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

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

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
ACALABRUTINIB Tablet 100 mg Calquence® ASTRAZENECA PTY LTD Category 2 (Change to existing listing) PBS General Schedule"	Mantle cell lymphoma (MCL)	To consider the sponsor's revised proposal for listing acalabrutinib for use in combination with bendamustine and rituximab for the first-line treatment of adult patients with Stage III or IV MCL who are ineligible for stem cell transplantation. This item was previously recommended by the PBAC at its July 2025 meeting. Authority Required (Telephone/Online)	Recommended	The PBAC recommended acalabrutinib (in combination with bendamustine and rituximab, ABR) for the first line treatment of Stage III or IV mantle cell lymphoma (MCL) in patients who are ineligible for stem cell transplantation. The PBAC welcomed the input received via the Consumer Comments facility on the PBS website which highlighted the need for better treatment options for patients who are ineligible to receive a stem cell transplant in the first line setting noting these patients have a poor prognosis with existing therapies. The PBAC acknowledged the high need for new treatment options in this setting. Compared with the evidence in the submission considered at the July 2025 PBAC meeting, the submission presented updated results from the ECHO trial with longer follow-up. Based on this, the PBAC remained satisfied that ABR was more effective at preventing progression of MCL for some patients than treatment with bendamustine and rituximab alone. The PBAC considered the estimates of the benefits of acalabrutinib in support of the requested price were more realistic than those presented in the July 2025 submission. The PBAC noted the sponsor had proposed a lower price and a revised financial arrangement to manage the risk that the cost to the PBS of

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				listing acalabrutinib is higher than expected. The PBAC advised that acalabrutinib would be acceptably cost-effective with a further small price reduction in order to reflect more realistic estimates of benefits and costs. The PBAC further advised that the financial arrangement should account for expected reductions in use of Bruton tyrosine kinase inhibitors in relapsed/refractory MCL. The PBAC indicated that flow-on changes to the existing bendamustine restriction would be required to allow use in combination with acalabrutinib and rituximab.
AFLIBERCEPT Solution for intravitreal injection 3.6 mg in 90 microlitres (40 mg per mL) pre-filled syringe Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) Eydenzelt® CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 3 (New PBS listing) PBS General Schedule	Branch retinal vein occlusion with macular oedema Central retinal vein occlusion with macular oedema Diabetic macular oedema Subfoveal choroidal neovascularisation due to age-related macular degeneration	To request listing of four new indications for the Eydenzelt brand of aflibercept that mirror the originator brand's current listings. Eydenzelt was originally recommended for listing as a biosimilar brand of aflibercept at the November 2025 PBAC meeting for the subfoveal choroidal neovascularisation due to pathologic myopia indication. Authority Required	Recommended	The PBAC was in favour of extending the existing recommendation of aflibercept (Eydenzelt) 2 mg/0.05 mL vial (vial) and pre-filled syringe (PFS) for intravitreal injection. The PBAC recommended the addition of four treatment indications under the same conditions as the reference biologic aflibercept (Eylea): • Subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) • Diabetic macular oedema (DMO) • Branch retinal vein occlusion (BRVO) with macular oedema (MO) • Central retinal vein occlusion (CRVO) with macular oedema (MO)

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				The PBAC noted that the recommendation was on a cost-minimisation basis and the equi-effective dose is 1 mg Eydenzelt = 1 mg Eylea. The PBAC advised Eydenzelt, Eylea and Afqlir should be considered equivalent for the purposes of substitution (i.e. 'a'-flagged in the Schedule). The PBAC noted flow-on changes to Eylea and Afqlir to include administrative advice about 'a'-flagging.
AGALSIDASE ALFA AGALSIDASE BETA Solution for I.V. injection 3.5 mg in 3.5 mL vial Powder for I.V. infusion, 5 mg vial Powder for I.V. infusion, 35 mg vial Replagal® Fabrazyme® TAKEDA PHARMACEUTICALS AUSTRALIA PTY LTD SANOFI AUSTRALIA AND NEW ZEALAND Other matters (New PBS listing) PBS General Schedule	Fabry disease	For advice on whether agalsidase alfa and agalsidase beta are suitable for PBS listing for the treatment of Fabry disease under the same conditions as the PBAC's recommendations for the PBS listing of pegunigalsidase alfa at its July 2025 meeting.	Recommended	The PBAC recommended the PBS listing of agalsidase alfa and agalsidase beta for the treatment of Fabry disease under the same conditions as the PBAC's recommendation for the PBS listing of pegunigalsidase alfa at its July 2025 meeting. The PBAC recommended flow-on changes to the PBS listing of migalastat and the recommended listing of pegunigalsidase alfa, including amendment of the restriction to allow patients to switch between migalastat, pegunigalsidase alfa, agalsidase alfa and agalsidase beta, inclusion of a 12-month standard timeframe to the grandfather restriction of the PBS listing of migalastat and the recommended listing of pegunigalsidase alfa when the last enzyme replacement therapy transitions from the LSDP, and administrative advice stipulating that the PBS-subsidised treatments for Fabry disease are agalsidase alfa, agalsidase beta, migalastat and pegunigalsidase alfa.

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AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN Oral powder 400 g (GA1 Anamix infant) Sachets containing oral powder 18 g, 30 (GA1 Anamix Junior) GA1 Anamix Infant® GA1 Anamix Junior® NUTRICIA AUSTRALIA PTY LTD Committee secretariat (Change to existing listing) PBS General Schedule	Pyridoxine-Dependent Epilepsy (PDE)	To request listing of GA1 Anamix Infant and GA1 Anamix Junior for the dietary management of infants and children diagnosed with PDE who require a lysine-free, arginine-supplemented amino-acid formula in combination with pyridoxine. Restricted Benefit	Recommended	The PBAC recommended extending the current General Schedule Restricted Benefit listings for amino acid formula with vitamins and minerals without lysine and low in tryptophan (Glutaric Aciduria Type 1 (GA1) Anamix Infant and GA1 Anamix Junior) to include use in pyridoxine-dependent epilepsy (PDE) deficiency. The PBAC noted and supported advice from the Nutritional Products Working Party that these products are clinically appropriate for the dietary management of PDE deficiency. The PBAC noted that only a small patient population in Australia is likely to require dietary management of PDE deficiency. The PBAC considered the estimated financial impact of the proposed listing extension was appropriate.
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE Oral powder 400 g (MSUD Anamix infant) Sachets containing oral powder 36 g, 30 (MSUD Anamix Junior) Oral liquid 125 mL, 30 (MSUD Lophlex LQ 20) Oral powder 500 g (MSUD Maxamum) MSUD Anamix Infant® MSUD Anamix Junior®	Short-chain enoyl-CoA hydratase (ECHS1) deficiency	To request listing of MSUD Anamix Infant, MSUD Anamix Junior, MSUD Lophlex LQ 20 and MSUD Maxamum for the dietary management of infants and children with ECHS1 deficiency (the same dietary management approach used in Maple Syrup Urine Disease (MSUD)). Restricted Benefit	Recommended	The PBAC recommended extending the General Schedule Restricted Benefit listings for MSUD Anamix Infant, MSUD Anamix Junior, MSUD Lophlex LQ 20 and MSUD Maxamum to include patients with short-chain enoyl Co-A hydratase 1 (ECHS1) deficiency and 3-hydroxyisobutyryl Co-A hydrolase (HIBCH) deficiency. The PBAC noted and supported advice from the Nutritional Products Working Party that these products are clinically appropriate for the dietary management of ECHS1 and HIBCH deficiencies. The PBAC also welcomed input

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MSUD Lophlex LQ 20® MSUD Maxamum® NUTRICIA AUSTRALIA PTY LTD Committee secretariat (Change to existing listing) PBS General Schedule				from the Mito Foundation, which supported the proposed extension and highlighted the benefits of improved access to clinically recommended dietary therapy for patients with these rare metabolic disorders. The PBAC considered the estimated financial impact of the proposed listing extension was appropriate.
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE Sachets containing oral powder 25 g, 30 (MSUD express 15) MSUD express 15® VITAFLO AUSTRALIA PTY LIMITED Category 3 (Change to existing listing) PBS General Schedule	Short-chain Enoyl Co-A Hydratase (ECHS1) deficiency and 3-Hydroxyisobutyryl Co-A Hydrolase (HIBCH) deficiency	To request listing of MSUD express15 for the dietary management of patients aged 3 years and over with a proven diagnosis of either ECHS1 or HIBCH deficiency. Restricted Benefit	Recommended	The PBAC recommended the General Schedule Restricted Benefit listing of MSUD express 15® for patients aged 3 years of age or older with a proven diagnosis of either Short-chain Enoyl Co-A Hydratase 1 (ECHS1) deficiency and 3-Hydroxyisobutyryl Co-A Hydrolase (HIBCH) deficiency. The PBAC considered that MSUD express 15 should be listed under the same circumstances and price as the current PBS listing of MSUD express15 for the indication of Maple Syrup Urine Disease (MSUD), with the same maximum quantity units and number of repeats. The PBAC noted and supported advice from the Nutritional Products Working Party that MSUD express15 is clinically appropriate for the dietary management of ECHS1 and HIBCH deficiencies. The PBAC considered that only a small patient population in Australia is likely to require dietary management of ECHS1 and HIBCH deficiencies.
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE, ISOLEUCINE AND	Short-chain Enoyl Co-A Hydratase (ECHS1) deficiency and 3-Hydroxyisobutyryl Co-	To request listing of MSUD explore5 for the dietary management of patients aged 6 months to 5 years	Recommended	The PBAC recommended the General Schedule Restricted Benefit listing of MSUD Explore5® on the PBS for patients aged 6 months to 5 years with a proven diagnosis of either Short-chain

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SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID Sachets containing oral powder 12.5 g, 30 (MSUD Explore5) MSUD explore5® VITAFLO AUSTRALIA PTY LIMITED Category 3 (Change to existing listing) PBS General Schedule	A Hydrolase (HIBCH) deficiency	with a proven diagnosis of either ECHS1 or HIBCH deficiency. Restricted Benefit		Enoyl Co-A Hydratase 1 (ECHS1) deficiency and 3-Hydroxyisobutyryl Co-A Hydrolase (HIBCH) deficiency. The PBAC considered that MSUD Explore5 should be listed under the same circumstances and price as the current PBS listing of MSUD Explore 5 for the indication of Maple Syrup Urine Disease (MSUD), with the same maximum quantity units and number of repeats. The PBAC noted and supported advice from the Nutritional Products Working Party that MSUD Explore 5 is clinically appropriate for the dietary management of ECHS1 and HIBCH deficiencies. The PBAC considered that only a small patient population in Australia is likely to require dietary management of ECHS1 and HIBCH deficiencies.
AMIVANTAMAB Solution for subcutaneous injection 1600 mg in 10 mL Solution for subcutaneous injection 2240 mg in 14 mL Solution for subcutaneous injection 2400 mg in 15 mL Solution for subcutaneous injection 3520 mg in 22 mL Rybrevant SC® JANSSEN-CILAG PTY LTD Category 2 (New PBS listing)	Non-small cell lung cancer (NSCLC)	To request listing of a new subcutaneous form of amivantamab for the first-line treatment (in combination with platinum-based chemotherapy) and second-line treatment (as monotherapy) of adult patients with locally advanced or metastatic NSCLC with an epidermal growth factor receptor gene mutation. Authority Required (Telephone/Online)	Recommended	The PBAC recommended subsidy of a subcutaneous (SC) injection form of amivantamab through the PBS for the treatment of locally-advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion positive mutation. The PBAC welcomed input received from consumers and acknowledged that an SC presentation of amivantamab may reduce the time-burden associated with cancer care. The PBAC considered the amivantamab regimen delivered subcutaneously provided the same benefits as the amivantamab regimen delivered intravenously.

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PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy)				The PBAC considered the subcutaneous form of amivantamab would be value for money if it cost the same as intravenous amivantamab. The PBAC noted that listing amivantamab SC on the PBS would not result in an increase to government expenditure.
ANIFROLUMAB Solution for subcutaneous injection 120 mg in 0.8 mL Saphnelo® ASTRAZENECA PTY LTD Category 3 (New PBS listing) PBS General Schedule	Systemic lupus erythematosus (SLE)	To request listing of a new subcutaneous form of anifrolumab for use as add-on treatment for adult patients with severe SLE with persistent disease activity (supported by a SLE Disease Activity Index 2000 score of at least 10 points) despite standard of care with hydroxychloroquine, immunosuppressant medication and prednisolone (or equivalent). Authority Required (Written)	Recommended	The PBAC recommended the Section 85 Authority Required listing for anifrolumab pre-filled pen auto-injector for subcutaneous injection (referred to as anifrolumab SC) for the treatment of adults with severe systemic lupus erythematosus (SLE) and high disease activity despite the standard of care. The PBAC recommended the listing on a cost-minimisation basis to the currently Section 100-listed anifrolumab for intravenous administration (anifrolumab IV). The PBAC advised the equi-effective doses to be anifrolumab 120 mg SC weekly as equivalent to the 300 mg IV infusion given every 4 weeks, so that four pre-filled 120 mg pens (i.e., total dose 480 mg) are equivalent to the 300 mg infusion over a 28-day period.
APADAMTASE ALFA WITH CINAXADAMTASE ALFA (RECOMBINANT ADAMTS13) Powder for injection 500 I.U. with solvent Powder for injection 1500 I.U. with solvent Adzynma®	Congenital thrombotic thrombocytopenic purpura (cTTP)	To request listing of apadamtase alfa with cinaxadamtase alfa (an enzyme replacement therapy) for the prevention of acute events in adult and paediatric patients with chronic, severe cTTP who have a confirmed ADAMTS13 genetic mutation and ADAMTS13 activity levels less than	Recommended	The PBAC recommended subsidy of recombinant ADAMTS13 (rADAMTS13) enzyme replacement therapy through the PBS for both prophylactic and on-demand treatment of patients with chronic, severe congenital thrombotic thrombocytopenia purpura (cTTP).

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TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. Category 1 (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)		10% and who cannot tolerate, or are hypersensitive to, preventative treatment with fresh frozen plasma. Authority Required (Telephone/Online)		Enzyme replacement therapy for cTTP works by administering rADAMTS13 replacing the persons missing ADAMTS13 enzyme which in turn helps restore functions, helping to prevent dangerous blood clots, reduce disease episodes, protect organs, and potentially to improve day-to-day quality of life compared with standard treatment with fresh frozen plasma (FFP). The PBAC welcomed input from individuals, health care professionals and medical organisations highlighting there is a high need for clinically effective therapies. The PBAC acknowledged the input supported the recommended PBS listing which is broader than the population initially requested by the supplying company. The PBAC accepted that prophylactic treatment with rADAMTS13 would reduce the risk of breakthrough episodes that may lead to blood clots, low platelet counts, anaemia, and organ damage compared to standard treatment with FFP. The PBAC was satisfied that in the context of an extremely rare and life-threatening disease with high unmet clinical need, that the cost-effectiveness of rADAMTS13 would be acceptable at the price requested.

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ATEZOLIZUMAB Solution for subcutaneous injection 1875 mg in 15 mL Tecentriq SC® LICENSED STERILE COMPOUNDERS OF AUSTRALIA LIMITED Other matters (New PBS listing) PBS Section 100 (Efficient funding of Chemotherapy)	Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Extensive-stage small cell lung cancer Resected early stage (Stage II to IIIA) non-small cell lung cancer Locally advanced or metastatic non-small cell lung cancer Stage IV (metastatic) non-small cell lung cancer	To request that the listings for the subcutaneous form of atezolizumab transition to the Section 100 (Efficient Funding of Chemotherapy) program. Authority Required	Not applicable	This item was withdrawn.
AZACITIDINE Powder for injection 100 mg Azacitidine Accord® Azacitidine Dr Reddy's® Azacitidine Euglia® Azacitidine Juno® Azacitidine MSN® Azacitidine Sandoz® Azacitidine SXP® LICENSED STERILE COMPOUNDERS OF AUSTRALIA LIMITED	Acute Myeloid Leukemia Myelodysplastic syndrome Chronic Myelomonocytic Leukemia	To request that the listings for azacitidine transition to the Section 100 (Efficient Funding of Chemotherapy) program. Authority Required	Not applicable	To be considered at a future PBAC meeting.

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Category 3 (New PBS listing) PBS Section 100 (Efficient funding of Chemotherapy)				
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 Standard re-entry (New listing) PBS Section 100 (Efficient Funding of Chemotherapy)	Relapsed and/or refractory multiple myeloma (MM)	Resubmission to request listing of belantamab mafodotin for use in combination with bortezomib and dexamethasone for the treatment of relapsed and/or refractory MM in patients who have progressive disease after at least one prior line of therapy. This item was previously considered by the PBAC at its November 2025 meeting. Authority Required (Telephone/Online)	Recommended	The PBAC recommended subsidy of belantamab mafodotin (Blenrep®) through the PBS, for use in combination with bortezomib and dexamethasone (BmBd) for the treatment of multiple myeloma that has returned or is not responding to treatment, specifically relapsed and/or refractory multiple myeloma (RRMM). The PBAC welcomed input from individuals, health professionals and organisations which strongly supported the resubmission and highlighted the longer survival time associated with BmBd. The PBAC considered the proposed use of BmBd in patients who have received at least one prior treatment for RRMM was appropriate. The PBAC accepted that BmBd was more effective at delaying disease progression and extending patients' lives compared to current standards of care including daratumumab (in combination with bortezomib and dexamethasone) and carfilzomib (in combination with dexamethasone). The PBAC again noted that belantamab mafodotin was associated with side effects that affected the eyes, including blurred vision, dry eye and visual impairment that affected a patients ability to read and drive.

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				The PBAC considered that BmBd would provide value for money at a lower price. The PBAC considered the Sponsor's updated estimation of how many patients would use BmBd was appropriate and advised a risk sharing arrangement was appropriate.
BEMPEDOIC ACID BEMPEDOIC ACID WITH EZETIMIBE Tablet 180mg Tablet 180mg bempedoic acid with 10 mg ezetimibe Nexletol® Nexlizet® SEQIRUS (AUSTRALIA) PTY LTD Category 2 (New PBS listing) PBS General Schedule	Hypercholesterolaemia	To request listing of bempedoic acid, as monotherapy and in combination with ezetimibe, for the treatment of adult patients with hypercholesterolaemia (heterozygous familial and non-familial) at high risk of a first cardiovascular event or with established symptomatic atherosclerotic cardiovascular disease who have statin intolerance or are on maximally tolerated statin therapy, and despite treatment with ezetimibe, continue to have low-density lipoprotein cholesterol (LDL-C) levels greater than 1.8 mmol/L. Authority Required (STREAMLINED)	Not Recommended	The PBAC did not recommend bempedoic acid and bempedoic acid with ezetimibe for the treatment of adult patients with hypercholesterolaemia (heterozygous familial (HeFH) and non-familial) at high risk of a first cardiovascular (CV) event or with established symptomatic atherosclerotic cardiovascular disease (ASCVD). The proposed listing included patients who cannot tolerate statins or are on maximally tolerated statin therapy, and despite treatment with ezetimibe, continue to have low-density lipoprotein cholesterol (LDL) levels above 1.8 mmol/L. The PBAC welcomed the comments from health professionals and organisations supporting the PBS listing of bempedoic acid. The input noted the benefits of bempedoic acid included its oral administration, favourable tolerability, and evidence from the CLEAR OUTCOMES trial demonstrating fewer cardiovascular events with bempedoic acid compared with placebo in patients who could not tolerate statin therapy. The PBAC acknowledged that there remains a clinical need for additional treatment options, particularly for patients who are statin-

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				intolerant or who are not adequately managed with statins or ezetimibe but are not eligible for PCSK9 inhibitors. The PBAC noted that the trial evidence suggested bempedoic acid reduced major adverse cardiovascular events and reduced LDL cholesterol compared with placebo. However, the PBAC considered that it was uncertain whether the benefits shown in the main clinical trial would be seen in the Australian population as the trial population did not adequately reflect the target population of the proposed listing. As a result, the PBAC noted that the expected size of benefit in the proposed population would also be uncertain. The PBAC considered that the economic model was subject to substantial uncertainty and required further revision, particularly in relation to the modelling of costs over time. The PBAC considered that a price reduction together with a risk sharing arrangement was likely required to achieve a listing that would be value for money. Sponsor's Comment: The sponsor had no comment.
BIRCH TRITERPENES Gel containing 100 mg per 1 g, 23.4 g Filsuvez® CHIESI AUSTRALIA PTY LTD	Dystrophic or junctional epidermolysis bullosa (EB)	To request listing of birch triterpenes for the treatment of patients aged 6 months and older with partial thickness skin wounds caused by dystrophic or junctional EB.	Not Recommended	The PBAC did not recommend birch triterpenes topical gel for listing on the PBS for the treatment of partial thickness wounds associated with dystrophic or junctional epidermolysis bullosa.

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Category 1 (New PBS listing) PBS General Schedule		Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment		The PBAC welcomed the input from health care professionals and organisations highlighting the high clinical need for effective therapies for this debilitating disease. The PBAC noted the input supported listing birch triterpenes topical gel on the PBS and described the lengthy and often extremely painful process of dressing changes and wound management, and the effect of the disease on quality of life. The PBAC acknowledged there is a high need for an effective treatment option. Based on the clinical evidence in the submission, the PBAC accepted that for some patients with dystrophic or junctional epidermolysis bullosa, some wounds treated with birch triterpenes gel would close faster compared to current treatment (standard of care) involving wound management, pain/itch control and monitoring and management of complications, and acknowledged that this would be of value to the patients who obtained benefit. However, the PBAC considered the benefit was modest noting that not all patients responded to the gel and longer term data from the trial suggested no difference in wound closure between patients treated with birch triterpenes gel and patients managed with current treatment. The PBAC did not accept that birch triterpenes gel was as safe as standard of care because wound-complication adverse events (including wound re-opening) occurred more often in patients treated with

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				birch triterpenes gel compared to control gel in the key clinical trial. Overall, the PBAC considered that PBS listing of birch triterpenes gel was not adequately supported . The PBAC considered that the sponsor's approach to justify its requested price, which relied on estimates of long-term benefits was unreliable. The PBAC considered that it was not possible to determine the value of any long-term benefits from the data presented. Sponsor's Comment: The sponsor had no comment.
BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® AMGEN AUSTRALIA PTY LIMITED Category 3 (Change to existing listing) PBS Section 100 (Efficient Funding of Chemotherapy)	Acute lymphoblastic leukaemia (ALL) Precursor B-cell ALL (Pre-B-cell ALL)	To request revision of the current combined blinatumomab/inotuzumab ozogamicin Risk Sharing Arrangement (RSA) for ALL and Pre-B-cell ALL. Authority Required	Recommended	The PBAC advised that it would be appropriate to increase the subsidisation caps under the existing blinatumomab Risk Sharing Arrangement (RSA) to account for additional utilisation of blinatumomab to treat minimum residual disease (MRD)-negative paediatric B-precursor acute lymphoblastic leukaemia (B-ALL).
BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris®	Hodgkin lymphoma	To request listing of brentuximab vedotin for use in combination with a multi-drug chemotherapy regimen for the first-line treatment of adult patients with advanced stage CD30 positive Hodgkin lymphoma.	Recommended	The PBAC recommended expanding the listing of brentuximab vedotin for the first-line treatment of advanced CD30 positive classical Hodgkin lymphoma (cHL) to include use of the BrECADD regimen (brentuximab vedotin, etoposide, cyclophosphamide, doxorubicin and dexamethasone).

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TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. Category 2 (Change to existing listing) PBS Section 100 (Efficient Funding of Chemotherapy)		Authority Required (Written)		The PBAC welcomed input from health care professionals, and organisations, supporting the listing. The input highlighted the need for treatments that improve outcomes while reducing short-term and long-term treatment toxicity when used as first-line treatment for patients, many of whom are diagnosed at a young age and may experience treatment-related consequences for decades after achieving remission. The PBAC was satisfied that BrECADD provides, for some patients, a significant improvement in delaying disease progression over the existing treatment eBEACOPP (escalated combination of bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone). The PBAC considered brentuximab vedotin had similar safety compared to treatment with eBEACOPP. The PBAC considered brentuximab vedotin may be less likely to affect fertility. This was based on data on hormone levels from clinical studies and may be particularly important as BrECADD will mainly be used by younger patients. The PBAC considered that more patients may be eligible for treatment than estimated in the submission, and that the treatment was likely to be used more widely than predicted. The PBAC considered the expanded listing for advanced cHL, which includes BrECADD and

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				A+AVD (brentuximab vedotin plus doxorubicin, vinblastine, and dacarbazine) regimens, was cost-effective at the revised brentuximab vedotin price requested by the sponsor before the PBAC meeting.
BRIVARACETAM Oral solution 10 mg per mL, 300 mL Briviact® UCB AUSTRALIA PROPRIETARY LIMITED Category 4 (Change to existing listing) PBS General Schedule	Intractable focal onset seizures	To request that brivaracetam oral liquid be considered as an exempt item under section 84AH of the National Health Act 1953. Where a pharmaceutical item is determined to be an exempt item, that pharmaceutical item is excluded from fifteen year Anniversary Price, first new brand and price disclosure reductions. Exempt items are not exempt from five and ten year Anniversary Price reductions. Authority Required (STREAMLINED)	Advice Provided	The PBAC advised the Minister, under subsection 101(4AB) of the National Health Act 1953, that brivaracetam oral solution, 10 mg per mL, 300 mg (Briviact®) met particular circumstances to be considered an exempt item under section 84AH of the Act. The PBAC considered that the oral solution form of brivaracetam was the only suitable PBS listed option for the treatment of intractable focal onset seizures for patients who cannot swallow tablets, or who require accurate weight-based dosing.
CLOZAPINE Tablet 12.5mg (orally disintegrating) Tablet 25mg (orally disintegrating) Tablet 50mg (orally disintegrating) Tablet 100mg (orally disintegrating) Tablet 200mg (orally disintegrating) Clozaril® VIATRIS PTY LTD Category 4	Schizophrenia	To request listing of new orally disintegrating tablet forms of clozapine for the treatment of patients with schizophrenia under the same restrictions as the currently listed tablet forms. Authority Required (STREAMLINED)	Recommended	The PBAC recommended listing Clozaril ODT® on the PBS for the treatment of schizophrenia in patients who are non-responsive to, or unable to tolerate, other antipsychotic medicines. Clozaril ODT® is an orally disintegrating tablet form of clozapine. The PBAC noted that the requested listings were consistent with the current PBS restrictions for clozapine. The PBAC also noted the introduction of a 12.5 mg strength ODT form and considered that the new formulation would provide an alternative dosage form without changing the eligible patient population or overall use of clozapine. The PBAC advised that

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(New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)				Clozaril ODT® should be treated as interchangeable on an individual patient basis with other clozapine oral tablets.
DARATUMUMAB Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL Darzalex SC® LICENSED STERILE COMPOUNDERS OF AUSTRALIA LIMITED Category 3 (New PBS listing) PBS Section 100 (Efficient funding of Chemotherapy)	Newly diagnosed systemic light chain amyloidosis Untreated multiple myeloma Relapsed and/or refractory multiple myeloma	To request that the listings for the subcutaneous form of daratumumab transition to the Section 100 (Efficient Funding of Chemotherapy) program. Authority Required	Not applicable	To be considered at a future PBAC meeting.
DELGOCITINIB Cream 20 mg per g, 60 g Anzupgo® LEO PHARMA PTY LTD Category 3 (New PBS listing) PBS General Schedule	Chronic hand eczema (CHE)	To consider the sponsor's revised proposal for listing delgocitinib for the treatment of moderate to severe CHE where topical corticosteroids failed to achieve an adequate response or are medically inappropriate. This item was previously recommended by the PBAC at its November 2025 meeting. Authority Required (Written)	Not Recommended	The PBAC welcomed the consumer input received in relation to this submission. The input highlighted severe chronic hand eczema is an ongoing condition that causes pain and physical distress. The PBAC acknowledged the need for new and effective treatment options for patients, particularly as topical corticosteroid therapies have known adverse effects. At its November 2025 meeting, the PBAC recommended delgocitinib be listed on the PBS. At that time, it was concerned that the sponsor’s approach to justifying the requested

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				price was unreliable. In particular, the estimates of benefits in the economic model did not reflect the clinical evidence in the submission. The model included multiple treatment cycles, although clinical evidence was available for only one cycle, and several inputs were based on insufficient data. The PBAC advised that a simpler analysis of benefits and costs over a single 16-week cycle of delgocitinib treatment would be adequate to determine an appropriate treatment cost per patient and recommended listing on that basis. The PBAC also noted that limits on the prescribable quantity and number of repeats would help prevent use outside the subsidised criteria, including use on other areas of the body, which could result in use beyond the cost-effective estimate. The company that supplies delgocitinib did not agree with the PBAC's conclusions at its November 2025 meeting, and made a new submission with a revised economic analysis seeking to address the concerns of the PBAC raised at its November 2025 meeting. The PBAC concluded the revised economic analysis lodged by the sponsor did not adequately address its previous concerns regarding cost-effectiveness and therefore did not provide a basis to vary the previous recommendation. The PBAC noted that the submission did not contain new financial estimates, although

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				claimed that listing delgocitinib on the PBS would result in significant cost savings due to the replacement of dupilumab. This claim was not accepted by the PBAC as it considered that the extent to which delgocitinib would replace dupilumab was likely to be small given the treatments have a different place in therapy. The PBAC provided further advice regarding the restriction, recommending that the maximum quantity be reduced to 1 with 1 repeat and that the restriction be split into three treatment phases to better reflect the intended pattern of use in clinical practice. Sponsor's comment: LEO Pharma remains committed to achieving a PBS listing for Anzupgo for Australians living with chronic hand eczema and we are working with the PBAC and the Department of Health, Disability and Ageing to that goal.
DEPEMOKIMAB Solution for subcutaneous injection 100 mg in 1 mL Exdensur® GLAXOSMITHKLINE AUSTRALIA PTY LTD Category 2 (New PBS listing)	Uncontrolled severe eosinophilic asthma	To request listing of depemokimab for the treatment of uncontrolled severe eosinophilic asthma in patients aged 12 years or older with a blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months, or with a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months.	Recommended	The PBAC recommended listing of depemokimab for the treatment of uncontrolled severe eosinophilic asthma in patients aged 12 years or older. The PBAC welcomed the input from healthcare professionals and organisations supporting the listing of depemokimab for this use. The comments emphasised the potential for depemokimab to help patients stay on treatment and make treatment easier to

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PBS Section 100 (Highly Specialised Drugs Program)		Authority Required (Written) for initial treatment Authority Required (STREAMLINED) for continuing treatment		manage as it only needs to be given every 6 months. However, the PBAC also noted a possible concern that some people may think they do not need regular asthma check-ups because the medicine is given less often. Based on the evidence included in the submission, the PBAC was satisfied that depemokimab was as effective as mepolizumab at reducing asthma exacerbations and had similar safety. The PBAC advised that the cost of depemokimab would be acceptable if it cost no more than the least costly biologic for asthma over a 1-year time frame. The PBAC considered the equi-effective doses for uncontrolled severe asthma were: • DEPE 100 mg by subcutaneous (SC) injection 6 monthly (2 doses over one year); • MEPO 100 mg by SC injection every 4 weeks (13 doses over 1 year). The PBAC advised that the equi-effective doses for depemokimab and other biologics for asthma should be based on that previously accepted by the PBAC at the time those biologics were recommended.
DONIDALORSEN Solution for injection 80 mg in 0.8 mL pre-filled pen Zirdawny®	Hereditary angioedema	To request listing of donidalorsen for the long-term prophylaxis (prevention) of recurrent attacks in patients with hereditary angioedema.	Recommended	The PBAC recommended donidalorsen for the prevention of recurrent attacks of hereditary angioedema (HAE) Types I and II. The PBAC acknowledged input from individuals, health professionals and organisations which

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OTSUKA AUSTRALIA PHARMACEUTICAL PTY. LTD Category 2 (New PBS listing) PBS General Schedule		Authority Required (Written)		emphasised the value of an additional option for preventive treatment. The PBAC noted that patients may respond differently to different therapies and that the distinct mechanism of action, pre-filled pen device and potential for less frequent dosing with donidalorsen may support more individualised treatment. The PBAC considered the clinical evidence and was satisfied that donidalorsen provides comparable effectiveness to lanadelumab and garadacimab at reducing the number of HAE attacks. The PBAC considered that 80 mg every four weeks of donidalorsen would be equivalent to 300 mg every 4 weeks of lanadelumab. Further, the PBAC considered that, over two years, 2,087 mg of donidalorsen would be equivalent to 5,000 mg of garadacimab. The PBAC calculated the doses relative to garadacimab over a two-year period to account for the loading dose required for garadacimab. The PBAC recommended flow-on changes to the restrictions for other PBS listed medicines that treat HAE (i.e. garadacimab and lanadelumab) to allow switching from donidalorsen to garadacimab or lanadelumab and to prevent combination use of these three medicines. The PBAC advised that donidalorsen should join

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				the existing lanadelumab risk sharing arrangement with similar arrangements to garadacimab.
DUPILUMAB Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 200 mg in 1.14 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled pen Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD Category 3 (Change to existing listing) PBS General Schedule	Chronic severe atopic dermatitis	To consider the sponsor's revised proposal for listing dupilumab for the treatment of chronic severe atopic dermatitis in children aged 6 months to 11 years who have had lesions for at least 6 months from the time of the initial diagnosis affecting either the whole body or the face/hands. This item was previously recommended by the PBAC at its March 2022 meeting. Authority Required (Telephone/Online)	Not Recommended	The PBAC recalled that it previously recommended dupilumab for severe atopic dermatitis in patients aged less than 12 years at its March 2022 meeting. The PBAC noted that the supplying company had not taken the steps needed proceed to PBS listing after that meeting. This submission sought PBAC consideration of updated use estimates and a revised risk sharing arrangement for the expanded listing. The PBAC decided not to revise its previous recommendation to expand the PBS listing of dupilumab to include treatment of atopic dermatitis in patients aged less than 12 years on the basis that the proposal did not support a cost-effective listing for dupilumab. The PBAC welcomed inputs from consumers, health care professionals and organisations. The PBAC acknowledged that there is a high clinical need for treatments for severe atopic dermatitis in children, noting the disease has a significant impact on many aspects of quality of life and broader impacts on development for younger patients. The PBAC acknowledged the importance of expanding eligibility to enable equitable access to younger patients. The PBAC noted that clinical guidelines state that dupilumab is the preferred treatment for

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				patients with severe atopic dermatitis, who have not responded to daily topical therapy (corticosteroid/calcineurin inhibitor) and that few other treatments are available for patients aged <12 years. The submission presented revised estimates of how many patients would use dupilumab and an updated Risk Sharing Arrangement proposal. The submission did not propose any additional restriction criteria for the <12 years population to restrict treatment to the most severely affected paediatric population with the highest need. The PBAC noted that the submission proposed a price per month for paediatric patients that was higher than the current price in the adolescent/adult population (aged 12+). The PBAC maintained its advice that dupilumab would be cost-effective at the same price per month for children as for the adolescent/adult population. The PBAC considered that there was no clear evidence provided to support or quantify any additional benefits for paediatric patients and that at the higher proposed price, use of dupilumab in children <12 years was not acceptably cost-effective. The PBAC considered that the RSA proposed in the submission did not address uncertainty in use estimates and did not adequately address the potential for use outside the intended population, or the potential continuing use in patients who do not have adequate response or

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				where patients' disease has resolved and no longer requires treatment. Overall, the PBAC considered that the price proposed, the changes to the financial estimates, and the proposed parameters for the RSA were not acceptable. Thus, the PBAC advised that its March 2022 recommendation for dupilumab remained unchanged. The PBAC considered that if the supplying company is unable to progress the intent of the March 2022 PBAC recommendation, an alternative approach may be to explore mechanisms to limit treatment to children with the highest need. The PBAC noted that, depending on the approach, the way forward could include either: • Reduce the price, substantially reduce the use estimates, and revise the RSA proposal, so that the listing is cost-effective and the economic and financial risks associated with the listing are adequately managed; or • Propose revisions to the restriction criteria, allowed prescriber types, restriction authority level, and RSA caps for the <12 years population reflecting a more limited population and requirements for trial of stopping treatment. If a higher cost per month is requested for the <12 years population compared with the

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				adolescent/adult population, a justification for the price would be required. Sponsor's comment: Sanofi is disappointed by the PBAC's recent decision, particularly as Dupixent remains the only TGA-approved biologic for uncontrolled severe atopic dermatitis (AD) in children under 12. Sanofi has supported hundreds of children with a high unmet clinical need through compassionate access, in addition to leading Australian children's hospitals also funding therapy for severe cases. We deeply appreciate the medical and patient community for their advocacy throughout this journey, including the many individual letters sent to the PBAC during the public consultation period, highlighting the need for advanced therapy such as Dupixent to treat severe AD and reduce the significant burden this chronic skin condition has on the health and quality of life of young children and their families. We remain committed to working collaboratively toward a viable PBS listing, so that dermatologists and immunologists can prescribe an effective advanced therapy for young patients with uncontrolled severe AD.
ELACESTRANT Tablet 86 mg (as dihydrochloride) Tablet 345 mg (as dihydrochloride) Orserdu® A.MENARINI AUSTRALIA PTY LIMITED	Breast cancer	Resubmission to request listing of elacestrant for the treatment of estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) locally advanced or metastatic breast cancer with an activating estrogen receptor 1 mutation in patients who	Not Recommended	The PBAC did not recommend elacestrant (Orserdu®) for the treatment of estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) locally advanced or metastatic breast cancer with an activating estrogen receptor 1 (ESR1) mutation in patients whose disease has progressed following at least one line of endocrine therapy,

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Standard re-entry (New listing) PBS General Schedule		have disease progression following at least one line of endocrine therapy, including at least 12 months of treatment with a cyclin-dependent kinase 4/6 inhibitor. This item was previously considered by the PBAC at its March 2025 meeting. Authority Required (Telephone/Online)		including at least 12 months of treatment with a cyclin-dependent kinase 4/6 inhibitor (CDK4/6i). The PBAC previously considered elacestrant for this population at its March 2025 meeting. At that time, the PBAC did not recommend listing, and advised the supplying company that a resubmission should clarify the clinical place of elacestrant and provide evidence that it is more effective than the standard of care for the requested patient population. The PBAC welcomed input from healthcare professionals and organisations and recalled the input it received in March 2025. The input highlighted there is some clinical need for alternative treatments for ER+/HER2- locally advanced or metastatic breast cancer that have fewer adverse effects or that allow patients to avoid or delay the use of chemotherapy. The supplying company's July 2026 resubmission nominated everolimus with exemestane as the relevant standard of care for second and later lines of treatment. The PBAC did not agree this was the right treatment to compare to elacestrant, because it is not often used in patients whose disease has progressed after treatment with a CDK4/6i. The PBAC considered the evidence presented in the resubmission did not allow confidence that

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				elacestrant would enable patients to live longer without cancer progression, or cause fewer adverse events, than treatment with everolimus with exemestane. This was because the resubmission compared some patients from the elacestrant trial with a small number of patients from a registry who had used everolimus with exemestane. This meant the differences in cancer progression could be due to factors other than the true differences in effectiveness between elacestrant and everolimus with exemestane. Consequently, the PBAC did not consider elacestrant would be cost-effective at the proposed price, because the clinical evidence did not adequately support the sponsor's estimated benefits over everolimus and exemestane. Sponsor's Comment: The sponsor had no comment.
ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR Pack containing 28 sachets containing granules elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets containing granules ivacaftor 75 mg Trikafta®	Cystic fibrosis	To request a change to the existing listing for Trikafta (granules formulation) for the treatment of cystic fibrosis to allow patients aged 6-11 years weighing less than 30 kg to use either the granule or tablet formulation of the same dose. Authority Required (Written)	Recommended	The PBAC recommended a change to the restriction criteria for elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules to allow prescribing for patients aged between 6 years to 11 years. This would allow young patients (who weigh less than 30 kg) to access a granule formulation.

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VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD. Committee Secretariat (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)				
ELTROMBOPAG Tablet 75 mg (as olamine) Revolade® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 4 (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Severe aplastic anaemia Severe thrombocytopenia	To request listing of a new 75 mg strength of eltrombopag for the treatment of patients with severe aplastic anaemia and severe thrombocytopenia under the same restrictions as the currently listed tablet forms. Authority Required (Written or Telephone/Online)	Recommended	The PBAC recommended the listing of eltrombopag 75 mg tablets for severe thrombocytopenia and severe aplastic anaemia on the Section 100 Highly Specialised Drugs Program under the same circumstances as the eltrombopag 25 mg and 50 mg listed strengths. The PBAC welcomed input from individuals and organisations describing the benefits of a 75 mg tablet in supporting medication management for patients with complex dosing schedules. The PBAC recommended that the new eltrombopag 75 mg dosage strength have a price that is equivalent on a per-milligram basis to the PBS-listed eltrombopag dosage strengths. The PBAC accepted the estimated financial impact of the new listing but noted there may be some minor costs to the R/PBS due to changes in co-payments.
EPCORITAMAB Solution concentrate for subcutaneous injection 4 mg in 0.8 mL	Relapsed or refractory diffuse large B-cell lymphoma	To request that the listings for epcoritamab transition to the Section 100. (Efficient Funding of Chemotherapy) program.	Not applicable	This item was withdrawn.

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Solution for subcutaneous injection 48 mg in 0.8 mL Epkinly® LICENSED STERILE COMPOUNDERS OF AUSTRALIA LIMITED Other matters (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy)		Authority Required		
ESTRADIOL WITH PROGESTERONE Capsule containing estradiol 1mg (as hemihydrate) with progesterone 100mg Bijuva® THERAMEX AUSTRALIA PTY LTD Category 3 (New PBS listing) PBS General Schedule	Vasomotor symptoms in post-menopausal women	To consider the sponsor's revised proposal for listing estradiol with progesterone for the treatment of moderate to severe vasomotor symptoms in post-menopausal women. This item was previously recommended by the PBAC at its November 2025 meeting. Unrestricted Benefit for 30-day listing Restricted Benefit for 60-day listing	Recommended	The Pharmaceutical Benefits Advisory Committee provided further consideration of its November 2025 recommendation to list oral estradiol with progesterone (Bijuva) as a General Schedule unrestricted benefit listing, and corresponding General Schedule restricted benefit listings for 60-day maximum dispensed quantity. The PBAC considered that the risk of venous thromboembolism (VTE) associated with Bijuva may be acceptable to women without risk factors for VTE who cannot tolerate topical MHT or where topical MHT is not suitable. The PBAC advised that a claim of non-inferior safety for the risk of endometrial hyperplasia would be reasonable for Bijuva compared to oral estradiol and progesterone prescribed separately and Estrogel Pro.

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				The PBAC reiterated its previous advice that there is a need to maintain a diverse range of MHT options on the PBS. The PBAC noted that there is currently no oral fixed dose combination product containing estradiol and progesterone (or a progestogen) for continuous MHT listed on the PBS. Overall, the PBAC was satisfied that inclusion of Bijuva, as a combined oral capsule, would offer additional options to women requiring MHT and facilitate individualised treatment choices, and that it may offer a meaningful difference to some patients compared to MHT options currently PBS-listed. The PBAC noted that the price requested for Bijuva was at a modest monthly premium over the individual components, but advised that listing at the requested price was acceptable, given the need to maintain diverse treatment options for women requiring MHT.
ETONOGESTREL Subcutaneous implant 68 mg Implanon NXT® ORGANON PHARMA PTY LTD Category 3 (Change to existing listing) PBS General Schedule	Contraception	To request a revised price for the current listing of etonogestrel for patients requiring contraception. Unrestricted Benefit	Not Recommended	The PBAC did not recommend a price increase for etonogestrel 68 mg subcutaneous implant (Implanon-NXT®). The PBAC noted that the submission requested a price increase consistent with the price per month of newer combined oral contraceptives. The PBAC welcomed input from individuals which described the relative ease of insertion for Implanon compared to an intimate gynaecological procedure required for an intrauterine device such as Mirena.

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				The PBAC noted that the sponsor referred to the outcomes of an oral contraceptive stakeholder meeting in October 2024. The PBAC recalled its recommendations for newer oral contraceptives was based on defined benefits for some women other than contraceptive efficacy. The PBAC advised that the submission did not provide evidence that Implanon-NXT had any newly identified benefits that the PBAC had not previously considered. The PBAC considered that the clinical claims in the submission were not adequately supported by the data provided. The PBAC noted the requested price increase would result in a high cost to the PBS/RPBS and was not justified by the submission evidence. Sponsor's Comment: The sponsor had no comment.
EVOLOCUMAB Injection 140 mg in 1 mL single use pre-filled pen Repatha® AMGEN AUSTRALIA PTY LIMITED Category 4 (New PBS listing)	Non-familial hypercholesterolaemia Familial heterozygous hypercholesterolaemia Familial homozygous hypercholesterolaemia	To request new listings for evolocumab with increased maximum dispensed quantities for all currently listed indications to allow for 60-day prescriptions. Authority Required	Recommended	The PBAC recommended listing of evolocumab with increased maximum dispensed quantities (MDQs) consistent with the Government's 60-day prescription initiative for the treatment of homozygous familial hypercholesterolaemia (HoFH), heterozygous familial hypercholesterolaemia (HeFH) and non-familial hypercholesterolaemia (non-FH). The PBAC considered that evolocumab meets the criteria for an increased MDQ based on the exclusion

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PBS General Schedule				criteria established at the December 2022 PBAC meeting when the PBAC considered a list of PBS medicines indicated for the treatment of chronic conditions for their suitability for listing with increased MDQs per dispensing.
FINERENONE Tablet 10 mg Tablet 20 mg Tablet 40 mg Kerendia® BAYER AUSTRALIA LTD Category (New PBS listing) PBS General Schedule	Heart failure	To request listing of finerenone for the treatment of adult patients with symptomatic heart failure (New York Heart Association (NYHA) Class II-IV) and a left ventricular ejection fraction (LVEF) of greater than or equal to 40%. Authority Required (STREAMLINED)	Not Recommended	The PBAC did not recommend PBS subsidy of finerenone for the treatment of adults with symptomatic heart failure (New York Heart Association Class II–IV) and left ventricular ejection fraction (LVEF, the percentage of blood pumped out of the heart's main chamber after each beat) of greater than or equal to 40%. This includes patients with heart failure with mildly reduced or preserved ejection fraction (HFmrEF/HFpEF), that is, heart failure where the heart's pumping function is relatively normal or only mildly impaired. The PBAC considered that the evidence showed finerenone was more effective than current treatment. However, the main benefit from the clinical evidence was a reduction in hospitalisations and it remains unclear whether finerenone reduces cardiovascular death. The PBAC welcomed comments from an organisation, which highlighted the substantial burden of heart failure and the ongoing need for additional effective therapies. It noted that finerenone may reduce worsening of heart failure symptoms that require urgent medical treatment, and improve symptoms and wellbeing, but that without PBS subsidy it would be unaffordable for many patients.

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				The PBAC noted that the submission overestimated finerenone's health benefits and considered that further review and revision of the estimated benefits were required. The PBAC advised the medicine would be cost-effective with a price reduction reflecting more realistic estimates of benefits and costs. The PBAC considered that the estimate of the cost to the PBS if finerenone was listed also required revision. The PBAC advised that these issues could be addressed in an early re-entry submission. Sponsor's Comment: The sponsor had no comment.
GUSELKUMAB Solution for I.V. infusion 200 mg in 20 mL vial Injection 100 mg in 1 mL single use pre-filled pen Injection 200 mg in 2 mL single use pre-filled pen Injection 100 mg in 1 mL single use pre-filled syringe Injection 200 mg in 2 mL single use pre-filled syringe Tremfya® JANSSEN-CILAG PTY LTD	Severe Crohn disease (CD)	To consider the sponsor's revised proposal for listing guselkumab for the treatment of adult patients with severe CD who have failed to achieve an adequate response to prior systemic therapy (i.e. corticosteroids and at least 3 months of immunosuppressive therapy). This item was previously recommended by the PBAC at its July 2025 meeting. Authority Required (Written)	Recommended	The PBAC recommended subsidy of guselkumab for the treatment of adults with severe Crohn's disease (CD) through the PBS. The PBAC welcomed input from individuals, health professionals and organisations. The input received highlighted the significant quality of life impact severe CD has on patients and the importance of having additional treatment options available, particularly medicines with different mechanisms of action to treat CD. The PBAC noted that guselkumab had similar effectiveness to ustekinumab for achieving clinical remission and response. Guselkumab was likely more effective than ustekinumab

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Category 2 (New PBS listing) PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)				when treatment responses were measured using endoscopic outcomes during maintenance treatment. However, the PBAC noted the difference in the proportion of patients achieving an endoscopic remission after 48 weeks of treatment was modest (9-15%). Furthermore, the additional evidence provided by the supplying company to support claims that improvement in endoscopic outcomes would translate to better long-term outcomes for patients showed only very modest potential benefit. Evidence that endoscopic remission translated to better clinical remission was weak and evidence that it translated to improved quality of life was inconsistent. The PBAC considered there may be a small potential reduction in surgery/ hospitalisation for patients who achieve endoscopic outcomes, but that this was uncertain and could not be reliably estimated with the available data. To support its requested price, the company claimed in its economic model that guselkumab would provide benefits which were not supported by the available data presented in the submission. It did not enable a reliable estimate of how much benefit guselkumab would deliver for the cost. In context of the potential increase in the proportion of patients achieving a response measured by endoscopic outcomes and the

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				clinical need for additional treatment options, the PBAC considered guselkumab would be cost effective with a cost per patient over two years that is higher than for ustekinumab. Noting the higher cost per patient compared to all other biologic or targeted synthetic disease-modifying antirheumatic drugs (b/tsDMARDs), the PBAC considered it would be appropriate for the subsidy of guselkumab to be restricted to patients who had not responded to at least one other PBS listed b/tsDMARDs for severe Crohn's disease. The PBAC considered it would be appropriate for guselkumab to be listed with a higher level of restriction than other b/tsDMARDs i.e., as an 'Authority Required – In Writing (full assessment)' item. The PBAC advised the restriction criteria should be finalised in consultation with the relevant professional bodies prior to listing. For the financial estimates, the PBAC considered the estimated utilisation of guselkumab should be reduced to account for the more restricted patient population.
LONCASTUXIMAB TESIRINE Powder for I.V. infusion 10 mg Zynlonta® SWEDISH ORPHAN BIOVITRUM PTY LTD Early Re-entry (New listing)	Diffuse large B-cell lymphoma (DLBCL)	Resubmission to request listing of loncastuximab tesirine for the treatment of adult patients with relapsed or refractory DLBCL who have received two or more prior lines of therapy.	Recommended	The PBAC recommended the listing of loncastuximab tesirine for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) who have received two or more prior lines of therapy. The PBAC welcomed input from one organisation and also reconsidered the consumer input for loncastuximab tesirine from

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PBS Section 100 (Efficient Funding Of Chemotherapy)				the March 2026 PBAC meeting. The PBAC again acknowledged the need for therapies for patients unsuitable for, or relapsing after, CAR-T or bispecific therapies. The PBAC recalled that in March 2026 it had considered that limitations in the submission evidence did not allow confidence about the extent to which loncastuximab tesirine was more effective than chemoimmunotherapy. However, the PBAC had accepted that it was likely reasonable, if uncertain, that loncastuximab tesirine would improve overall survival (the length of time patients remain alive) compared to chemoimmunotherapy. The PBAC had also previously considered it was reasonable to accept that the safety of loncastuximab tesirine was similar to chemoimmunotherapy. After reviewing additional information provided by the sponsor in the resubmission, the PBAC maintained its previous conclusions about the effectiveness and safety of loncastuximab tesirine. The PBAC previously considered that the claims made by the sponsor about the benefits of loncastuximab tesirine to justify its requested price were too optimistic given the uncertain benefits from the clinical data. The PBAC previously advised that a further price reduction would be required to achieve cost-effectiveness. The PBAC also indicated that a financial arrangement with the sponsor would

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				be appropriate to manage risks that the cost to the PBS of listing loncastuximab tesirine is higher than expected. The PBAC considered that the price requested by the sponsor in the resubmission was acceptable. The PBAC also considered that the estimates of how many patients may use loncastuximab tesirine and of costs to the PBS presented in the resubmission were reasonable. The PBAC accepted the financial arrangement proposed by the sponsor to manage financial risks associated with listing loncastuximab tesirine on the Pharmaceutical Benefits Scheme.
METHOXSALEN Solution for blood fraction 20 microgram per mL, 10 mL Uvadex® HEALTH TECHNOLOGY ANALYSTS PTY LIMITED Category 3 (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Cutaneous T-cell lymphoma (CTCL) Chronic graft versus host disease (cGVHD)	To request a change to the existing listings for methoxsalen for CTCL and cGVHD to allow consultant or specialist dermatologists to prescribe treatment. Authority Required (STREAMLINED)	Recommended	The PBAC recommended extending the current listing for methoxsalen (Uvadex®) for the treatment of cutaneous T-cell lymphoma (CTCL) and chronic graft-versus-host disease (cGVHD) to allow treatment by a dermatologist, or treatment by a medical practitioner working under the supervision of a dermatologist, as part of treatment with integrated, closed system extracorporeal photopheresis (ECP). The PBAC considered the eligible population for methoxsalen will likely be unchanged by the amendment of the treatment criteria and considered that there would be nil financial impact to the PBS.

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MIFEPRISTONE AND MISOPROSTOL Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms MS-2 Step® MS HEALTH PTY LTD Category 2 (Change to existing listing) PBS General Schedule	Termination of an intra-uterine pregnancy	To request a change to the existing listing of mifepristone and misoprostol for the termination of an intra-uterine pregnancy, such that the condition must be an intra-uterine pregnancy of up to 70 days of gestation (compared to 63 days of gestation with the existing listing). Authority Required (STREAMLINED)	Recommended	The PBAC recommended extending the PBS listing of mifepristone and misoprostol (MS-2 Step®) for the medical termination of intra-uterine pregnancy from up to 63 days of gestation to up to 70 days of gestation. The PBAC also recommended the inclusion of a prescribing instruction requiring patients to undertake a follow-up pregnancy test to confirm that the medical termination of the intra-uterine pregnancy is completed. The PBAC acknowledged the consumer comments received strongly supported the submission. The PBAC considered that medical termination of pregnancy (MTOP) using MS-2 Step® at a gestation age of 64 to 70 days is an effective option, noting that a small number of patients would require a follow-up procedure following MTOP to complete the medical termination of the intra-uterine pregnancy. The PBAC also considered that the cost comparison of MTOP and STOP was appropriate, and that MTOP with MS-2 Step® was cost saving. The PBAC considered that the estimated financial impact of extending the restriction for MS-2 Step® for use up to 70 days of gestation was reasonable.
ODEVIXIBAT Capsule 200 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms Bylvay®	Alagille syndrome (ALGS)	Resubmission to request listing of odevixibat for the treatment of cholestatic pruritis in ALGS in patients aged 6 months and older.	Recommended	The PBAC recommended the PBS listing of odevixibat (Bylvay®), for the treatment of cholestatic pruritus (severe itching caused by bile acid build up) in people with Alagille syndrome (ALGS). The PBAC acknowledged input from consumers, healthcare professionals and organisations,

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IPSEN PTY LTD Early Re-entry (Change to existing listing) PBS General Schedule				describing the substantial burden of cholestatic pruritus in ALGS in this vulnerable population. The PBAC noted that ALGS is a rare condition and cholestatic pruritus can have severe impacts on quality of life, including sleep, comfort and wellbeing. The PBAC recalled that it previously noted there was evidence showing odevixibat can reduce itching for some patients with ALGS, however it does not treat the underlying disease, and the long-term benefits remain uncertain. The PBAC considered that a higher price than previously recommended could be supported; however, a price reduction from that proposed in the resubmission would still be required to ensure odevixibat was cost effective in this population. The PBAC considered the estimated number of patients likely to be treated was reasonable however a risk sharing arrangement would be required to manage uncertainty regarding the average cost per patient per year (as each dose of odevixibat should be administered according to body weight which will impact the average cost per patient per year).
ONASEMNOGENE ABEPARVOVEC 1 vial solution for intrathecal injection 1.2 x 1014 vector genomes per mL, 3 mL OAV101 IT®	Spinal muscular atrophy (SMA)	To request listing of intrathecal onasemnogene abeparvovec for the treatment of symptomatic SMA in patients at least 2 years of age but yet to turn 19 years old who have experienced at least two of the defined signs and symptoms of SMA	Recommended	The PBAC recommended onasemnogene abeparvovec intrathecal (ONA IT) for the treatment of symptomatic spinal muscular atrophy (SMA) in patients at least 2 years of age who have experienced at least two of the defined signs and symptoms of SMA Type I, II or IIIa prior to 3 years of age. The PBAC

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NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 2 (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)		Type I, II or IIIa prior to 3 years of age. Authority Required (Written)		acknowledged that some patients missed the opportunity to receive ONA IV due to their age and timing of diagnosis. However, the PBAC considered that the introduction of the Newborn Bloodspot Screening program is likely to reduce the number of patients requiring treatment with ONA after 2 years of age in the future. The PBAC noted that the evidence was limited, because SMA is a rare disease. Nevertheless, the PBAC considered that ONA IT is likely to provide similar benefits to the alternative treatments (nusinersen and risdiplam), including motor function outcomes. The PBAC noted that the submission requested a higher price for ONA IT than the price previously accepted for onasemnogene abeparvovec administered intravenously (ONA IV) for use in patients aged no older than 9 months and in patients weighing up to 21 kg. However, the PBAC considered that the higher treatment cost proposed for older patients was not justified and considered that ONA IT would be acceptably cost-effective at the same cost per patient as ONA IV, with the same outcomes-based RSA conditions applied.
PEGCETACOPLAN Solution for subcutaneous infusion 1,080 mg in 20 mL Empaveli® SWEDISH ORPHAN BIOVITRUM PTY LTD	Complement 3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN)	Resubmission to request listing of pegcetacoplan for the treatment of patients aged 12 years and older with C3G or primary IC-MPGN.	Recommended	The PBAC recommended expanding PBS subsidy for pegcetacoplan to include treatment of complement 3 glomerulopathy (C3G) and primary immune complex membranoproliferative glomerulonephritis (IC-MPGN). The PBAC considered that there is a high clinical need for treatments for C3G and primary IC-MPGN, which are rare conditions

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Early Re-entry (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)				that impact predominantly young people and cause decline in kidney function. The PBAC recalled it previously accepted that pegcetacoplan may slow progression to end-stage kidney disease for some patients. The clinical evidence also showed that pegcetacoplan was less safe than standard of care, as it increased risk of infection. The PBAC noted the resubmission presented a cost-per-responder analysis with a reduced cost for pegcetacoplan and provided revised financial models to address the Committee's previous concerns that the cost of pegcetacoplan was not commensurate with the benefits estimated. The PBAC considered the cost-effectiveness of pegcetacoplan would be acceptable with a further reduction to the price consistent with comparable conditions in patient populations of a similar size. The PBAC noted that the revised financial impact for pegcetacoplan had increased substantially compared with the previous submission and advised that amendments to the proposed Risk Sharing Arrangement were required to manage the risk of use in a larger population than expected, or for longer than expected.
PEGVALIASE Injection 2.5 mg in 0.5 mL pre-filled syringe	Patients with phenylketonuria (PKU) that is inadequately	Resubmission to request listing of pegvaliase for the treatment of patients aged 16 years and older	Recommended	The PBAC recommended pegvaliase for the treatment of patients with phenylketonuria (PKU) who have inadequate blood

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Injection 10 mg in 0.5 mL pre-filled syringe Injection 20 mg in 1 mL pre-filled syringe Palynziq® BIOMARIN PHARMACEUTICAL AUSTRALIA PTY LTD Matters outstanding (New PBS listing) PBS General Schedule	controlled with a Phe restricted diet and sapropterin	with PKU who have inadequate blood phenylalanine control (baseline blood phenylalanine level above 600 micromoles per L) despite prior management with available treatment options (including a phenylalanine restricted diet and sapropterin). An inadequate response to a trial of sapropterin is defined as failure to achieve a 30 per cent or greater reduction in blood phenylalanine from baseline following initial treatment with sapropterin. The submission also seeks PBAC consideration for extending eligibility to patients aged 16 years and older with PKU who have a protein tolerance of less than 15 grams per day, even if sapropterin responsive. This item was previously considered by the PBAC at its March 2026 meeting. Authority Required (Telephone/Online)		phenylalanine (Phe) control despite prior treatment with a Phe-restricted diet and sapropterin. In March 2026, the PBAC had deferred making a recommendation for pegvaliase to allow further consultation with the sponsor and Department regarding how best to implement the intent of the sponsor's pricing structure and financial arrangement proposal. At that time, the PBAC considered it was unclear how the proposed pricing structure and financial arrangement would achieve a cost-effective price for pegvaliase and adequately manage the financial risk associated with listing pegvaliase on the PBS. The PBAC considered that the listing proposal, submitted in response to the March 2026 deferral, provided increased confidence that the intended level of cost-effectiveness could be achieved and the financial risk to the Commonwealth would be appropriately managed. The PBAC acknowledged the challenges of living with PKU including the severe and lifelong burden of dietary restrictions and the cognitive impacts of high Phe levels including difficulty concentrating, reduced mental clarity, anxiety and fatigue. The PBAC reaffirmed its view that there is a high unmet clinical need for effective treatments in the proposed patient population.

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				The PBAC maintained its view from its March 2026 consideration of pegvaliase, that pegvaliase is more effective than a Phe-restricted diet alone at reducing blood Phe levels. The PBAC also recalled that pegvaliase was associated with higher rates of hypersensitivity and skin reactions compared with a Phe-restricted diet alone. The PBAC also considered that it would be reasonable to flow-on changes to all PBS listings of sapropterin, to allow nurse practitioner prescribing in consultation with a metabolic physician in the initial treatment and prevent concomitant use of pegvaliase and sapropterin for just this indication.
PEGZILARGINASE Solution for injection 2 mg in 0.4 mL Loargys® ILLUMINATE HEALTH CONSULTING PTY LIMITED Category 1 (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Arginase 1 deficiency (ARG1-D)	To request listing of pegzilarginase for the treatment of ARG1-D (also known as hyperargininaemia) in patients aged 2 years or older. Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment	Not applicable	The PBAC recommendation cannot be made public until the TGA outcomes is known.

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PIRTOBRUTINIB Tablet 50mg Tablet 100mg Jaypirca® ELI LILLY AUSTRALIA PTY LTD Category 2 (New PBS listing) PBS General Schedule	Chronic lymphocytic leukaemia (CLL) Small lymphocytic lymphoma (SLL)	To request listing of pirtobrutinib for the treatment of adult patients with relapsed or refractory CLL/SLL who have received at least one prior therapy (as second or subsequent-line treatment) and require treatment according to the International Workshop on CLL (iwCLL). Authority Required (Telephone/Online)	Not applicable	The PBAC recommendation cannot be made public until the TGA outcomes is known.
PROGESTERONE Pessary 400 mg Utrogestan® BESINS HEALTHCARE AUSTRALIA PTY LTD Category 2 (New PBS listing) PBS General Schedule	Unexplained threatened miscarriage	To request listing of progesterone for the treatment of unexplained threatened miscarriage in the first trimester, with vaginal bleeding in the current pregnancy and a history of previous miscarriage. Authority Required (STREAMLINED)	Recommended	The PBAC recommended the listing of progesterone (Utrogestan®) for the treatment of unexplained threatened miscarriage during the first trimester, in patients with vaginal bleeding in the current pregnancy and a history of three or more prior miscarriages. The PBAC welcomed the consumer input received for this item and noted the input strongly supported the submission and highlighted the equity and cost concerns for patients. The PBAC noted that the submission requested a listing for use in patients with a history of at least one prior miscarriage. However, this did not align with the indication approved in Australia by the Therapeutic Goods Administration (TGA). Use of progesterone for unexplained threatened miscarriage in patients with one or two prior miscarriages, was not well supported by the evidence presented in the submission by the pharmaceutical

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				company. Therefore, the PBAC recommended a listing within the TGA's approved uses TGA, which is for use in patients with a history of three or more prior miscarriages, where evidence demonstrated that treatment with progesterone significantly improves live birth rates. The PBAC considered that the economic evaluation based on an incremental cost per live birth was acceptable.
SEBELIPASE ALFA Solution for injection 20 mg in 10 mL vial Kanuma® ALEXION PHARMACEUTICALS PTY LIMITED Category 2 (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Late-onset lysosomal acid lipase deficiency (LAL-D)	To request listing of sebelipase alfa (as a long-term enzyme replacement therapy) for the treatment of children and adults with late-onset LAL-D who are receiving, or enrolled to receive, professional nutritional support including dietetic and weight management advice. Authority Required (Written)	Not Recommended	The PBAC did not recommend the PBS listing of sebelipase alfa (Kanuma®) for the treatment of children and adults with late-onset lysosomal acid lipase deficiency (LAL-D), a rare genetic disease that causes fats to build up in the liver and other organs. The PBAC acknowledged LAL-D is an ultra-rare disease and effective treatments are needed. The PBAC noted that there is much more variation in late-onset disease compared to infantile-onset LAL-D. Late-onset LAL-D can affect people in different ways including age of onset, symptoms experienced, and how quickly the disease worsens. The PBAC also noted that LAL-D is currently underdiagnosed. The PBAC welcomed inputs from consumers and healthcare professionals and acknowledged the impact of late-onset LAL-D which can include liver and cardiovascular disease, fatigue and impacts on participation in everyday activities.

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				The PBAC accepted that sebelipase alfa treatment improves laboratory measures including liver enzymes and cholesterol. However, the proposed eligible population in the submission was not clearly defined and did not account for variation in the disease course between patients. The extent of clinical benefit that might be provided by sebelipase alfa was therefore highly uncertain as it depended on which patients with late-onset LAL-D would be treated. Consequently, the total cost and value for money at the price sought by the supplying pharmaceutical company were highly uncertain. The PBAC considered that a resubmission should more clearly define the population who should be treated with sebelipase alfa, and account for the variation in the disease course and expected treatment benefit. This information would better inform estimates of the extent and clinical meaningfulness of treatment benefit, value for money and costs. Sponsor's Comment: The sponsor had no comment.
TEPLIZUMAB Solution for injection 2 mg in 2 mL Tzield® SANOFI-AVENTIS AUSTRALIA PTY LTD	Type 1 diabetes (T1D)	To request listing of teplizumab for the treatment of Stage 2 T1D in patients aged 8 years or older in order to delay the onset of Stage 3 T1D. Authority Required	Not Recommended	The PBAC did not recommend listing teplizumab (Tzield®) to delay the onset of Type 1 diabetes (T1D, Stage 3) in patients aged 8 years or older with Stage 2 T1D. Stage 2 type 1 diabetes is an early stage of T1D where the immune system attacks the insulin-

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Category 1 (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)				producing cells in the pancreas and blood sugar levels start to become abnormal, however the person has not yet developed symptoms. Over time, people with Stage 2 T1D can develop Stage 3 T1D – where blood sugar levels are high enough to cause symptoms and require treatment with insulin. The PBAC welcomed input from consumers, health care professionals and organisations. The PBAC acknowledged the need for treatments that reduce the impact of T1D. The PBAC noted that the submission was based on one clinical trial that randomised 76 patients called the TN-10 trial, which included 44 patients treated with teplizumab and 32 patients treated with placebo. The PBAC considered that the submission's proposed approach to identify patients with Stage 2 T1D through screening family members of those with diagnosed T1D and through studies of T1D screening would not provide equitable access to the medicine. This view was formed as the majority of individuals diagnosed with T1D do not have a family member with the condition. The PBAC considered a coordinated approach to diagnosing Stage 2 T1D would be important to ensure equitable early diagnosis and access to potential treatments such as teplizumab.

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				The PBAC considered that teplizumab is effective in delaying the onset of Stage 3 T1D when compared with placebo. The PBAC also noted that teplizumab was associated with a higher rate of adverse events, including serious adverse events when compared with placebo. The PBAC considered that delaying the onset of Stage 3 T1D would be beneficial for all patients, but especially for children and adolescents, as it would provide additional time free from symptomatic T1D, and the demands of insulin treatment and blood glucose management. However, the PBAC considered that the limited evidence presented in the submission did not adequately support the submission's claim regarding long-term benefits of teplizumab after being diagnosed with Stage 3 T1D such as increased life expectancy and reductions in cardiovascular diseases or other long-term complications of T1D. Further, the PBAC considered that the value of a delay in onset of Stage 3 T1D would likely differ by age, and that patients treated as children or adolescents are likely to benefit most. As a result, the PBAC considered that the results of the economic evaluation were highly uncertain and the submission had not demonstrated that teplizumab would be value for money at the price sought by the supplying company. Sponsor's comment: Sanofi is disappointed with the PBAC's decision

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				not to recommend teplizumab (Tzield) to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and paediatric patients aged 8 years and older with Stage 2 type 1 diabetes. As the first new therapy available for T1D in over 100 years, teplizumab (Tzield) offers a new approach for the treatment of this autoimmune condition. We thank patients, clinicians and organisations for their valuable contributions to the PBAC process and we are committed to working with all stakeholders to resubmit teplizumab again for funding consideration at the earliest opportunity.
TEPROTUMUMAB Powder for I.V. infusion 500 mg Tepezza® AMGEN AUSTRALIA PTY LIMITED Category 3 (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Thyroid eye disease (TED)	To consider the sponsor's revised proposal for listing teprotumumab for the treatment of adult patients with active, moderate-to-severe TED who have a clinical activity score (CAS) or three or more for the most severely affected eye. This item was previously recommended by the PBAC at its May 2025 meeting. Authority Required (Telephone/Online) for initial treatment Authority Required (STREAMLINED) for continuing treatment	Recommended	The PBAC recommended the listing of teprotumumab on the PBS for the treatment of active, moderate-to-severe thyroid eye disease (TED). The PBAC reaffirmed its previous view that there is a high clinical need for patients with this condition. The PBAC welcomed comments from health care professionals, consumers seeking access to teprotumumab and the Orbital Plastics and Lacrimal (OPAL) and Ocular Rheumatology (EORC) units from the Royal Victorian Eye and Ear Hospital (RVEEH). Their comments emphasised the high clinical need for effective treatment options for patients living with active moderate-to-severe TED. The comments described the substantial burden of TED and highlighted the limited effectiveness and safety concerns associated with current therapies. The PBAC noted comments also described

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				teprotumumab as a targeted therapy with clinical benefits observed in trials, although hearing impairment was identified as a key adverse effect requiring careful patient selection and monitoring. The PBAC noted the PBS listing for this population, recommended at its May 2025 meeting, could not be progressed, as the previously proposed price was no longer considered feasible by the sponsor. The PBAC considered that the revised average vial use per treatment course was highly uncertain and likely underestimated utilisation in practice. The PBAC considered that a price reduction would be required to achieve a cost-effective listing, together with changes to the risk sharing arrangement (RSA) to manage uncertainty related to the estimated vial usage per patient.
TISLELIZUMAB Solution concentrate for I.V. infusion 100 mg in 10 ml Solution concentrate for I.V. infusion 150 mg in 15 ml Tevimbra® BEONE MEDICINES AUS PTY LTD Category 2 (New PBS listing)	Gastro-oesophageal cancer	To request listing of tislelizumab for advanced or metastatic gastro-oesophageal cancer such that patients can be administered treatment with 150 mg once every two weeks (Q2W) and 300 mg once every four weeks (Q4W) as an alternative to the current dosing regimen of 200 mg once every 3 weeks (Q3W). The submission also seeks listing of a new 150 mg vial form of tislelizumab. Authority Required (STREAMLINED)	Not applicable	The PBAC recommendation cannot be made public until the TGA outcome is known.

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PBS Section 100 (Efficient Funding of Chemotherapy)				
USTEKINUMAB Injection 45 mg in 0.5 mL vial Injection 45 mg in 0.5 mL single use pre-filled pen Injection 90 mg in 1 mL single use pre-filled pen Steqeyma® CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 4 (New PBS listing) PBS General Schedule	Severe chronic plaque psoriasis Severe psoriatic arthritis Severe Crohn disease Complex refractory fistulising Crohn disease Moderate to severe ulcerative colitis	To request listing of new forms of the Steqeyma biosimilar brand of ustekinumab that mirror the originator brand's current listings with equivalent forms and strengths. Authority Required	Recommended	The PBAC recommended the listing of ustekinumab (Steqeyma®) 45 mg/0.5 mL vial, 45 mg/0.5 mL pre-filled pen and 90 mg/1 mL pre-filled pen for the treatment of severe chronic plaque psoriasis, severe psoriatic arthritis, severe Crohn disease, complex refractory fistulising Crohn disease and moderate to severe ulcerative colitis. The PBAC recommended listing on a cost-minimisation basis compared with currently listed ustekinumab products of the same strengths. The PBAC also considered that the application of biosimilar uptake drivers to Steqeyma would be clinically appropriate and would not impact cost-effectiveness The PBAC considered that listing these additional Steqeyma presentations would provide additional biosimilar options for patients and prescribers. The PBAC recommended that the current biosimilar uptake arrangements should continue to apply for the severe chronic plaque psoriasis and severe psoriatic arthritis indications. Whilst for severe Crohn disease, complex refractory fistulising Crohn disease and moderate to severe ulcerative colitis, the PBAC considered that the new Steqeyma presentations should align with the recent December 2025 and March 2026 PBAC recommendations.

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				The PBAC considered it appropriate for ustekinumab pre-filled syringe and pre-filled pen presentations of the same strength to be treated as equivalent for the purposes of substitution. The PBAC also advised that the Steqeyma 45 mg/0.5 mL vial and Stelara 45 mg/0.5 mL vial should be treated as equivalent for substitution, but did not advise that vial presentations should be treated as equivalent to pre-filled syringe or pre-filled pen presentations.
USTEKINUMAB Injection 45 mg in 0.5 mL Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Solution for I.V. infusion 130 mg in 26 mL Yesintek® GENERIC HEALTH PTY LTD Category 3 (New PBS listing) PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Severe chronic plaque psoriasis Severe psoriatic arthritis Severe Crohn disease Complex refractory fistulising Crohn disease Moderate to severe ulcerative colitis	To request listing of a new ustekinumab biosimilar that mirrors the originator brand's current listings. Authority Required	Recommended	The PBAC recommended General Schedule and Section 100 Highly Specialised Drugs listing of a new ustekinumab biosimilar (Yesintek®) in 45 mg injection, 45 mg and 90 mg pre-filled syringe (PFS), and solution for intravenous (I.V.) infusion 130 mg in 26 mL forms. This was for the treatment of paediatric and adult patients with severe chronic plaque psoriasis (CPP), severe psoriatic arthritis (PsA), severe Crohn's disease (CD), complex refractory fistulising Crohn's disease, and moderate to severe ulcerative colitis (MSUC). The proposed listing was on a cost-minimisation basis and under the same conditions as its reference biologic (Stelara®). The PBAC advised the equi-effective dose to be 1 mg Yesintek = 1 mg Stelara. The PBAC considered that the current biosimilar uptake arrangements should continue to apply for the CPP and PsA indications for Yesintek and that the application of biosimilar uptake drivers

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				would be clinically appropriate and would not impact cost-effectiveness. The PBAC advised that the PBAC's December 2025 recommendation for bDMARDs would apply for the MSUC and CD indications of Yesintek. This change would apply new restrictions that support access for people who started advanced therapy during childhood. Additionally, the PBAC advised that the PBAC's March 2026 recommendation for IBD indications would apply for Yesintek. This change would consolidate restrictions for initial and continuing treatment for CD, MSUC and fistulising CD for Yesintek.
VUTRISIRAN Injection 25 mg (as sodium) in 0.5 mL pre-filled syringe Amvuttra® MEDISON PHARMA AUSTRALIA PTY LIMITED Category 2 (Change to existing listing) PBS General Schedule	Transthyretin amyloid cardiomyopathy (ATTR-CM)	To request listing of vutrisiran for the treatment of adult patients with wild-type or hereditary ATTR-CM with documented evidence of the transthyretin precursor protein present who have experienced at least one episode of hospitalisation that was a direct result of heart failure or have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement. Authority Required (Written) for initial treatment	Recommended	The PBAC recommended listing vutrisiran (Amvuttra®) on the PBS for the treatment of transthyretin amyloidosis with cardiomyopathy (ATTR-CM) in patients with New York Heart Association (NYHA) Class I or II disease. The PBAC did not recommend listing in patients with NYHA Class III disease as the comparator, tafamidis, is not PBS listed for this group and the submission did not provide an economic analysis to justify the proposed price. The PBAC welcomed input from individuals and organisations supporting the listing. The input highlighted the severe impact of ATTR-CM on quality of life and the importance of additional treatment options, especially for patients who do not adequately respond to or cannot tolerate tafamidis.

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		Authority Required (Telephone/Online) for continuing treatment		The PBAC considered the main clinical comparison of vutrisiran and tafamidis in the submission to be uncertain, however based on the totality of the available evidence, was satisfied that vutrisiran is likely to be similarly effective to tafamidis at reducing mortality and recurrent cardiovascular events. The PBAC also considered vutrisiran likely has similar safety to tafamidis. The PBAC advised the cost of vutrisiran would be acceptable if the annual cost of treatment was not higher than that of tafamidis. The PBAC considered that vutrisiran given as one 25 mg injection every 12 weeks was equivalent to once daily oral tafamidis 61 mg. The PBAC considered the vutrisiran restriction should ensure combination use with tafamidis is not permitted (but switching between agents is acceptable) and this should flow on to the existing tafamidis listings.
Azithromycin for the treatment of diphtheria Tablet 500 mg (as dihydrate) Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL Various brands Various sponsors	Diphtheria	To request advice on options for expanding the PBS subsidy arrangements of azithromycin in response to the diphtheria outbreak in the Northern Territory and Western Australia.	Recommended	The PBAC considered representations from the National Aboriginal Community Controlled Health Organisation (NACCHO) and Northern Territory (NT) Health to consider expanding the PBS subsidy arrangements of azithromycin in response to the diphtheria outbreak. The PBAC noted that, as at June 2026, the Communicable Diseases Network Australia (CDNA) and NT interim guidelines recommend azithromycin as

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(Other matters)				the preferred first-line treatment for confirmed and suspected cases of diphtheria. The PBAC recommended temporarily amending the restriction for azithromycin 500 mg tablets, 2-pack, to an unrestricted benefit and increasing the maximum quantity to 8 tablets to support a full 7-day diphtheria treatment course under one co-payment. The PBAC also recommended removing the administrative advice that prevents increases to the maximum quantity or repeats for the 200 mg/5 mL, 15 mL oral liquid, as the current one-bottle maximum is insufficient for many children requiring treatment for diphtheria. The PBAC recommended that a period of 12 months would be appropriate for the unrestricted benefit listing of azithromycin to support management of the current diphtheria outbreak. The PBAC requested that the matter be brought back for its consideration before the end of the 12-month period to assess whether the time period for unrestricted benefit listing of azithromycin should be extended.
Designated registered nurse prescribing (Other matters)	Various Indications	The Pharmaceutical Benefits Advisory Committee (PBAC) is being asked to review and provide advice on the department's recommendations for assessed medicines for designated registered nurse (RN) prescribing.	Recommended	The PBAC recommended adding designated RN prescribers as authorised PBS prescribers for selected medicines in the ATC B, D and N body systems with some medicines restricted to continuing therapy only. The PBAC considered certain medicines are unsuitable for PBS prescribing by designated RN

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				prescribers at this time, but noted its willingness to reconsider this recommendation in 12 months time following implementation of designated RN prescribing, or when sufficient experience with designated RN prescribing is available.
High clinical unmet need and high added therapeutic value Project Update (Other matters)	Not applicable	To note an update regarding the research project into areas of high unmet clinical need (HUCN) and high added therapeutic value (HATV), including agreed definitions for these terms.	Noted	The PBAC noted the update regarding the project to undertake the Early Reform Action to develop a definition for high clinical unmet need (HUCN) and high added therapeutic value (HATV). The PBAC noted the review of international definitions, and the stakeholder engagement with the consultation process to develop potential Australian definitions. The PBAC looked forward to receiving the final project report.
Increase maximum amounts for cetuximab, doxorubicin, fluorouracil, ifosfamide, infliximab, rituximab and tocilizumab Various forms and strengths Various brands Various sponsors Other matters (Change to existing listing)	Various	To seek advice form the PBAC regarding changes to the maximum quantities/maximum amounts for various weight-based dose medicines for chemotherapy and rheumatic conditions.	Advice Provided	The full outcome is not yet available.
PBAC GUIDELINES AND STREAMLINED ASSESSMENT PROJECT UPDATE (Other matters)	Not applicable	To note an update regarding the amendments to the PBAC Guidelines for discount rate and comparator selection, and the development of	Noted	The PBAC noted the update regarding the Early Reform Action projects relating to updating the PBAC Guidelines and consultation on Streamlined Assessment Pathways. The PBAC

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		new streamlined pathways for cost-minimisation submissions and co-dependent submissions.		noted the ongoing engagement through surveys investigating potential improvements to the wording in the PBAC Guidelines regarding discount rates and comparator selection, and the feedback from stakeholder workshops for developing options to streamline the assessment of cost-minimisation applications and co-dependent applications. The PBAC looked forward to receiving the final advice and reports for these projects following the completion of consultations.
Prescribing conditions for lanreotide 60 mg/0.2 mL injection 0.2 mL syringe 60 mg/0.5 mL injection 0.5 mL syringe 90 mg/0.3 mL injection 0.3 mL syringe 90 mg/0.5 mL injection 0.5 mL syringe 120 mg/0.5 mL injection 0.5 mL syringe Various brands Various sponsors (Other matters)	Acromegaly; Functional carcinoid tumour; Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)	The PBAC is requested to advise whether initial treatment and prescribing of lanreotide should remain restricted to hospital associated medical practitioners and specialists.	Recommended	The PBAC recommended amending the section 100 (s100) Highly Specialised Drugs (HSD) Program Community Access (CA) listings of lanreotide (Somatuline Autogel, Mytolac, LACREO) to remove the requirement that initial treatment and prescribing be restricted to hospital associated medical practitioners and specialists. As a flow-on to the recommendation to amend the s100 HSD Program CA listings of lanreotide, the PBAC noted that the s100 HSD Program public hospital and private hospital listings of lanreotide (all brands/forms) would be removed. The PBAC noted that the amended s100 HSD Program CA listings of lanreotide will provide access in community, public hospital, and private hospital settings.
TRANCHE 3 – REVIEW OF PBS PRESCRIBER BAG Levonorgestrel 1.5 mg tablet or levonorgestrel 0.75 mg tablets	Various indications	The PBAC is being asked to consider further information on proposed additions to the Prescriber Bag prepared by the Department, and provide advice on whether, based on	Advice provided	The PBAC considered utilisation data and access issues for a range of medicines that have been proposed for inclusion in the PBS Prescriber Bag and provided advice. For emergency contraception products (levonorgestrel and

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Ulipristal tablet Mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack Prednisolone oral liquid Corticosteroid tablets Naloxone nasal spray Oxytocin Oxytocin + ergometrine Midazolam Various brands Various sponsors (Other matters)		the further information provided, any medicines should be recommended for inclusion in the Prescriber Bag.		ulipristal), the PBAC noted increasing use over time. The PBAC considered that these medicines are already readily available through community pharmacies and that their cost-effectiveness has not been evaluated through the PBS listing process. The PBAC also considered MS-2 Step (mifepristone and misoprostol) and acknowledged the potential benefits of immediate access for some vulnerable patients. However, the PBAC noted quality use of medicines, clinical governance, and equity considerations, and concluded that the potential risks outweighed the benefits of inclusion in the Prescriber Bag at this time. The PBAC considered prednisolone oral liquid and prednisone/prednisolone tablets and recognised the potential benefits of timely access to corticosteroid treatment for a range of acute conditions. The PBAC deferred making a recommendation for inclusion in the Prescriber Bag pending further work being undertaken by the Department in relation to medicines available through Medicare Urgent Care Clinics, with the matter to be brought back to a future meeting. The PBAC also noted that no sponsors had expressed interest in seeking PBS listing for oxytocin or oxytocin with ergometrine products. While acknowledging the clinical importance of these medicines, the PBAC was unable to recommend their inclusion in the Prescriber Bag at this time. The PBAC noted that further work is underway regarding

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				naloxone nasal spray and midazolam, with updates to be considered at a future meeting.
APALUTAMIDE Tablet 240 mg Erlyand® JANSSEN-CILAG PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Treatment of m0CRPC and mHSPC for patients undergoing concurrent androgen deprivation therapy	To request the PBAC review its July 2024 recommendation that has not yet been accepted by the applicant.	Recommendation extended	In July 2026, the PBAC extended it's July 2024 recommendation for this drug for a further 12 months.
LEVODOPA WITH CARBIDOPA AND ENTACAPONE Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg and with entacapone 20 mg per mL, 47 mL Lecigon® STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)	Advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment	To request the PBAC review its July 2024 recommendation that has not yet been accepted by the applicant.	Recommendation extended	In July 2026, the PBAC extended it's July 2024 recommendation for this drug for a further 12 months.

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PROGESTERONE Capsule 300 mg Utrogestan® BESINS HEALTHCARE AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Twice daily on the basis it should be available only under special arrangements covered under the PBS section 100 (IVF Program) for LPS as part of an ART treatment cycle	To request the PBAC review its July 2024 recommendation that has not yet been accepted by the applicant.	Recommendation extended	In July 2026, the PBAC extended it's July 2024 recommendation for this drug for a further 12 months.

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.