for people with locally advanced or metastatic cholangiocarcinoma. The PBAC acknowledged that survival outcomes are very poor for patients with advanced or metastatic cholangiocarcinoma. The PBAC was of a mind to recommend futibatinib but noted that Medical Benefits Scheme (MBS) funding for testing for the FGFR2 variant in cancer tissue was not recommended by the Medical Services Advisory Committee (MSAC) in July 2025 and would be reconsidered at the November 2025 MSAC meeting. The PBAC recalled it did not recommend futibatinib in March or July 2025 due to outstanding issues related to how the costs were calculated and whether benefits justified the price sought by the Sponsor. The PBAC considered a price reduction by the Sponsor has addressed these issues. The PBAC accepted that additional calculations provided more confidence that the proposed price would be in alignment with the benefits demonstrated in the submission." Sponsor comment: The sponsor had no comment.

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GIVOSIRAN Solution for injection 189 mg in 1 mL Givlaari® MEDISON PHARMA AUSTRALIA PTY LIMITED Matters outstanding (New PBS listing)	Acute hepatic porphyria (AHP)	To request listing of givosiran for the treatment of AHP in adults and adolescents aged 12 years and older. This matter was deferred at the July 2025 PBAC Meeting. Authority Required	Recommended	The PBAC recommended the listing of givosiran on the PBS for treatment of Acute Hepatic Porphyria (AHP) in patients aged 12 years and older. At its July 2025 meeting, the PBAC had deferred making a recommendation to list givosiran so that additional clinical input could be obtained on patient numbers, the likely circumstances of use, and treatment continuation. The PBAC considered this additional information would be necessary for establishing a risk sharing arrangement. The PBAC was satisfied that givosiran had greater efficacy than the current standard of care at reducing the number of porphyria attacks requiring hospitalisation, urgent healthcare visits or the need for intravenous hemin administration. The additional expert clinical input addressed the concerns PBAC had raised at its July 2025 meeting about uncertainty in the number of patients who would receive givosiran, how it would likely be used, and circumstances around stopping therapy. The PBAC considered that a lower price together with the risk sharing agreement proposal provided by the Sponsor adequately addressed concerns regarding the cost-effectiveness of givosiran.
GLYCOPYRRONIUM Cream containing glycopyrronium (as bromide) 8 mg per g (2.2 mg per actuation), 50 g Axhidrox® ACTOR PHARMACEUTICALS PTY LTD Category 2 (New PBS listing)	Primary axillary hyperhidrosis	To request listing of glycopyrronium for the treatment of patients aged 18 years and older with severe primary axillary hyperhidrosis. Authority Required (STREAMLINED)	Recommended	The PBAC recommended glycopyrronium cream (GPB) for the treatment of patients with severe primary axillary hyperhidrosis (PAHH). The PBAC acknowledged PAHH can be a burdensome condition for some patients, as the symptoms can lead to anxiety and social isolation, especially for young people. The consumer inputs highlighted GPB would allow easier access to PAHH treatment for patients. The PBAC also acknowledged that the only other treatment option on the PBS for PAHH, botulinum toxin A (BTA), can be costly, difficult to access, especially for regional and rural patients, and its administration in this condition was known to be painful. However, the PBAC also noted high-strength aluminium containing antiperspirants are available as over the counter products and are effective for some patients. Overall, the Committee considered there to be a moderate clinical need for additional options on the PBS for PAHH, given the known access issues for BTA.

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				The PBAC accepted BTA as the primary comparator. The PBAC acknowledged the proposed restriction and treatment algorithm previously accepted for BTA for PAHH, however considered the relative ease of access to GPB through general practitioners and typical out of pocket cost to patients for high strength aluminium-based treatments would likely result in GPB directly replacing these in practice. Therefore, the PBAC considered high strength topical aluminium-based treatments to be an additional comparator, however acknowledged the limited available clinical evidence for these products would prevent a reliable comparison with GPB. Based on the simple side-by-side comparisons of the GPB and BTA trials (with no formal statistical methods) provided in the submission, the PBAC considered GPB to be less effective than BTA. The PBAC considered the submission's claim that GPB had fewer side effects and was preferable to patients than BTA was not adequately supported. The limitations of the clinical evidence resulted in the submission's subsequent economic analysis comparing GPB and BTA to be largely uninformative. To address these concerns, the PBAC noted the pharmaceutical company proposed a price reduction to GPB based on the difference in naïve response rates of GPB and BTA. The PBAC noted further useful clinical information will likely not be forthcoming. In recognition of the unmet need for additional and more accessible treatments for PAHH, the PBAC considered the price proposed for GPB in the pre-PBAC response was unlikely to be good value for money and a further price reduction would be required. The PBAC considered a risk sharing arrangement would be required to manage the risk of use in patients with less severe PAHH. The PBAC advised that the listing would require changes to the PBS listing for BTA to allow only one PBS-subsidised therapy be used for PAHH at a

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				time. Additionally, the PBAC advised updating the criteria to require prior failure or intolerance to topical aluminium chloride, replacing aluminium chloride hexahydrate (a discontinued product) in the current BTA listing.
IMIGLUCERASE ELIGLUSTAT VELAGLUCERASE ALFA TALIGLUCERASE ALFA Powder for IV infusion, 400 units Capsule containing eliglustat tartrate, 100 mg Powder for IV infusion, 400 units Powder for IV infusion, 200 units Cerezyme® Cerdelga® Vpriv® Elelyso® SANOFI-AVENTIS AUSTRALIA PTY LTD SANOFI-AVENTIS AUSTRALIA PTY LTD TAKEDA PHARMACEUTICALS	Gaucher disease (type 1)	Referral from the LSDP Expert Panel seeking the PBAC's advice on whether eliglustat, imiglucerase, taliglucerase alfa, velaglucerase afla, would be cost-effective and suitable for PBS listing for the treatment of GD1. This matter was deferred at the July 2025 PBAC Meeting.	Not Recommended	The PBAC did not recommend listing medicines for the treatment of Gaucher disease type 1 (GD-1), imiglucerase, taliglucerase, velaglucerase and eliglustat on the Pharmaceutical Benefits Scheme (PBS). The PBAC noted and welcomed the input from clinicians and patient representatives regarding the benefits and concerns of listing these medicines on the PBS. The PBAC noted that the sponsors of enzyme replacement therapies provide access to various support programs, which included home infusion services. The types of other support measures, such as diagnostic testing and monitoring, varied between sponsors. The PBAC advised that it was uncertain that the full cost to the health system of listing these medicines on the PBS, including the need for expanding services on the MBS, could be accurately estimated based on the information currently available. The PBAC advised that a consideration of listing these medicines on the PBS was not suitable at this time. Sponsor comment: The sponsors had no comment.

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AUSTRALIA PTY LTD PFIZER AUSTRALIA PTY LTD Matters outstanding (New PBS listing)				
IPTACOPAN Capsule 200 mg Fabhalta® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD Category 1 (Change to existing listing)	Complement 3 glomerulopathy (C3G)	To request listing of iptacopan for the treatment of adults with C3G with either native kidneys or disease recurrence following a kidney transplant. Authority Required (Written)	Not Recommended	The PBAC did not recommend iptacopan for treatment of complement 3 glomerulopathy (C3G) in adults with either native kidneys (not having had a kidney transplant) or with disease recurrence following a kidney transplant. The PBAC welcomed input from individuals, health professionals and organisations. The PBAC considered that there is a high clinical need for treatments for C3G, which is a condition that impacts relatively young people and causes decline in kidney function. The PBAC acknowledged that existing treatments provide only modest improvements in maintaining kidney function. The PBAC acknowledged the impact of C3G on individuals who are often young adults, working, and raising or starting families. The PBAC noted that symptoms of end-stage kidney disease (where patients require dialysis or kidney transplant) frequently require healthcare visits or hospitalisation and impact their ability to attend school and work. The PBAC noted the impact of chronic kidney disease, relapses and treatment burden on their ability to participate in daily activities and their mental health. It also noted the toll of transplantation on patients and carers, and the difficulties of accessing dialysis for people in rural and remote areas. The PBAC reviewed the clinical evidence comparing the effectiveness and safety of iptacopan with the current standard of care regarding for both people with native kidneys and with C3G recurrence following kidney transplantation. The PBAC considered it is possible that iptacopan is more effective for some patients in terms of slowing progression to end-stage kidney disease. However, the PBAC noted the clinical benefit was not sufficiently supported as there are limited data showing the relationship

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				between change in proteinuria (unusually high levels of protein in urine), and delaying kidney transplant or dialysis in patients with C3G. There was also no significant difference in eGFR (estimated glomerular filtration rate; a test that measures how well kidneys are filtering waste from the blood) shown in the trial. Overall, the submission evidence did not allow confidence in the extent to which iptacopan would delay kidney transplant or dialysis for Australians with C3G. The clinical evidence also showed that iptacopan was less safe than standard of care, with increased risk of infection. The PBAC considered that the benefits claimed by the sponsor to justify its requested price were improbable and not supported by the clinical evidence included in the submission, particularly its claims about the avoidance of long-term dialysis and transplant. The PBAC considered that the cost-effectiveness of iptacopan had not been established. Sponsor comment: Novartis is disappointed with the PBAC's decision not to recommend iptacopan (Fabhalta®) for C3G. While we welcome the PBAC's acknowledgment of the significant burden and unmet need, C3G is an ultra-rare disease that typically affects younger people and leads to progressive kidney decline, making it critical that the value of iptacopan (Fabhalta®) is appropriately recognised for Australian patients and the healthcare system. We sincerely thank patients, clinicians, and organisations for their valuable contributions to the PBAC process.

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LAMOTRIGINE Tablet 5 mg Tablet 25 mg Tablet 50 mg Tablet 100 mg Tablet 200 mg Various brands Various sponsors Post-market review (Change to existing listing)	Bipolar disorder	The PBAC is being asked to consider the cost estimates to the R/PBS for a separate Restricted Benefit listing for lamotrigine for bipolar disorder.	Recommended	The PBAC recommended a new Restricted Benefit listing for all existing PBS-listed strengths of LTG tablets for the treatment of bipolar disorder, to be priced equivalently to the existing LTG listings for epileptic seizures. The PBAC recalled that in May 2025 it considered a Review of clinical guidelines and cost estimates for the use of anti-epileptic drugs (AEDs) for the treatment of epilepsy and considered there may be an unmet need to subsidise LTG for mental illnesses such as bipolar disorder. The PBAC noted pre-PBAC responses from the Royal Australian and New Zealand College of Psychiatrists (RANZCP), the Royal Australian College of General Practitioners (RACGP), the National Aboriginal Community Controlled Health Organisation (NACCHO) and one sponsor, which supported the proposed listing of LTG for this indication. The PBAC also noted that Australian clinical guidelines recommend LTG as a first-line monotherapy for bipolar depression and as a second-line monotherapy for the prevention of bipolar disorder in both adults and young people. The PBAC noted that, although both the RANZCP and NACCHO supported an Unrestricted Benefit listing, only three of the eight brands of LTG available on the PBS (Lamictal, Lamotrigine GH, and Sandoz Lamotrigine) are approved by the TGA for the treatment of bipolar disorder. Consequently, the PBAC recommended that the new Restricted Benefit listing should be limited to these three brands only. The PBAC accepted the financial estimates and considered the estimated net cost to the R/PBS of the proposed listing reasonable. The PBAC considered it is likely that LTG is cost-effective and represents reasonable value for money for this indication for the following reasons: • LTG is recommended as a first-line treatment for bipolar disorder in Australian clinical guidelines, suggesting its clinical effectiveness is comparable (non-inferior) to other PBS-listed alternatives.

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				• LTG is likely to offer improved safety and tolerability compared to other PBS-listed medicines for bipolar disorder, with a lower risk of teratogenic effects than alternatives such as valproate. • Cost comparisons per defined daily dose indicate that LTG is similar in price to other PBS-listed treatments for bipolar disorder, such as quetiapine. • As an F2 medicine, LTG is subject to statutory price reductions, price disclosure, and supply guarantees under the National Health Act 1953. Consequently, its cost-effectiveness for bipolar disorder is expected to improve further as prices decrease over time. The PBAC recommended that the department monitor the use of LTG following implementation of the new listing and advised that it would be prepared to reconsider the appropriateness of an Unrestricted Benefit listing for this medicine at a future meeting.
LURBINECTEDIN Powder for I.V. infusion 2 mg Powder for I.V. infusion 4 mg Zepzelca® SPECIALISED THERAPEUTICS PHARMA PTY LTD Category 1 (New PBS listing)	Small cell lung cancer (SCLC)	To request listing of lurbinectedin for use in combination with atezolizumab for first line maintenance treatment of extensive-stage SCLC for patients who have not progressed on or after first line induction therapy with atezolizumab, a platinum-based antineoplastic drug, and etoposide. Authority Required (STREAMLINED)	Not Recommended	The PBAC did not recommend listing lurbinectedin (Zepzelca®) on the PBS, when used in combination with atezolizumab, as ongoing treatment for extensive-stage small cell lung cancer (ES-SCLC) in patients who have received, and not progressed after, induction therapy with atezolizumab, a platinum-based anticancer drug, and etoposide. The PBAC, noting the aggressive nature of ES-SCLC, acknowledged that there was a high clinical need for effective therapies and welcomed the input and support for the submission from health professionals and organisations. The PBAC noted that lurbinectedin plus atezolizumab was associated with some improvement in patients living longer compared to atezolizumab alone, but that lurbinectedin plus atezolizumab was also associated with higher rates of side effects. The PBAC considered the benefits of lurbinectedin claimed by the Sponsor in its economic model were uncertain and overly optimistic. In particular,

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				the PBAC considered that the benefits in terms of preventing disease progression and improving survival were overestimated. The PBAC noted that treatment options for ES-SCLC were changing and considered lurbinectedin, as a single drug treatment, may be more appropriately used in patients who have received prior therapies and experienced disease worsening while on or after prior platinum-containing therapy. The PBAC considered the use of lurbinectedin in this setting would be in line with its current TGA approved indication. Sponsor comment: The sponsor had no comment.
MIRVETUXIMAB SORAVTANSINE Solution for I.V. infusion 100 mg in 20 mL vial Elahere® ABBVIE PTY LTD Matters outstanding (New PBS listing)	Epithelial ovarian, fallopian tube or primary peritoneal cancer	To request listing of mirvetuximab soravtansine 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. This matter was deferred at the July 2025 PBAC Meeting. Authority Required (Telephone/Online)	Recommended	The PBAC recommended listing of mirvetuximab soravtansine for the treatment of patients with platinum-resistant high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received at least one prior systemic treatment regimen, and have high folate receptor alpha (FRα) tumour cell expression. The PBAC recalled that at its July 2025 meeting, it was of a mind to recommend listing mirvetuximab soravtansine, but noted that, to determine which patients would benefit from mirvetuximab soravtansine, FRα expression testing was required and this test was yet to be considered by the MSAC. The PBAC also recalled that it was waiting for confirmation from the Therapeutic Goods Administration (TGA, Australia's regulator of medicines and therapeutic goods) that it would approve mirvetuximab soravtansine for ovarian cancer. The PBAC noted that MSAC had now indicated it was supportive of FRα expression testing and that the TGA delegate was supportive of the application to include mirvetuximab soravtansine on the ARTG. The PBAC maintained that there is a need for additional treatments for people with these types of cancers, acknowledging the severe symptoms and impact on

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				patient quality of life. The PBAC also noted that currently available chemotherapy options have significant side effects and are only modestly effective. At its July 2025 meeting, the PBAC noted that mirvetuximab soravtansine provides a modest benefit in slowing cancer progression and improving survival for the small group of patients whose ovarian cancer has high FRα tumour cell expression. The PBAC also noted patients whose ovarian cancer does not have a high level of FRα tumour cell expression may have worse outcomes if treated with mirvetuximab soravtansine compared with currently available standard treatments. The PBAC maintained that mirvetuximab soravtansine would be cost-effective with a substantial reduction in the price, to reflect the modest benefit, and significant uncertainty about the extent of benefits that would be realised in practice.
NITISINONE Capsule 2 mg Capsule 5 mg Capsule 10 mg Capsule 20 mg Oral suspension 4 mg per mL, 90 mL Orfadin® A. MENARINI PTY LTD Matters outstanding (New PBS listing)	Hereditary tyrosinaemia Type 1 (HT-1)	Referral from the LSDP Expert Panel seeking the PBAC's advice on whether nitisinone would be cost-effective and suitable for PBS listing for the treatment of HT-1. This matter was deferred at the July 2025 PBAC Meeting.	Recommended	The PBAC recommended listing nitisinone on the PBS as a Section 100 (S100) Highly Specialised Drugs Program (HSD) listing for the treatment of hereditary tyrosinaemia type 1 (HT-1). The PBAC noted outcomes of the Department's stakeholder consultation. The PBAC noted that the sponsor maintained that the LSDP remained the appropriate funding mechanism for nitisinone and expressed concerns that a transition from the LSDP to the PBS may affect patient access. The PBAC noted that consumers raised concerns about the introduction of patient co-payments associated with access through the PBS. However, overall, the consumer and clinical input did not raise any concerns that a transition from the LSDP to the PBS would disadvantage patients clinically. The PBAC noted clinical input that nitisinone needs to be prescribed by specialists with a thorough knowledge of hereditary tyrosinaemia type-1. The PBAC noted that, where applicable, Orfadin products had undergone a price reduction since the last time of consideration by the PBAC. Taking into consideration these price reductions, the PBAC advised that the current

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				pricing of nitisinone on the Life Saving Drugs Program (LSDP) was acceptable.
OMAVELOXOLONE Capsule 50 mg Skyclarys® BIOGEN AUSTRALIA PTY LTD Standard re-entry (New PBS listing)	Friedreich's ataxia	Resubmission to request listing of omaveloxolone for the treatment of Friedreich's ataxia in people aged 16 years and older. Authority Required (Telephone/Online)	Recommended	The PBAC recommended the listing of omaveloxolone (Skyclarys®) on the PBS for the treatment of Friedreich's ataxia (FA) in adults and adolescents aged 16 years and over. The PBAC welcomed input from individuals, health professionals and organisations. This input strongly supported the resubmission and described the debilitating effects of FA on patients and their caregivers. The PBAC also acknowledged that there was a high unmet need for treatments for FA. The PBAC considered that omaveloxolone was likely more effective than best supportive care at slowing the progression of FA. However, the PBAC noted that the effect of omaveloxolone in preventing loss of physical function would likely be modest. The PBAC considered that given the progressive nature of FA, stabilisation of disease would still be beneficial for patients and their caregivers. The PBAC also noted that omaveloxolone was less safe than best supportive care, noting its association with cardiotoxicity, increased liver enzymes and headaches. The benefits the sponsor claimed omaveloxolone would deliver in support of its requested price in the economic model. In particular, the duration of benefit claimed by the sponsor was well beyond the average life expectancy of people with FA. It also did not account for a potential waning of treatment effect. The PBAC advised the omaveloxolone would be cost effective with a significant price reduction, which would reflect more realistic estimates of benefits and costs. The PBAC considered that the estimates of eligible patients, treatment numbers and associated costs presented in the resubmission were acceptable and that the estimated financial impact would be reasonable at the recommended price, but that a risk sharing arrangement with the sponsor would be required to mitigate risk associated with use outside of the proposed restriction criteria.

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ONASEMNOGENE ABEPARVOVEC Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 8 vials solution for I.V. infusion 20 trillion vector genomes	Spinal muscular atrophy (SMA)	To expand the current PBS listing for onasemnogene abeparvovec for the treatment of SMA to include paediatric patients weighing up to 21 kg. Authority Required (Written)	Recommended	The PBAC recommended expanding the current listing of onasemnogene abeparvovec (ONA) to include treatment of SMA patients with: • Symptomatic Type I-IIIa SMA, weighing up to 21 kg • Pre-symptomatic SMA with 1-3 copies SMN2, weighing up to 21 kg, where treatment with disease modifying treatments (DMTs) was initiated prior to 36 months of age • Pre-symptomatic SMA with 1-3 copies SMN2, up to 36 months of age, where patients are untreated with DMTs. The PBAC welcomed input from the National Paediatric Medicines Forum in support of the submission. The PBAC also acknowledged input from clinical experts indicating it would be preferable for the listing for patients with symptomatic SMA to not be limited to Type I, so as not to exclude patients with onset of symptoms at >6 months of age. The PBAC recommended expanding the listings on the basis that there may be a clinical need for a small number of patients who have not received ONA prior to 9 months of age, however the PBAC noted that earlier initiation of disease-modifying treatment for SMA remains the preferred approach. The PBAC considered that although the evidence available was limited, ONA appears to be just as effective and as safe in patients older than 9 months as it is in patients younger than 9 months. The PBAC considered that ONA would be acceptably cost-effective in the older population at the same cost per patient as in the younger population.

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per mL, 8.3 mL Pack containing 9 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Zolgensma® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD Category 2 (Change to existing listing)				
OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® ASTRAZENECA PTY LTD Early re-entry (Change to existing listing)	Non-small cell lung cancer (NSCLC)	Resubmission to request listing of osimertinib for first line treatment of Stage IIIB (locally advanced) or Stage IV (metastatic) epidermal growth factor receptor mutation-positive (EGFRm) NSCLC in combination with pemetrexed and platinum-based chemotherapy. Authority Required (Telephone/Online)	Not applicable	This item was withdrawn.
PEGCETACOPLAN Solution for intravitreal injection 15 mg in 0.1 mL (150 mg per mL) Syfovre® APELLIS AUSTRALIA PTY LTD	Bilateral geographic atrophy (GA) secondary to age-related macular degeneration (AMD)	To request listing of pegcetacoplan for initial and continuing treatment of bilateral GA secondary to AMD where the treated eye has an intact fovea and central vision is threatened by growth of GA lesions and the non-	Recommended	The PBAC recommended the listing of pegcetacoplan for the treatment of geographic atrophy (GA) or dry AMD secondary to age-related macular degeneration. The PBAC welcomed input from consumers, health care professionals and organisations on the benefits associated with slowing progression of GA and preservation of existing eyesight, as these outcomes most directly contributed to maintenance of quality of life and

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Category 1 (New PBS listing)		treated eye does not have an intact fovea. Authority Required (Written or Telephone/Online) initial treatment Authority Required (STREAMLINED) for continuing treatment		independence. The PBAC acknowledged the high clinical need for treatments for GA, which is a leading cause of irreversible vision loss in older Australians. The PBAC noted evidence from the clinical trials showed pegcetacoplan reduced GA lesion growth by around 21% with monthly dosing and 16% with every-other-month dosing at 24 months compared to sham treatment. The PBAC considered that, although the clinical trials did not demonstrate clear improvements in vision related activities, it was reasonable to assume that protecting the structure of the eye by slowing GA lesion growth will result in slower loss of functional vision than current care. Despite uncertainty in the magnitude of this benefit on vision, the PBAC was satisfied that pegcetacoplan provides, for some patients, a significant improvement in efficacy over best supportive care. The PBAC considered there was some uncertainty about the extent to which benefits claimed by the sponsor in support of its proposed price would be realised in practice. In particular, there was uncertainty around how microperimetry outcomes (the number of spots where perception of light is lost and where they are located) would translate to improvements in vision in practice. The duration of benefit estimated by the sponsor was overly optimistic. The PBAC therefore considered pegcetacoplan would be acceptably cost-effective with a price reduction. In addition, the PBAC considered a financial agreement with Apellis Australia was required to manage uncertainty in the number of patients who will use pegcetacoplan and to ensure PBS reimbursement was for treatment in one eye only.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda®	Head and neck squamous cell carcinoma (HNSCC)	To request listing of pembrolizumab for the neoadjuvant treatment (i.e. prior to the main treatment) of patients with resectable locally advanced HNSCC, continued as adjuvant treatment (i.e. after the main	Recommended	The PBAC recommended pembrolizumab for the treatment of resectable locally advanced head and neck squamous cell carcinoma (LA HNSCC). The proposed use includes treatment prior to surgical resection, followed by treatment after surgical resection in combination with radiotherapy, with or without chemotherapy, and subsequently as stand-alone therapy (PEM+SoC). The PBAC noted and welcomed the input from health care professionals,

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MERCK SHARP & DOHME AUSTRALIA PTY LTD Category 2 (Change to existing listing)		treatment) in combination with radiotherapy with or without chemotherapy, and then as a single agent. Authority Required (STREAMLINED)		consumers and organisations. The PBAC noted the input described the clinical meaningfulness of treatment with pembrolizumab before and after surgery, providing the potential of a reduced risk of the disease reoccurring and morbidity associated with current standard of care by minimising surgical invasiveness and reducing the intensity of chemoradiotherapy following surgery. The PBAC agreed that there is a high clinical need for patients living with HNSCC, noting the poor clinical outcomes and severe complications associated with current standard of care. The PBAC was satisfied that PEM+SoC improved the length of time that patients lived without their cancer progressing compared to the current standard of care. However, the PBAC considered that the survival estimates from the key trial were unlikely to reflect Australian clinical practice, due to low use of immunotherapy in the standard of care arm for patients who experienced disease recurrence. The PBAC therefore considered that the full survival gain observed in the trial would not be realised in Australia. The PBAC accepted that the submission's revised estimates of benefits and costs of pembrolizumab provided prior to the November 2025 meeting had provided greater certainty and that pembrolizumab was likely cost-effective at the reduced price proposed.

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POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28 Systane® ALCON LABORATORIES (AUSTRALIA) PTY LTD Category 4 (New PBS listing)	Severe dry eye syndrome	To request listing of a new pack size of Systane (i.e., from 30 x 0.8 mL unit doses to 28 x 0.8 mL unit doses) for the treatment of severe dry eye syndrome. Authority Required (STREAMLINED)	Recommended	The PBAC recommended the General Schedule listing of a 28-pack size of 0.8 mL single dose unit polyethylene glycol-400 0.4% with propylene glycol 0.3% eye drops (Systane®) under the same circumstances as the 30-pack listing. The PBAC accepted the 30-pack as the appropriate comparator.
RECOMBINANT ZOSTER VACCINE Powder and suspension for injection (0.5mL) Shingrix® GLAXOSMITHKLINE AUSTRALIA PTY LTD Category 2 (Change to existing NIP listing)	Herpes zoster virus	To request a National Immunisation Program listing with age eligibility criteria for non-Indigenous adults reduced from individuals aged 65 years of age and over to individuals aged 60 years of age and over.	Not Recommended	The PBAC did not recommend a change to the circumstances under which recombinant zoster vaccine (RZV) is made available as a designated vaccine for the purposes of the *National Health Act 1953*. RZV (Shingrix) prevents shingles infection, caused by the herpes zoster (HZ) virus. The submission sought to lower the age of vaccination from 65 years of age to 60 years of age on the National Immunisation Program. The PBAC welcomed input from health care professionals, medical organisations, consumer groups and individuals. The PBAC noted the potential long-term impact of HZ and post-herpetic neuralgia (PHN) (pain in the nerves and skin that can occur in some patients after infection with HZ) on patients' health and quality of life. In comparing RZV to no vaccination in individuals 60 to 64 years of age, the PBAC considered that RZV was more effective but less safe than no vaccine. The PBAC considered the submission evidence showed RZV would result in durable protection against HZ and PHN for up to approximately 8 to 10 years, but that protection from the vaccine would likely reduce over time. As such, the PBAC considered vaccinating individuals at 60 years of age

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				would result in a reduction in protection in older individuals when the prevalence of HZ and PHN was higher and morbidity could be more severe. Noting that it is unclear how long vaccine effectiveness lasts, the PBAC considered it was uncertain whether RZV would be cost-effective at the price proposed by the sponsor. The PBAC also noted the financial cost to the Commonwealth of lowering the age of vaccination was high. Sponsor's comment: GSK acknowledges the PBAC's decision regarding Shingrix for adults aged 60–64 years. We remain committed to ensuring Australians have access to effective prevention against shingles and its complications. Herpes zoster continues to impose a significant impact on health, productivity and quality-of-life burden, and vaccination is the most effective way to reduce this risk. We look forward to continuing to work with the Government to improve coverage in the existing populations, while also seeking to expand eligibility for Shingrix vaccination on the NIP to populations who remain at risk of shingles.
RESPIRATORY SYNCYTIAL VIRUS VACCINE Solution for injection 50 µg in 0.5 mL pre-filled syringe mResvia® MODERNA AUSTRALIA PTY LTD Category 2 (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request a National Immunisation Program listing for the prevention of lower respiratory tract disease caused by RSV in individuals aged over 75 years and Aboriginal and Torres Strait Islander people aged over 60 years.	Deferred	The PBAC deferred its consideration of respiratory syncytial virus (RSV) vaccine mRNA-1345 (mRESVIA®) for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals aged 75 years of age and above, and for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years of age. Consistent with its previous advice, the PBAC considered there is a high clinical need for vaccines against RSV to reduce the risk of infection in older adults, especially for those aged over 75 years, for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years of age, and for those vulnerable due to existing medical conditions. The PBAC acknowledged input from the Australian College of Nurse Practitioners, Asthma Australia, and Lung Foundation Australia and noted that they supported listing a vaccine against RSV. The organisations did not preference a particular RSV vaccine in their input.

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				The PBAC considered that the clinical place of mRNA-1345 is uncertain and impacted by the potential NIP listing of previously recommended RSV vaccines, RSVPreF (Abrysvo®) and RSVPreF3 OA (Arexvy®). Based on the clinical evidence included in the submission, the PBAC was satisfied that mRNA-1345 was more effective at preventing lower respiratory disease than no vaccination for adults aged 60 years and over for up to 16 months. The PBAC was not satisfied that mRNA-1345 was more effective than no vaccination for people over 75 years old. The PBAC was also not satisfied that the evidence included in the submission demonstrated that mRNA-1345 would be as effective as RSVPreF and/or RSVPreF3 OA. Sponsor's comment: Moderna notes the PBAC's decision to defer its recommendation for mRNA-1345 (mRESVIA) for NIP listing, and remains confident in the evidence supporting the clinical profile and public health values of mRNA-1345, including protection in adults aged 60 years and over. Moderna will continue to work with the PBAC and the Department of Health, Disability and Ageing to support a shared understanding of the evidence and study design, address the PBAC's outstanding questions, and supports timeliness access for populations at higher risk of RSV disease.

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RETIFANLIMAB Solution concentrate for I.V. infusion 500 mg in 20 mL Zynyz® SPECIALISED THERAPEUTICS ALIM PTY LTD Category 1 (New PBS listing)	Merkel cell carcinoma (MCC)	To request listing of retifanlimab for the treatment of metastatic or recurrent, locally advanced MCC not amenable to curative surgery or radiation. Authority Required (STREAMLINED)	Deferred	The PBAC deferred making a recommendation for the listing of retifanlimab for the treatment of Merkel cell carcinoma (MCC, a type of skin cancer) which has spread to another part of the body or recurred and is cannot be cured by surgery or radiation. The PBAC welcomed input from individuals, health care professionals and organisations. The PBAC acknowledged that MCC is a rare and aggressive form of cancer. The PBAC noted that there are other treatment options such as avelumab and chemotherapy and considered there was a small need for new therapies. The PBAC noted potential benefits associated with retifanlimab compared to avelumab, including less frequent dosing and a faster infusion rate, which would likely improve access for rural and regional patients. The PBAC noted the availability of retifanlimab will provide access to a small number of extra patients with locally advanced MCC. The PBAC did not accept the sponsor's claim that retifanlimab is more safe and effective than avelumab for the treatment of MCC but accepted that retifanlimab is as safe and effective as avelumab for MCC. The PBAC deferred making a decision on the PBS listing of retifanlimab as it is unknown at this stage whether the Therapeutic Goods Administration (TGA) is inclined to approve the registration of retifanlimab. Pending the provision of a positive evaluation by the TGA, the PBAC was of a mind to recommend retifanlimab at a cost no higher than that of avelumab for a course of treatment with a small increase in the overall financial cost because of the additional locally advanced MCC patients. The PBAC considered that 500 mg of retifanlimab every 4 weeks would be equivalent to 800 mg of avelumab every 2 weeks, based on the flat dosing regimens recommended in their respective product information. Sponsor's comment: The sponsor had no comment.

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RETIFANLIMAB Solution concentrate for I.V. infusion 500 mg in 20 mL Zynyz® SPECIALISED THERAPEUTICS ALIM PTY LTD Category 1 (New PBS listing)	Squamous cell anal carcinoma (SCAC)	To request listing of retifanlimab for use in combination with carboplatin and paclitaxel for the treatment of inoperable locally recurrent or metastatic SCAC not previously treated with systemic chemotherapy. Authority Required (STREAMLINED)	Deferred	The PBAC deferred making a decision on whether retifanlimab should be subsidised on the PBS when used together with chemotherapy (carboplatin and paclitaxel), to treat people with cancer of the lining of the anus, specifically squamous cell anal cancer (SCAC) where the cancer cannot be removed by surgery, has spread, and has not been previously treated with chemotherapy. The PBAC was inclined to recommend retifanlimab once a positive assessment from the TGA is available, based on evidence from a randomised clinical trial (RCT) showing that adding retifanlimab to chemotherapy helped people live longer without their cancer getting worse compared to chemotherapy alone. The PBAC welcomed input from health professionals and organisations. These comments described the serious impact of advanced SCAC on people's lives and the need for better treatments. The PBAC acknowledged that improving treatment response and survival is the most important outcome for people living with this disease. The PBAC also acknowledged that there is a high need for new treatments for this rare cancer. Current chemotherapy options are only moderately effective, and the cancer usually returns or gets worse. The PBAC accepted that retifanlimab was more effective than chemotherapy alone at delaying cancer progression. There is likely an improvement in how long people live overall, but the size of this benefit is uncertain because the survival data is still immature and many patients in the trial switched treatments after their cancer had progressed. The PBAC also concluded that retifanlimab caused more side effects than chemotherapy alone, as is expected when adding an immunotherapy drug. The PBAC considered that the medicine would be acceptable at a lower price. Sponsor's comment: The sponsor had no comment.

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RISDIPLAM Tablet 5 mg Evrysdi® ROCHE PRODUCTS PTY LTD Category 4 (New PBS listing)	Spinal muscular atrophy (SMA)	To request listing of a new form of risdiplam for the treatment of SMA. Authority Required	Recommended	The PBAC recommended the listing of risdiplam 5 mg tablets for the treatment of patients with spinal muscular atrophy. The PBAC considered the tablet formulation to be non-inferior to the oral solution in both clinical effectiveness and safety. The PBAC welcomed consumer input and noted that, for some patients, the tablet formulation is a more convenient alternative to the oral solution, due to its transportability and dispersibility properties.
SEMAGLUTIDE Solution for injection 0.25 mg in 0.5 mL single dose pre-filled pen Solution for injection 0.5 mg in 0.5 mL single dose pre-filled pen Solution for injection 1 mg in 0.5 mL single dose pre-filled pen Solution for injection 1.7 mg in 0.75 mL single dose pre-filled pen Solution for injection 2.4mg in 0.75mL single dose pre-filled pen Wegovy® NOVO NORDISK PHARMACEUTICALS PTY LIMITED Standard re-entry (Change to existing listing)	Established cardiovascular disease (eCVD) with obesity	Resubmission to request listing of semaglutide for the treatment of patients with eCVD living with overweight or obesity. Authority Required (Telephone/Online)	Recommended	The PBAC recommended that semaglutide be subsidised through the Pharmaceutical Benefits Scheme (PBS) for adults with established cardiovascular disease (eCVD) with obesity. Patients must have already experienced a cardiovascular event such as a heart attack, stroke, or have symptomatic peripheral arterial disease. The PBAC noted the submission proposed three potential patient populations based on different Body Mass Index (BMI) cut-offs: ≥27 kg/m2, ≥35 kg/m2 and ≥40 kg/m2. To best reach patients at high risk and considering the high cost of treatment, the PBAC determined it would be appropriate to limit PBS access to people with a BMI of 35 kg/m² or higher, or 32.5 kg/m² or higher for people of Asian, Aboriginal, or Torres Strait Islander ethnicity. The PBAC welcomed comments from individuals, health care professionals and organisations. Many highlighted the benefits of treatment with semaglutide for people who have eCVD with obesity and the financial barriers to accessing semaglutide privately. Healthcare professionals and organisations also emphasised the importance of different eligibility criteria for people of Aboriginal, Torres Strait Islander and Asian ethnicity who have higher risk at lower BMI levels. The PBAC also noted the importance of weight loss to support patients' ability to adhere 'to other cardiac health improving interventions such as exercise and dietary

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				changes. The PBAC acknowledged that, while there are effective treatments on the PBS for people with eCVD, they still face residual risk of future cardiovascular events and adding semaglutide to current therapies may help reduce this risk. The PBAC noted that flow on changes to GLP-1 RA listings for type 2 diabetes mellitus would be required to only allow access under the subsequent PBS prescription phase if received semaglutide under the first PBS-prescription phase. The PBAC considered evidence from a large clinical trial involving over 17,000 people. In this trial, people who took semaglutide alongside their usual heart medicines had a lower chance of having another major cardiovascular event (such as a heart attack) compared to those who took usual heart medicines only. The PBAC estimated that based on the trial results, for every 1,000 people treated with semaglutide over 3.5 years that also had a BMI ≥35 kg/m2, there would be 39 fewer major heart events and 4 fewer deaths compared to those who did not take semaglutide. However, the PBAC considered the reduction in major cardiovascular events may be smaller in practice than what was observed in the clinical trial. Based on patient experience using semaglutide overseas, the PBAC expected patients would transition more slowly to the most effective high doses, there would be ongoing use of lower doses and higher rates of treatment discontinuation. The PBAC also noted that the reduction in cardiovascular events in the clinical trial may only be partially attributed to reductions in weight. The PBAC considered some of the assumptions the sponsor used to justify its requested price were inaccurate and that the sponsor had overstated the benefits of semaglutide, particularly in the duration of benefit for people who discontinue treatment. The PBAC advised that a reduction in the price was required to reflect more realistic estimates of benefits. The

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				PBAC considered there was a significant risk that people would access subsidy for semaglutide outside of the proposed criteria (particularly for patients with established cardiovascular disease and a BMI of less than 35 kg/m2) and patients with high cardiovascular risk but no prior cardiovascular event). It therefore advised that a risk sharing arrangement with the sponsor was required to adequately manage the expenditure risk to the Commonwealth.
TAFASITAMAB Powder for I.V. infusion 200 mg Minjuvi® SPECIALISED THERAPEUTICS ALIM PTY LTD Category 2 (New PBS listing)	Relapsed and/or refractory follicular lymphoma (FL)	To request listing of tafasitamab for use in combination with lenalidomide and rituximab for the treatment of patients with relapsed and/or refractory FL. Authority Required (Telephone/Online)	Deferred	The PBAC deferred making a recommendation for listing tafasitamab on the PBS for use in combination with lenalidomide and rituximab for the treatment of follicular lymphoma that has progressed or is resistant to previous treatment. The PBAC deferred its decision because the TGA Delegate's Overview was not available at the time of PBAC consideration. However, the PBAC was of a mind to recommend the listing of tafasitamab on the basis that the price would be justified with a further price reduction to that proposed by the Sponsor in its pre-PBAC response. The PBAC welcomed input from health care professionals and organisations which highlighted the unmet needs for patients with follicular lymphoma, particularly those who are not fit for or unable to access stem cell transplantation. The PBAC accepted that tafasitamab (in combination with lenalidomide and rituximab) is more effective than the standard of care in Australian clinical practice (rituximab-based chemotherapy) at extending survival without cancer progressing, and extending time to next treatment. However, the PBAC was concerned that the benefits observed in the clinical trial would not be realised in the Australian healthcare setting. This was due to the lack of evidence from clinical studies comparing tafasitamab with rituximab-based chemotherapy. Further the clinical trials presented in the submission were conducted over a short period of time and therefore did not provide information about the extent to which tafasitamab would extend survival. The PBAC also noted that people who received tafasitamab

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				in clinical trials experienced higher rates of adverse events compared to rituximab-based chemotherapy. The PBAC considered that the benefits claimed by the sponsor to justify its requested price were too optimistic, particularly its estimates of overall survival. The PBAC considered that the price would be justified if reduced to reflect more realistic estimates of benefits. The PBAC considered the cost to the government to be overestimated and advised that adjustments were required in estimating a more accurate cost. Sponsor's comment: The sponsor had no comment.
TESTOSTERONE Transdermal cream 10 mg per mL, 50 mL AndroFeme 1® LAWLEY PHARMACEUTICALS PTY LTD Category 1 (New PBS listing)	Hypoactive sexual desire dysfunction (HSDD)	To request listing of testosterone for the treatment of HSDD in postmenopausal women that have failed to be treated by appropriate education and correction of modifiable biopsychosocial factors according to the International Society for the Study of Women's Sexual Health process of care. Restricted Benefit	Not Recommended	The PBAC did not recommend testosterone 1% cream (AndroFeme1®) for the treatment of hypoactive sexual desire dysfunction (HSDD) in postmenopausal women. The PBAC welcomed input from individuals, health professionals and organisations that raised issues of undertreatment and gender inequity, and acknowledged the impact of HSDD on postmenopausal women. The PBAC noted that some comments supporting the listing of testosterone were not related to HSDD. This included describing benefits that have not been evaluated and benefits that are outside the approved TGA indication (e.g., brain fog, memory or mood issues, hot flushes). The PBAC also noted that many inputs inappropriately equated HSDD with low libido. The PBAC questioned the clinical place of testosterone in treating HSDD, noting it is difficult to define the condition and an appropriate scope of use. The PBAC considered the strength of the clinical evidence comparing testosterone with placebo presented in the submission to be low. It noted that the restrictions used to select trial participants were not representative of the proposed PBS listing, and some trials used inconsistent definitions of sexual dysfunction. The PBAC also noted that inappropriate use of testosterone is associated with adverse effects

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				including the potential for androgenisation if testosterone levels are not carefully monitored. Overall, it considered the clinical data did not show that testosterone was more effective than placebo, or as safe, for the relevant patients. The PBAC noted that the requested price was not supported by the claimed clinical benefits in HSDD and hence it was unknown if the price reflected value for money. The PBAC also considered that there would be a high risk of use outside the restriction and that the screening test had a high risk of bias. The PBAC considered there was insufficient evidence to support a resubmission, but that the submission was eligible for an Independent Review. Sponsor's comment: Regrettably, the sponsor notes the PBAC's decision not to recommend PBS listing of AndroFeme® 1. The sponsor has provided further information on its website.
TEZEPELUMAB Solution for injection 210 mg in 1.91 mL single dose pre-filled pen (110 mg per mL) Tezspire® ASTRAZENECA PTY LTD Category 1 (New PBS listing)	Asthma	To request listing for the treatment of severe uncontrolled asthma in patients 12 years and older who have failed to achieve adequate control with optimised asthma therapy. Authority Required (Written)	Recommended	The PBAC recommended listing of tezepelumab on the Pharmaceutical Benefits Scheme (PBS) for the treatment of patients aged 12 years and older with severe uncontrolled asthma (SUA) that is non-eosinophilic and non-allergic. The PBAC also recommended listing tezepelumab for the treatment of patients aged 12 years and older with SUA that is eosinophilic or allergic. The PBAC welcomed input from healthcare professionals and organisations supporting the listing of tezepelumab for these indications. The PBAC noted that comments emphasised that there is a clinical need for patients with non-eosinophilic and non-allergic SUA as they are ineligible, and not suitable, for biologics currently subsidised through the PBS. The PBAC accepted there was a clinical need for alternative biologic treatment for patients with SUA on the PBS, particularly for non-eosinophilic and non-allergic population, given there are no specific agents currently available for these patients.

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				The PBAC noted that there were a number of alternative biologics available for the eosinophilic or allergic population. **Non-eosinophilic and non-allergic severe uncontrolled asthma** Based on the evidence included in the submission, the PBAC was satisfied that tezepelumab is more effective than the current standard of care at reducing the frequency of asthma exacerbations for some people with non-eosinophilic and non-allergic SUA. However, in the PBAC's view, the size of this benefit was uncertain and likely to be modest due to only marginal differences being observed in trials. The PBAC was also satisfied that tezepelumab had similar safety to the current standard of care. The PBAC considered the assumptions used by the sponsor to justify its requested price were overly optimistic - particularly assumptions of benefits being realised over many years that were based on approximately 1 year of clinical trial data. The PBAC considered the cost of tezepelumab would be acceptable with a price reduction to reflect more realistic estimates of benefits. **Eosinophilic or allergic severe uncontrolled asthma** Based on the evidence included in the submission, the PBAC was satisfied tezepelumab was as effective as dupilumab, benralizumab, mepolizumab and omalizumab at reducing asthma exacerbations and had similar safety. The PBAC advised that the cost of tezepelumab would be acceptable if it cost no more than the least costly biologic for the eosinophilic SUA population and the allergic SUA population over a 1-year time frame. The PBAC considered the equi-effective doses for eosinophilic SUA were: • tezepelumab 210 mg by subcutaneous (SC) injection every 4 weeks (13 doses over 1 year) • dupilumab 400 mg (non-OCS dependent) or 600 mg (OCS dependent) by SC injection followed by 200 mg (non-OCS

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				dependent) or 300 mg (OCS dependent) SC given every 2 weeks (27 doses over 1 year) • benralizumab 30 mg by SC injection every 4 weeks for the first 3 doses, then every 8 weeks (7.5 doses over 1 year) • mepolizumab 100 mg by SC injection every 4 weeks (13 doses over 1 year). In patients with allergic SUA, the PBAC considered the equi-effective doses were: • tezepelumab 210 mg by SC injection every 4 weeks (13 doses over 1 year) • dupilumab 400 mg (non-OCS dependent) or 600 mg (OCS dependent) by SC injection followed by 200 mg (non-OCS dependent) or 300 mg (OCS dependent) given every 2 weeks (27 doses over 1 year) • omalizumab 398 mg by SC injection every 4 weeks (dosed at 2 or 4 weeks depending on patient weight and immunoglobulin E levels; 13 doses over 1 year)
TOCILIZUMAB Concentrate for injection 80 mg in 4 mL Concentrate for injection 200 mg in 10 mL Concentrate for injection 400 mg in 20 mL Injection 162 mg in 0.9 mL single use pre-filled pen Injection 162 mg in 0.9 mL single use pre-filled syringe	Severe active juvenile idiopathic arthritis Severe active rheumatoid arthritis Systemic juvenile idiopathic arthritis Active giant cell arteritis	To request listings of a new tocilizumab biosimilar that mirrors the originator brand's current listings. Authority Required	Recommended	The PBAC recommended the listing of a new tocilizumab biosimilar (Avtozma®) on a cost-minimisation basis and under the same conditions as its reference biologic (Actemra®), for the same indications. The PBAC advised the equi-effective doses to be 1 mg Avtozma = 1 mg Actemra. The PBAC considered that application of the biosimilar uptake policy (i.e. lowering the authority level in some cases and adding administrative advice encouraging uptake of biosimilar prescribing for treatment-naïve patients) is clinically appropriate for Avtozma.

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Avtozma® CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 3 (New PBS listing)				
TOFERSEN Solution for intrathecal injection 100 mg in 15 mL Qalsody® BIOGEN AUSTRALIA PTY LTD Category 1 (New PBS listing)	Amyotrophic lateral sclerosis (ALS)	To request listing of tofersen for the treatment of ALS associated with a mutation in the superoxide dismutase 1 gene in patients who have not experienced respiratory failure. Authority Required (Telephone/Online)	Not Recommended	The PBAC did not recommend listing tofersen (Qalsody®) on the PBS for the treatment of patients with amyotrophic lateral sclerosis (ALS) who have a superoxide dismutase 1 (SOD1) gene pathogenic variant. The PBAC welcomed input from individuals, health professionals and organisations. This input strongly supported the submission and described the debilitating effects of SOD1-ALS on patients and their carers. The PBAC also noted the high unmet need for targeted treatments for this rare subtype of ALS. The PBAC considered that, although not demonstrated statistically in the trial, tofersen was likely more effective than best supportive care at slowing the progression of SOD1-ALS and increasing overall survival. However, the PBAC noted that the effect of tofersen in preventing loss of physical function would likely be modest. The PBAC considered that given the progressive nature of SOD1-ALS, stabilisation of disease would still be beneficial for patients, their families and their carers. The PBAC also noted that tofersen was less safe than best supportive care, with side effects mainly associated with its administration via lumbar puncture. The benefits the sponsor claimed tofersen would deliver at the requested price were, in the PBAC's view, overly optimistic. In particular, the PBAC considered that the benefits of tofersen in terms of how quickly the disease progresses and how long people treated with tofersen live were

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				overestimated in the economic model. The PBAC advised that tofersen would be cost effective with a significant price reduction, which would reflect more realistic estimates of benefits and costs. The PBAC also considered that the estimates of eligible patients and associated costs presented in the submission were highly uncertain. The PBAC recommended that the utilisation estimates be recalculated and that a risk sharing arrangement with the sponsor would be required to mitigate risk associated with the uncertain long-term benefits of tofersen and the uncertain duration of therapy. The PBAC advised that the above issues could be addressed in an early re-entry submission. Sponsor's comment: Biogen welcomes that the PBAC has recognised the high and urgent unmet need for treatments for people with amyotrophic lateral sclerosis (ALS) who have a superoxide dismutase 1 (SOD1) mutation, and that on balance, tofersen is likely to provide a meaningful benefit compared with best supportive care, including maintaining function for longer and increasing overall survival. Biogen will continue to work collaboratively with the PBAC to deliver equitable access to tofersen for people with this rare condition in a timely manner. Biogen would like to take this opportunity to thank the ALS community and healthcare professionals who supported the submission.
TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® ASTRAZENECA PTY LTD Matters outstanding	Gastric or gastroesophageal junction (G/GOJ) cancer	To request listing of trastuzumab deruxtecan for the treatment of metastatic human epidermal growth factor receptor 2-positive (HER2+) G/GOJ cancer following trastuzumab therapy. Authority Required (Telephone/Online)	Not Recommended	The PBAC did not recommend trastuzumab deruxtecan (T-DXd) for treatment of metastatic human epidermal growth factor receptor 2-positive (HER2+) gastric or gastroesophageal junction (G/GOJ) cancer following trastuzumab therapy. In May 2025, the PBAC deferred making a recommendation to allow for further consultation with the sponsor about a potential pathway forward towards PBS listing. The PBAC considered there is a high clinical need for more effective treatments, given the poor prognosis of HER2+ G/GOJ adenocarcinoma when it progresses despite initial treatment

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(Change to existing listing)				(trastuzumab). The PBAC recalled input from health care professionals and organisations was supportive of the submission given the superior efficacy albeit at a risk of significant side effects. The PBAC was satisfied there was a clinical need for effective treatments for people whose cancer had progressed following trastuzumab treatment. It also acknowledged the financial burden of unfunded treatments. The PBAC previously considered that T-DXd was not as safe but was more effective than standard of care (chemotherapy). However, the submission evidence did not allow confidence in the extent the positive trial results would be realised for Australians because of differences in diagnosis, treatment and disease management between the trial and Australian clinical practice. The PBAC previously advised the medicine would be cost effective with a price reduction reflecting more realistic estimates of benefits and costs. The sponsor provided additional information for PBAC's consideration. However, the proposed approach was not consistent with the PBAC's previous advice and the PBAC considered the T-DXd was not cost effective at the proposed price. The PBAC noted that the sponsor may make a resubmission to incorporate any updated clinical data to support changes to the assumptions about the benefits for T-DXd. Sponsor's comment: The sponsor had no comment.

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TUCATINIB Tablet 50 mg Tablet 150mg Tukysa® PFIZER AUSTRALIA PTY LTD Category 2 (New PBS listing)	Breast cancer	Resubmission to request a listing of tucatinib for use in combination with trastuzumab and capecitabine for the treatment of metastatic (Stage IV) human epidermal growth factor receptor 2 positive breast cancer in patients who have received two prior lines of HER2-directed therapy and have progressed on trastuzumab deruxtecan. Authority Required (STREAMLINED)	Recommended	The PBAC recommended tucatinib be subsidised through the PBS for use in combination with the currently subsidised treatment trastuzumab plus capecitabine, for the treatment of metastatic (Stage IV) human epidermal growth factor receptor 2 positive (HER2-positve) breast cancer in patients who have received at least two prior lines of HER2-directed therapy or who have progressed while on treatment with trastuzumab deruxtecan. The PBAC welcomed the input from individuals, organisations and a health professional who described the significant challenges faced by people (on their third-line or more of treatment) living with metastatic HER2-positive breast cancer including pain, anxiety, fatigue and neurological symptoms. The PBAC acknowledged the substantial impact of this condition on quality of life and ability to work. Consumers identified improved survival (extending life) as the most important outcome at this stage of the condition. The PBAC recognised that, while several treatments are available on the PBS, there is a need for more effective options for people whose cancer has progressed after multiple lines of therapy, especially for those with brain metastases. The PBAC accepted that adding tucatinib to treatment with trastuzumab plus capecitabine is more effective than trastuzumab plus capecitabine alone. In the main clinical trial, people who received tucatinib in combination with trastuzumab and capecitabine lived a median of 24.7 months after starting treatment compared to 19.2 months for those who received trastuzumab and capecitabine alone. At two years, 51% of people taking tucatinib were still alive, compared to 40% in the comparator group. For people with brain metastases, tucatinib also improved the time before the cancer got worse. However, tucatinib was associated with higher rates of some side effects, such as diarrhoea (13% of people experienced severe diarrhoea compared to 9% in the comparator group). The PBAC considered tucatinib would be acceptably cost-effective at the cost-utility analysis (CUA) component price proposed, based on the

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				resubmission's comparison of tucatinib versus trastuzumab plus capecitabine. The PBAC did not accept that tucatinib would replace trastuzumab emtansine (T-DM1) and therefore considered that the price should be based only on tucatinib replacing trastuzumab and capecitabine alone. The PBAC considered that the estimates of the financial impact of listing tucatinib on the PBS should only be derived based on the assumption that tucatinib would replace trastuzumab plus capecitabine only.
VEDOLIZUMAB Powder for injection 300 mg Entyvio® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. Category 3 (Change to existing listing)	Severe Crohn disease (CD) Moderate to severe ulcerative colitis (MSUC)	To request a change to the existing listings for vedolizumab (powder for injection 300 mg) for severe CD and MSUC, that is, additional restrictions with increased repeats to allow for dosing every 4 weeks. Authority Required	Not Recommended	The PBAC did not recommend vedolizumab 300 mg IV dose escalation from every 8 weeks to every 4 weeks for the treatment of moderate to severe ulcerative colitis or severe Crohn disease. The PBAC considered that the submission did not account all the costs involved with more frequent infusions, and the modelling of expected usage and financial implications was incomplete. The PBAC noted that vedolizumab 4 weekly dosing had non-inferior safety and superior effectiveness to 8 weekly dosing in patients who no longer showed an adequate response to 8 weekly dosing. The evidence indicated that 4 weekly dosing could be beneficial for patients who have responded to induction therapy, but who could not maintain a response to 8 weekly dosing. The clinical criteria for dose escalation were poorly defined, and there was a high risk that dose escalation would be used outside of its intended indication, particularly for patients who had not responded to 8 weekly maintenance treatment and would usually trial a different medicine. The PBAC recognised the need for disease modifying treatments options for the management of inflammatory bowel diseases and welcomed input from Crohn's & Colitis Australia.

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				The PBAC highlighted that providing dose escalation via a sponsor access program to patients who would otherwise not respond to 8 weekly maintenance therapy, instead of transitioning to another therapy, is not appropriate in the absence of a PBAC recommendation that vedolizumab is cost-effective in this population. The PBAC likewise highlighted that usage of the Medicare Benefits Schedule for the infusion of non-PBS doses of vedolizumab is likewise not appropriate and is considered non-compliance. Sponsor's comment: The sponsor had no comment.
WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE Oral powder 400 g, 6 Renastart® VITAFLO AUSTRALIA PTY LIMITED Committee Secretariat Change to existing listing	Chronic renal failure	To request a minor formulation change to Renastart for the treatment of chronic renal failure.	Not applicable	This item was withdrawn.
ZANUBRUTINIB Tablet 160 mg Brukinsa®	Mantle cell lymphoma (MCL) Waldenstrom macroglobulinaemia (WM) Chronic lymphocytic	To request listing of a new form of zanubrutinib for the treatment of MCL, WM, and CLL or SLL. Authority Required	Recommended	The PBAC recommended the listing of a new 160 mg tablet form of zanubrutinib under the same circumstances as the PBS-listed zanubrutinib 80 mg capsule on a cost-minimisation basis. The PBAC welcomed input from medical organisations, and supporting the proposed listing to offers a simplified dosing regimen, improving patient

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BEIGENE AUS PTY LTD Category 4 (New PBS listing)	leukaemia (CLL) or small lymphocytic lymphoma (SLL)			adherence, reducing pill burden and enhancing patients' quality of life. The PBAC noted and welcomed input from health care organisations, as well as several individual patients and carers. The PBAC noted several potential benefits from Zanubrutinib, including that the 160 mg tablet offers a simplified dosing regimen, which may improve patient adherence, reduce pill burden, and enhance quality of life for people living with rare blood cancers. The PBAC acknowledged described reduced treatment burden and improved wellbeing for both patients and families. The PBAC advised the equi-effective daily dose of 320 mg to be 2 x 160 mg tablets, being equal to 4 x 80 mg capsules. The PBAC also advised that its previous pricing advice for zanubrutinib 80 mg should apply to zanubrutinib 160 mg for the same treatments.

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Monitoring system for final trial overall survival results for cancer medicines (PBS review)	Cancer	To provide advice on whether: - the monitoring system should be continued - if any further project work should be undertaken for 'red alert' items - if the monitoring system should be extended to any other disease areas.	Advice Provided	The PBAC noted the draft report on a 'Monitoring system for updated overall survival (OS) results for cancer trials' (the Report), prepared by Monash University. The PBAC considered that following up on trial results to ensure that they aligned with the Committee's expectations at the time of a positive recommendation was an important aspect of stewardship of the PBS. The PBAC considered that it would be worthwhile to continue the monitoring system for a further 2-3 years before evaluating the merits of the system but noted that the relative priority of this project compared to other potential post-market monitoring projects could be considered by the PBAC when reviewing the Post-market Review Workplan at a future meeting. The PBAC considered that if the monitoring system were continued for an additional period, that sponsors would be informed through an update to the published PMR Workplan and would continue to be consulted on the project following standard PBAC processes and timelines. The PBAC supported publication of the Report and associated PBAC Minutes on the PBS website and agreed that the Report should be provided to the HTA Review Implementation Advisory Group (IAG).
PBAC advice on equitable access to medicines for the treatment of obesity Glucagon-like peptide-1 receptor agonists (GLP-1s) Various brands Various sponsors (PBS review)	Obesity	To provide advice requested by Minister Butler on equitable access to GLP-1 obesity treatments through the PBS.	Advice Provided	The PBAC provided advice on priority groups to ensure equitable subsidised access to glucagon-like peptide-1 receptor agonists (GLP-1) for the treatment of obesity. Based on current evidence, PBAC considered this should include: people with established cardiovascular disease, Aboriginal and Torres Strait Islander patients with obesity-related comorbidities, people with syndromic obesity, people with medication-induced obesity, and patients requiring weight loss to be eligible for surgery. The PBAC invited sponsor submissions for these populations, noting that any PBS listing would be subject to the legislative requirements to demonstrate clinical and cost-effectiveness through a sponsor-initiated submission. The PBAC welcomed and considered input from individuals who have used GLP-1s, other individuals, health care professionals and organisations. The PBAC noted that the broad categories of people who had used the

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				medicines and provided inputs included: people with inherited and genetic causes of obesity; people using obesogenic medications; and people who find it difficult to exercise due to their obesity or other conditions, such as disabilities and autoimmune diseases that affect joints. Consumers had a wide range of comorbidities, including cardiovascular disease, kidney and liver disease, type 2 diabetes, endocrine disorders, autoimmune disease, musculoskeletal conditions, obstructive sleep apnoea, and mental health conditions. The PBAC noted that while cost was a concern and barrier to ongoing access for many consumers, private market data indicated that there was a high willingness to pay for obesity treatments among Australian consumers with around 420,000 people receiving a private market supply of semaglutide or tirzepatide in July 2025. The PBAC advised a slow and managed roll-out of access to PBS-subsidised GLP-1 treatments in the Australian health care system would help to manage leakage and uncertainties around long-term use and outcomes. The PBAC considered that there may be merit in broader subsidy of GLP-1s for early intervention and prevention of obesity-related comorbidities, but such subsidy would need to be established as a program outside of the PBS as it would be difficult to achieve a cost-effective price of providing obesity medicines for these broader purposes at this time. The PBAC noted that if a large population were to be treated with GLP-1s, there would be an increased likelihood of rare, serious adverse events, which may outweigh the benefits in patients without pre-existing comorbidities and would inform ongoing appropriate use. The PBAC noted the rapid emergence of research in obesity treatments and real-world evidence in this area, which is expected to drive significant changes in cost, supply, dosing, and utilisation over coming years. The PBAC noted the importance of real-world data to inform effective, equitable, safe and cost-effective use of GLP-1s.

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				The PBAC considered that there was a need to improve access to non-pharmacological interventions, such as diet and physical activity support, and that digital models may provide an equitable avenue for broad access to these supports. The PBAC considered that there should not be any mandatory requirements for use of wraparound services for PBS-subsidised access to GLP 1s, as this would create a barrier to accessing therapy, particularly for people who were already at higher risk of obesity and its associated comorbidities, such as Aboriginal and/or Torres Strait Islanders, those socioeconomically disadvantaged, and those living in regional and remote areas.
PBS-listed ocular lubricants Various forms and strengths Various brands Various sponsors (PBS review)	Severe dry eye	To consider the provided utilisation analysis and financial estimates of costs to the PBS to support its consideration of potential changes to PBS-listings for ocular lubricants for severe dry eye.	Recommended	The PBAC recommended limiting PBS prescribing of PF ocular lubricants to optometrists and ophthalmologists, to better align PBS restrictions with clinical guidelines and ensure that PF ocular lubricants are targeted to patients with severe dry eye who are most likely to require frequent dosing and specialist oversight. The PBAC considered that ophthalmologists and optometrists are the most appropriate practitioners to diagnose severe dry eye and determine the need for PF ocular lubricants, given the complexity of the condition and the associated risk of preservative-related ocular surface toxicity. The PBAC also considered that implementing this change may assist in moderating the upward trend in PBS expenditure for PF ocular lubricants. The PBAC acknowledged some patients may face additional time or financial burdens when accessing specialist care but concluded that this approach supports quality use of medicines and maintains PBS access to PF ocular lubricants for those with the greatest clinical need. In making this recommendation the PBAC considered a report presenting a utilisation analysis and financial estimates for potential changes to the restrictions for PBS listings of ocular lubricants in patients with severe dry eye report (“the Report”). The PBAC noted the advice received from the

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				Drug Utilisation Sub-Committee and the pre-PBAC responses received from sponsors and peak representative ophthalmology/optometric organisations. The PBAC noted that annual PBS prescriptions for ocular lubricants increased from 1.9 million in 2015 to 2.3 million in 2023, with total government expenditure doubling from $26.1 million to $52.3 million, and that this growth was driven by preservative-free (PF) ocular lubricants. Expenditure on PF ocular lubricants increased from $14 million to $42 million, while expenditure on preservative-containing (PC) ocular lubricants declined from $12 million to $10 million. The PBAC noted that modelled estimates of future prescriptions and total government expenditure on ocular lubricants indicated an increase in expenditure from $53.2 million in 2023 to $93.2 million in 2031. Expenditure on PF multi-dose ocular lubricants is expected to increase from $27.9 million in 2023 to $71.3 million in 2031 while expenditure on PC ocular lubricants is expected to decrease from $10.0 million in 2023 to $1.5 million by 2031. The PBAC noted the divergence in price between PF and PC ocular lubricants, despite the original intent for cost minimisation, and acknowledged the steady increase in patient numbers alongside a clinical preference to keep patients on the same products once treatment is established. The PBAC considered two options presented in the report for changing the PBS restrictions for PF ocular lubricants: • **Option 1**: downgrading of the restriction level for PF ocular lubricants to align with PC ocular lubricants, with an accompanying price reduction • **Option 2**: limiting PBS prescribing of PF ocular lubricants to optometrists and ophthalmologists The PBAC noted Option 1 would support continued patient access to allow switching from PC to PF ocular lubricants as needed, but that it may be

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				difficult to negotiate the substantial proposed price reductions with sponsors of PBS-listed PF products. The PBAC noted clinical advice that patients with severe dry eye disease typically require frequent administration of ocular lubricants, often exceeding six drops daily, and are therefore highly likely to be under the ongoing care of ophthalmologists or optometrists. PF ocular lubricants are clinically preferred in these cases due to the risk of preservative-related ocular surface toxicity. The PBAC recommended Option 2, limiting PBS prescribing of preservative-free ocular lubricants to optometrists and ophthalmologists to align with clinical guidelines, target patients with severe dry eye requiring specialist oversight, and help moderate PBS expenditure while maintaining access for those with greatest clinical need.
TENOFOVIR DISOPROXIL FUMARATE WITH EMTRICITABINE Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg CIPLA TENOFOVIR + EMTRICITABINE 300/200 TENOFOVIR/EMTRICITABINE 300/200 APX TENOFOVIR/EMTRICITABINE 300/200 ARX TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 TENOFOVIR/EMTRICITABINE SANDOZ 301/200	Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection	To request the PBAC consider whether increasing the number of repeats in the PBS listing for tenofovir disoproxil+ emtricitabine, for use as HIV PrEP, is appropriate.	Recommended	The PBAC recommended increasing the number of repeats specified in the PBS listings for tenofovir disoproxil with emtricitabine 200 mg tablet, for pre-exposure prophylaxis (PrEP) against HIV infection, from 2 to 5. The PBAC noted stakeholder correspondence requesting this change. The PBAC noted the basis of the request was to support patient access by reducing barriers, and to reduce rates of PrEP discontinuation in individuals with ongoing HIV acquisition risks. The PBAC agreed that this change would support access to tenofovir disoproxil with emtricitabine for patients who require HIV PrEP. The PBAC noted that change may result in an increased uptake in utilisation of tenofovir disoproxil with emtricitabine, however it was not expected to result in an additional cost to the PBS beyond what was previously considered.

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CIPLA AUSTRALIA PTY LTD ARROTEX PHARMACEUTICALS PTY LTD ALPHAPHARM PTY LTD SANDOZ PTY LTD (Correspondence)				

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CABOTEGRAVIR Suspension for injection 600 mg in 3 mL Apretude® ViiV HEALTHCARE PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Human immunodeficiency virus (HIV) prevention	To request the PBAC review its September 2023 recommendation that has not yet been accepted by the applicant.	In November 2025, the PBAC extended its September 2023 recommendation for this drug for a further 12 months.
LENACAPAVIR Injection set containing 2 vials lenacapavir sodium solution for injection 463.5 mg in 1.5 mL and 2 disposable syringes Sunlenca® GILEAD SCIENCES PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)	Human immunodeficiency virus (HIV)	To request the PBAC review its November 2023 recommendation that has not yet been accepted by the applicant.	In November 2025, the PBAC extended its November 2023 recommendation for this drug for a further 12 months.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (Australia) PTY LTD	Squamous cell carcinoma	To request the PBAC review its November 2023 recommendation that has not yet been accepted by the applicant.	In November 2025, the PBAC extended its November 2023 recommendation for this drug for a further 12 months.

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(Review of positive PBAC recommendations not accepted by applicants)			

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The following item was considered out-of-session between ordinary meetings (November 2025 - March 2026).

Please note that this item was considered prior to the publication date for the November 2025 PBAC meeting outcomes and hence has been included in this document:

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ACALABRUTINIB Tablet 100 mg Calquence® ASTRAZENECA PTY LTD Category 2 (Change to existing listing)	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)	To request listing of acalabrutinb for use in combination with venetoclax for the treatment of previously untreated CLL or SLL. Authority Required (Telephone/Online)	Recommended	The PBAC recommended acalabrutinib for use in combination with venetoclax (AV) as a fixed duration regimen for the treatment of patients with chronic lymphocytic leukaemia or small lymphocytic lymphoma that have not already been treated with drug treatment. The PBAC acknowledged the benefit of having an alternative fixed duration regimen that has a different tolerability profile to existing options. The PBAC considered that listing a second all oral, fixed duration option would increase access for rural and regional patients. The PBAC noted the support for this PBS listing from Lymphoma Australia and Rare Cancers Australia. The PBAC was satisfied that AV was as effective as venetoclax given in combination with obinutuzumab (VO) at preventing cancer progression. The PBAC advised that the cost of AV would be acceptable if the overall cost per course of treatment was not higher than that of VO. The PBAC considered there was a significant risk that people would access subsidy for AV outside of the proposed criteria. It therefore advised that a risk sharing arrangement with the sponsors of acalabrutinib and venetoclax would be required to mitigate this risk. The PBAC considered that 12.97 acalabrutinib scripts and 10.84 venetoclax scripts would be equivalent to one initial and 8.67 continuing venetoclax scripts plus 7.355 obinutuzumab scripts. The PBAC advised that flow-on changes to add a new listing for venetoclax to allow its use in combination with acalabrutinib would be required, and that flow-on changes to the listings for venetoclax and obinutuzumab would be required to prevent the use of acalabrutinib in triple therapy and grandfather restrictions may be required to allow patients to transition from non-PBS subsidised AV to PBS-subsidised treatment.

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Version 2:

Amendment: POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL (Systane®) – Amended 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.