PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
JULY 2024 PBAC MEETING

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

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen Hyrimoz® SANDOZ PTY LTD Category 4 (New PBS listing)	Severe Crohn disease Moderate to severe ulcerative colitis Severe active juvenile idiopathic arthritis Complex refractory fistulising Crohn disease Severe active rheumatoid arthritis Severe psoriatic arthritis Ankylosing spondylitis Severe chronic plaque psoriasis Moderate to severe hidradenitis suppurativa	To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listings for initial treatment and Authority Required (STREAMLINED) listings for subsequent continuing treatment of new forms of an existing biosimilar under the same conditions as the currently listed forms and strengths as its reference biologic.	Recommended	The PBAC recommended the listing of adalimumab (Hyrimoz) in the forms and strengths of 40 mg in 0.4 mL; 80 mg in 0.8 mL pre-filled pen (PFP); and 20 mg in 0.2 mL; 40 mg in 0.4 mL; 80 mg in 0.8 mL pre-filled syringe (PFS) under the same circumstances as the currently PBS-listed reference biologic, Humira® and other brands of adalimumab. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Hyrimoz PFP and PFS would be acceptable if it were cost-minimised to Humira PFP and PFS and all other biosimilar brands and formulations of adalimumab. The PBAC advised the equi-effective doses to be 1 mg of Hyrimoz = 1 mg of Humira and all other biosimilar brands and formulations of adalimumab. The PBAC advised that for the purposes of substitution: • PFS of Hyrimoz HCF should be treated as equivalent to the different brands of adalimumab of the same strength for specific indications (i.e. 'a' flagged in the schedule); with the exception that the 40 mg in 0.4 mL PFS of the different brands of adalimumab should also be treated as equivalent to the 40 mg in 0.8 mL PFS of the different brands of adalimumab. • PFP of Hyrimoz HCF should be treated as equivalent to the different brands of adalimumab of the same strength for specific indications (i.e. 'a' flagged in the schedule), with the exception that the 40 mg in 0.4 mL PFP of the different brands of adalimumab should also be treated as equivalent to the 40 mg in 0.8 mL PFP of the different brands of adalimumab. • The PBAC reaffirmed its advice from November 2023 that adalimumab PFP formulation should not be considered equivalent for the purposes of substitution with any adalimumab PFS formulation.

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ADRENALINE (EPINEPHRINE) I.M. injection 150 micrograms in 0.15 mL (as acid tartrate) single dose syringe auto injector I.M. injection 300 micrograms in 0.3 mL (as acid tartrate) single dose syringe auto injector Jext® Jnr Jext® HEALTH TECHNOLOGY ANALYSTS PTY LIMITED Category 4 (New PBS listing)	Acute allergic reaction with anaphylaxis	To request a General Schedule Authority Required (Telephone/Online) listing of a new form for the treatment of acute allergic reaction with anaphylaxis.	Recommended	The PBAC recommended the General Schedule Authority Required (Telephone/Online) listing of a new form of adrenaline (epinephrine) acid tartrate 150 micrograms/0.15 mL auto-injector (AI) (Jext Jr) and 300 micrograms/0.3 mL AI (Jext) under the same circumstances as the currently listed adrenaline (epinephrine) 150 microgram/0.3 mL AI (EpiPen®Jr, Anapen®Jr 150 and Adrenaline Jr Viatris®) and 300 micrograms/0.3 mL AI (EpiPen®, Anapen®300 and Adrenaline Viatris®) for the treatment of acute allergic reaction with anaphylaxis. The PBAC considered that the claim of non-inferior comparative effectiveness and safety were acceptable based on the TGA advice. The PBAC has advised, consistent with previous advice, that under Section 101(4AACD) of the *National Health Act 1953*, in the Schedule of Pharmaceutical Benefits, Jext Jr should be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution with EpiPen Jr, Anapen Jr 150 and Adrenaline Viatris Jr; and Jext should be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution with EpiPen, Anapen 300 and Adrenaline Viatris. The PBAC advised that the equi-effective doses for Jext Jr and Jext to be the following: • 1 x 150 micrograms/0.15 mL AI (Jext Jr) = 1 x 150 microgram/0.3 mL AI (Anapen Jr 150 or EpiPen Jr or Adrenaline Jr Viatris) • 1 x 300 micrograms/0.3 mL AI (Jext) = 1 x 300 micrograms/0.3 mL AI (Anapen 300 or EpiPen or Adrenaline Viatris)

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APALUTAMIDE Tablet 240 mg Erlyand® JANSSEN-CILAG PTY LTD Category 4 (New PBS listing)	Non-metastatic castration-resistant carcinoma of the prostate (m0CRPC) Metastatic castration-sensitive carcinoma of the prostate (mHSPC)	To request a General Schedule Authority Required (Telephone/Online) listing of a new strength for the treatment of m0CRPC and mHSPC.	Recommended	The PBAC recommended a General Schedule Authority Required (Telephone/Online) PBS listing of a new strength of apalutamide (tablet 240 mg) (Erlyand®) under the same conditions as the currently listed strength of apalutamide (tablet 60 mg) for the treatment of m0CRPC and mHSPC for patients undergoing concurrent androgen deprivation therapy. The PBAC's recommendation for listing was based on, among other matters, its assessment that apalutamide 240 mg would be cost-effective if it were cost-minimised to the lowest cost comparator of apalutamide (60 mg), enzalutamide or darolutamide, for the treatment of m0CRPC and mHSPC.
ARIPIPRAZOLE I.M. injection (modified release) 720 mg in 2.4 mL pre-filled syringe I.M. injection (modified release) 960 mg in 3.2 mL pre-filled syringe Abilify Asimtufii® LUNDBECK AUSTRALIA PTY LTD Category 2 (New PBS listing)	Schizophrenia	To request a General Schedule Authority Required (STREAMLINED) listing of new forms for the maintenance treatment of schizophrenia.	Not Applicable	To be considered at a future PBAC meeting

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BELZUTIFAN Tablet 40 mg Welireg® MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED Category 1 (New PBS listing)	Von Hippel-Lindau (VHL) disease	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with VHL disease who require therapy for associated renal cell carcinoma (RCC), central nervous system haemangioblastomas (CNS Hb), or pancreatic neuroendocrine tumours (pNET), not requiring immediate surgery.	Recommended	The PBAC recommended the listing of belzutifan, on the basis that it should be available as a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with VHL disease who require therapy for associated RCC, CNS Hb, or pNET. The PBAC is satisfied that belzutifan provides, for some patients, a significant improvement in efficacy over active surveillance. In making this recommendation, the PBAC accepted there is a high unmet clinical need for treatment options for patients with VHL-disease prior to the development of metastatic disease or debilitating tumour progression, and that belzutifan is effective in reducing tumour activity and the frequency of surgeries for these patients. The PBAC considered that the incremental cost-effectiveness was uncertain due to the limited amount of clinical data to inform the model, but that in the context of this rare and life-limiting disease, belzutifan would be considered acceptably cost-effective with a price reduction that resulted in an acceptable cost per patient per year. The PBAC noted that the estimated utilisation of belzutifan required further revisions to better reflect the eligible patient population and time on treatment. The PBAC considered that any remaining uncertainties could be managed by a risk sharing arrangement.

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BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® AMGEN AUSTRALIA PTY LIMITED Category 2 (Change to existing listing)	Measurable residual disease (MRD)-negative B-cell precursor acute lymphoblastic leukaemia (B-ALL)	To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of newly diagnosed B-ALL in patients who are MRD-negative after initial induction chemotherapy.	Deferred	The PBAC deferred blinatumomab for the treatment of patients with B-ALL who are MRD-negative following induction chemotherapy. The PBAC was of a mind to recommend blinatumomab, pending advice from the TGA Delegate. The PBAC noted that blinatumomab plus standard of care consolidation therapy provided a significant improvement in overall survival and relapse-free survival over standard of care consolidation therapy alone but considered the magnitude of benefit in the proposed PBS population was uncertain. The PBAC considered that the cost-effectiveness of blinatumomab was acceptable based on the revised base case and price in the pre-PBAC response. The PBAC considered that a risk sharing arrangement would be appropriate to address the uncertainty regarding the magnitude of benefit in the proposed PBS population and around the cost offsets associated with the reduced use of blinatumomab and inotuzumab ozogamicin in the relapsed/refractory setting. <u>Sponsor's Comment:</u> Amgen is committed to working with the PBAC and Department of Health and Aged Care to facilitate timely access to blinatumomab for patients with MRD-negative B-ALL.

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DIENOGEST Tablet 2 mg Visanne® BAYER AUSTRALIA LTD Category 2 (New PBS listing)	Endometriosis	To request a General Schedule Restricted Benefit listing for the treatment of endometriosis.	Recommended	The PBAC recommended that dienogest 2 mg be listed on the PBS as an Authority Required (STREAMLINED) benefit for the treatment of endometriosis. The PBAC noted that although dienogest is available on the private market, the price can be prohibitive for patients. Additionally, there is public health benefit in having more treatments for endometriosis available on the PBS. The PBAC considered that dienogest had comparable efficacy to oral medroxyprogesterone but offered a benefit for some women with endometriosis. The PBAC considered that a price premium over medroxyprogesterone was justified. The PBAC considered that dienogest would be acceptably cost-effective at the requested price. The PBAC considered that the utilisation of dienogest was uncertain, and that the costs were likely underestimated, but modest. The PBAC recommended that the Department undertake a utilisation review of medicines listed on the PBS that may be used for the treatment of endometriosis when 2 years of data post-listing of dienogest are available.

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DROSPIRENONE WITH ETHINYLESTRADIOL Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol (as betadex clathrate) and 4 inert tablets Yaz® Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets Yasmin® BAYER AUSTRALIA LTD Category 2 (New PBS listing)	Oral contraceptive Moderate acne vulgaris in women who seek oral contraception Premenstrual dysphoric disorder in women who have chosen oral contraceptives as their method of birth control	To request a General Schedule unrestricted listing.	Recommended	The PBAC recommended the listing of drospirenone with ethinylestradiol (Yaz and Yasmin) as Unrestricted benefit listings. The PBAC noted public interest in having multiple combined oral contraceptive (COC) options available on the PBS, and that alternative COCs are available if patients experience adverse effects with another COC. The PBAC also noted that the submission claimed drospirenone offers benefits over other progestogens due to its anti-mineralocorticoid and anti-androgenic effects, and comments from clinicians stating that Yaz and Yasmin provide additional non-contraceptive benefits, such as in the management of premenstrual dysphoric disorder and acne. However, the PBAC considered that there was a lack of evidence provided to support that Yaz and Yasmin offered any clinical advantages compared to other COCs listed on the PBS. The PBAC noted evidence on the risk of venous thromboembolism (VTE) with the use of COCs, and that this risk has been shown to be slightly higher with COCs containing the progestogen drospirenone compared to those with levonorgestrel, however the absolute risk of VTE in patients using COCs is small. The PBAC considered that Yaz and Yasmin did not provide significant benefits in terms of greater efficacy or reduction in toxicity compared to other PBS-listed COCs, and recalled it had previously recommended the listing of other COCs on a cost-minimisation basis with levonorgestrel 150 micrograms with ethinylestradiol 30 micrograms combination tablets. The PBAC therefore recommended listing Yaz and Yasmin on a cost-minimisation basis to the lowest cost COC currently PBS-listed, and advised the equi-effective doses to be one tablet of Yaz/Yasmin to one tablet of levonorgestrel 150 micrograms + ethinylestradiol 30 micrograms.

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ELRANATAMAB Solution for subcutaneous injection 44 mg in 1.1 mL (40 mg per mL) Solution for subcutaneous injection 76 mg in 1.9 mL (40 mg per mL) Elrexfio® PFIZER AUSTRALIA PTY LTD Category 1 (New PBS listing)	Relapsed or refractory multiple myeloma (RRMM)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of RRMM in patients who have received at least three prior therapies.	Not Recommended	The PBAC did not recommend the PBS listing of elranatamab for the treatment of RRMM. The PBAC noted the proposed listing was for patients who have received at least 3 prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 mAb, and that this likely reflected use as a third or later line treatment. The PBAC noted in the clinical evidence supporting the submission very few patients were treated third line with 75% of patients having received at least 5 prior therapies. The PBAC considered that the data presented likely supported a listing in a later line than that proposed in the submission. The PBAC noted that the submission nominated a basket of therapies, referred to as standard of care as the comparator. The PBAC considered that the nominated therapies, and their extent of use, did not reflect contemporary clinical practice, and that the use of a basket of therapies was inconsistent with the comparators included in recently recommended PBAC submissions for multiple myeloma treatments. The PBAC noted that although elranatamab was likely to be effective, the substantial transitivity and applicability issues with the indirect comparisons presented meant that the magnitude of its benefit was highly uncertain. Due to the uncertainty related to the clinical evidence presented, the PBAC considered that the economic model was highly uncertain. <u>Sponsor's Comment:</u> Pfizer will continue to work collaboratively with the PBAC and Department of Health and Aged Care to provide access to Elrexfio for the treatment patients with relapsed or refractory multiple myeloma as soon as possible.

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ESKETAMINE Nasal spray solution 28 mg in 0.2 mL (2 actuations) Spravato® JANSSEN-CILAG PTY LTD Standard re-entry (New PBS listing)	Treatment-resistant depression (TRD)	Resubmission to request a Section 100 (Highly Specialised Drug Program) Authority Required (Telephone/Online) listing for the treatment of TRD.	Deferred	The PBAC deferred making a recommendation for the listing of esketamine for the treatment of TRD in patients who have failed two or more prior oral anti-depressant drugs. The PBAC reiterated its previous consideration that, based on the available clinical evidence, esketamine was likely to be effective for some patients. The PBAC noted the economic model in the resubmission included provision for treatment beyond 12 months and retreatment (as requested in July 2023), and while it considered there were substantial uncertainties with the effectiveness of esketamine and the extent of use in these settings, esketamine was overall likely to be cost-effective at the price proposed in the resubmission. The PBAC deferred the item to enable the restriction criteria to be refined and the utilisation estimates to be revised. <u>Sponsor's Comment:</u> Janssen will continue to work with the PBAC to resolve remaining concerns around the financial estimates and restrictions so that Australian patients can receive timely access to esketamine through the PBS.
ESTRADIOL Transdermal gel 500 micrograms (as hemihydrate) in 0.5 g sachet Sandrena® ORION PHARMA (AUS) PTY LIMITED Category 4 (New PBS listing)	Climacteric symptoms after natural or surgical menopause	To request a General Schedule unrestricted listing.	Recommended	The PBAC recommended the listing of estradiol 500 microgram in 0.5 g gel sachet (Sandrena) as a General Schedule (Unrestricted Benefit) listing under the same circumstances as the existing Sandrena 1 mg in 1 g sachet PBS listings. The PBAC considered the option to prescribe a lower strength of estradiol gel sachet would allow greater flexibility in dosing; simplify dose titration for patients; and reduce product wastage. The PBAC recommended the following Administrative Advice for Sandrena 500 microgram in 0.5 g gel sachets: 'Estradiol should be used in conjunction with progestogen in women with an intact uterus', and recommended that this Administrative Advice also be flowed on to the Sandrena 1 mg in 1 gram gel sachets and estradiol patches listings to replace the current Administrative Advice about use in conjunction with an oral progestogen.

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FARICIMAB Solution for intravitreal injection 28.8 mg in 0.24 mL (120 mg per mL) Vabysmo® ROCHE PRODUCTS PTY LTD Category 2 (Change to existing listing)	Retinal vein occlusion (RVO)	To request a General Schedule Authority Required (Telephone/Online) listing for initial treatment and an Authority Required (STREAMLINED) listing for continuing treatment of RVO.	Recommended	The PBAC recommended the listing of faricimab for the treatment of macular oedema secondary to RVO. The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of faricimab would be acceptable if it were cost-minimised to the lowest cost alternative medicine currently PBS-listed for RVO. The PBAC noted there were uncertainties regarding the appropriate dose relativity but considered that, on balance, a relativity of 1:1 for faricimab and aflibercept 2 mg was likely to be conservative. The PBAC recommended that faricimab should be included under the existing risk sharing arrangement for anti-VEGF medicines used to treat RVO with no increase in expenditure caps.
FRUQUINTINIB Capsule 1 mg Capsule 5 mg Fruzaqla® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. Category 2 (New PBS listing)	Metastatic colorectal cancer (mCRC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with mCRC who have been previously treated with or who are not considered candidates for available therapies.	Not Applicable	To be considered at a future PBAC meeting

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IPTACOPAN Capsule 200 mg Fabhalta® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 1 (New PBS listing)	Paroxysmal nocturnal hemoglobinuria (PNH)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adults with PNH who have inadequate clinical response to Complement 5 (C5) inhibitor treatment.	Recommended	The PBAC recommended the listing of iptacopan for the treatment of adults with PNH who have inadequate clinical response to C5 inhibitor treatment. The recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of iptacopan would be acceptable if it were cost-minimised against pegcetacoplan, and included in the current Risk Sharing Arrangement for PNH. The PBAC considered the following equi-effective doses appropriate: • Iptacopan 146,048 mg (200 mg/capsule × 56 capsules/pack × 13.04 packs) is equivalent to pegcetacoplan 116,365 mg (1,080 mg/vial × 107.7 injections). The PBAC noted that flow on changes to the restriction criteria for eculizumab, ravulizumab and pegcetacoplan would be required.

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IVOSIDENIB Tablet 250 mg Tibsovo® SERVIER LABORATORIES (AUST.) PTY. LTD. Category 1 (New PBS listing)	Bile duct cancer (cholangiocarcinoma)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on chemotherapy and have a confirmed *IDH1* mutation.	Not Recommended	The PBAC did not recommend ivosidenib for treatment of patients with locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase 1 (*IDH1*) variant, who have previously progressed on chemotherapy. The PBAC considered that there was a high clinical need for treatments for patients with locally advanced or metastatic cholangiocarcinoma, who have a very poor prognosis. The PBAC considered the clinical evidence indicated that ivosidenib had a small progression free survival and moderate overall survival advantage compared with standard treatment, for the small subset of patients with *IDH1* mutations. The PBAC considered that the incremental cost-effectiveness ratio was high at the proposed price and likely to be underestimated in the submission base case due to optimistic assumptions in the economic model. The PBAC considered these issues could be addressed in an early re-entry submission. <u>Sponsor's Comment:</u> Servier is disappointed the PBAC did not recommend ivosidenib for PBS listing but welcomes the PBAC's recognition of the urgent need for treatment options for people diagnosed with locally advanced or metastatic cholangiocarcinoma with an *IDH1* mutation. Servier remains committed to working with the PBAC and Department of Health and Aged Care to make ivosidenib available on the PBS in a timely way.

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LANREOTIDE Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe Somatuline® Autogel IPSEN PTY LTD Category 3 (Change to existing listing)	Acromegaly Functional Carcinoid Tumour Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)	To request an amendment to the clinical criteria of the Section 100 (Highly Specialised Drug Program) Authority Required (STREAMLINED) listings for the treatment of acromegaly, functional carcinoid tumour, and non-functional GEP-NET.	Recommended	The PBAC recommended changes to the Section 100 (Highly Specialised Drug Program) Community Access (CA), Authority Required (STREAMLINED) listings of lanreotide 60 mg/0.5 mL, 90 mg/0.5 mL and 120 mg/0.5 mL injection forms to allow the initiation of the treatment of acromegaly and functional carcinoid tumour in the CA setting. The PBAC also recommended changes to the listing of lanreotide 120 mg/0.5 mL injection under the same circumstances to allow the initiation of the treatment of non-functional GEP-NET in the CA setting. The PBAC considered that initiating lanreotide in a CA setting should remain restricted to specialists or medical practitioners in consultation with a specialist. The PBAC considered that allowing initiation of lanreotide in a community setting would improve access for patients, particularly those in rural and remote areas.
LECANEMAB Solution concentrate for I.V. infusion 200 mg in 2 mL (100 mg per mL) Solution concentrate for I.V. infusion 500 mg in 5 mL (100 mg per mL) Leqembi® EISAI AUSTRALIA PTY LTD Category 1 (New PBS listing) WITHDRAWN	Early Alzheimer disease (EAD)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of EAD, comprising mild cognitive impairment due to Alzheimer disease (AD), prodromal AD, or mild AD dementia.	Not Applicable	This item was withdrawn.

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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 Early re-entry (New PBS listing)	Advanced Parkinson disease	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment.	Recommended	The PBAC recommended the listing of levodopa with entacapone and carbidopa intestinal gel (LECIG) for the treatment of advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of LECIG would be acceptable if it were cost-minimised against levodopa, carbidopa monohydrate intestinal gel (LCIG), and if LECIG would be included in the same risk sharing arrangements as LCIG to contain risks associated with the potential use of higher doses of LECIG through the PBS versus trial data or in a broader population given the different device. The PBAC considered that, with the equi-effective dose recommended by the Committee, the resubmission had addressed the substantive outstanding issues identified at the March 2024 PBAC meeting. The PBAC considered the following equi-effective dosing appropriate: • 1.7 cartridge of LECIG (each cartridge contains 47 mL with a total of 940 mg of levodopa) per day • 1.0 cassette of LCIG (each cassette contains 100 mL with a total of 2,000 mg of levodopa) per day.

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LINZAGOLIX Tablet 100 mg (as choline) Tablet 200 mg (as choline) Yselty® THERAMEX AUSTRALIA PTY LTD Category 2 (New PBS listing)	Moderate to severe symptomatic uterine fibroids	To request General Schedule Authority Required (Telephone/Online) for initiation and Authority Required (STREAMLINED) continuing listings for the treatment of moderate to severe symptomatic uterine fibroids.	Not Recommended	The PBAC did not recommend the listing of linzagolix for the treatment of symptomatic uterine fibroids. The PBAC noted that the final advice from the Therapeutic Goods Administration Delegate was pending. The PBAC noted that there were safety concerns regarding bone mineral density (BMD) loss, particularly at the higher 200 mg dose without add back hormonal therapy (ABT), and that in the short term, ABT did not fully ameliorate that risk. The PBAC also noted that long-term safety data with ongoing linzagolix treatment is currently limited. The PBAC considered the age of patients likely to be treated, the treatment duration, and the treatment aims were uncertain and considered that the place in therapy for linzagolix required further consideration with respect to reducing the risks associated with BMD loss and to targeting treatment to patients with the highest clinical need. The PBAC also noted there were substantial issues with the cost-effectiveness model and advised the economic model should capture the benefit and risks associated with likely use, particularly among younger patients. The PBAC considered the financial estimates were dependent on the population likely to be treated in Australian clinical practice and were therefore highly uncertain. <u>Sponsor's Comment:</u> The sponsor, Theramex is disappointed with the outcome but will work with the PBAC to address the concerns raised and aim to have linzagolix available for women at the earliest opportunity.

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METHOTREXATE Tablet 2.5 mg (as sodium) Tablet 10 mg (as sodium) Methoblastin® PFIZER AUSTRALIA PTY LTD Category 4 (New PBS listing)	Chemotherapy and inflammatory conditions	To request a General Schedule unrestricted listing of new forms and to request listing of a new pack size.	Recommended	The PBAC recommended a General Schedule Unrestricted Benefit listing of a new formulation of methotrexate, methotrexate (as sodium) 2.5 mg and 10 mg tablets (Methoblastin®) (MTX (as sodium)) under the same circumstances as the PBS-listed methotrexate 2.5 mg and 10 mg tablets (Methoblastin®) (MTX). The PBAC also recommended a new maximum quantity of 10 units and 5 repeats for the listing of MTX (as sodium) 10 mg 10-unit pack. The PBAC advised that the same pack size of MTX (as sodium) and other MTX listings should be treated as equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule).
MILK POWDER -SYNTHETIC Low calcium oral powder 400 g (Locasol) Locasol® NUTRICIA AUSTRALIA PTY LIMITED Committee secretariat (Change to existing listing)	Hypercalaemia	To request Locasol with new formulation continue to be listed on the PBS under the existing conditions.	Recommended	The PBAC recommended the new formulation of milk powder synthetic low calcium oral powder 400 g (Locasol®) continue to be listed on the PBS under the existing conditions as the current formulation. The PBAC noted the new formulation is expected to provide non-inferior clinical benefit and safety compared to the current formulation for the dietary management of hypercalcaemia.

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MORPHINE Tablet containing morphine sulfate pentahydrate 30 mg Anamorph® ARROW PHARMA PTY LTD Category 2 (New PBS listing)	Severe pain, cancer pain, severe disabling pain	To request a General Schedule Restricted Benefit listing for the treatment of severe pain and cancer pain, and a Palliative Care Schedule Authority Required (Telephone/Online) listing for the treatment of severe disabling pain.	Recommended	The PBAC recommended the General Schedule Restricted Benefit listing of morphine sulfate pentahydrate tablet 30 mg (Anamorph®) for the treatment of severe pain and cancer pain, and a Palliative Care Authority Required (Telephone/Online) listing for the treatment of severe disabling pain. The PBAC noted the unmet clinical need caused by recent discontinuations and that Anamorph remains the only solid oral immediate release form of morphine registered on the Australia Register of Therapeutic Goods.
NIRSEVIMAB Solution for injection 50 mg in 0.5 mL pre-filled syringe Solution for injection 100 mg in 1 mL pre-filled syringe Beyfortus® SANOFI-AVENTIS AUSTRALIA PTY LTD Category 1 (New PBS listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request a General Schedule Restricted Benefit listing for prevention of RSV lower respiratory tract disease (LRTD) in neonates and infants born during or entering their first RSV season; and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.	Not Recommended	The PBAC did not recommend the General Schedule Restricted Benefit PBS listing of nirsevimab for the prevention of RSV LRTD in neonates and infants born during or entering their first RSV season; and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The PBAC considered that nirsevimab was superior in terms of effectiveness compared to no immunisation, with an acceptable safety profile in the first RSV season. However, the PBAC considered the incremental cost-effectiveness ratio for nirsevimab for the first RSV season to be substantially underestimated and highly uncertain. The PBAC did not accept palivizumab as the main comparator for the second season, and noted there was limited clinical evidence to support the proposed listing of nirsevimab in the second season. <u>Sponsor's Comment:</u> Sanofi is disappointed with the outcome. Sanofi welcomes the Committee's recognition of the effectiveness and safety of nirsevimab for RSV prevention compared to no vaccination. Sanofi remains committed to working with the PBAC to enable timely and equitable access of nirsevimab to protect all Australian infants from RSV.

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NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Category 3 (Change to existing listing)	Unresectable malignant mesothelioma	To request the PBAC consider the previously estimated utilisation for nivolumab and ipilimumab for the treatment of unresectable malignant mesothelioma.	Not Recommended	The PBAC advised that no amendments be made to the current risk sharing arrangement (RSA) for nivolumab (Opdivo®) and ipilimumab (Yervoy®) for unresectable malignant mesothelioma. The PBAC advised that the evidence provided did not sufficiently justify the requested changes, and considered that the current RSA is working as intended to manage the uncertainty around the original financial estimates. <u>Sponsor's Comment:</u> The sponsor had no comment.
ODEVIXIBAT Capsule 200 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms Bylvay® IPSEN PTY LTD Category 1 (New PBS listing)	Progressive familial intrahepatic cholestasis (PFIC)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of PFIC.	Not Recommended	The PBAC did not recommend odevixibat for the treatment of PFIC. Although the PBAC recognised that there was a high clinical need for treatments for this rare condition, the PBAC noted that there were significant uncertainties regarding the proposed restriction, the clinical evidence presented, the economic model and the utilisation estimates. The PBAC advised a facilitated resolution pathway would be appropriate given the potentially high added therapeutic value and complex nature of the outstanding issues. <u>Sponsor's Comment:</u> Ipsen looks forward to working with the PBAC and Department of Health and Aged Care through the facilitated resolution process and meet the needs of patients with PFIC as soon as possible.

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OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® ASTRAZENECA PTY LTD Category 2 (Change to existing listing)	Human epidermal growth factor 2 (HER2) negative metastatic breast cancer with a confirmed *BRCA1* or *BRCA2* mutation	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HER2-negative metastatic breast cancer for patients with a confirmed *BRCA1* or *BRCA2* mutation.	Recommended	The PBAC recommended the listing of olaparib for the treatment of patients with HER2-negative metastatic breast cancer and a confirmed *BRCA1* or *BRCA2* pathogenic variant. The PBAC is satisfied that olaparib provides, for some patients, a significant improvement in efficacy compared with chemotherapy in terms of progression free survival. Although a statistically significant difference in overall survival was not demonstrated in the trial, the PBAC considered a survival benefit was plausible as there was a trend to improved overall survival in the trial and increased subsequent use of poly-ADP ribose polymerase (PARP) inhibitors in the control arm. The PBAC noted that olaparib is PBS-listed for patients with high-risk early breast cancer, but considered there remains a clinical need for access to olaparib for patients not eligible in the early setting, particularly lower risk patients who have progressed to metastatic disease and patients diagnosed with de-novo metastatic disease. The PBAC considered the incremental cost-effectiveness ratio (ICER) remained high at the price proposed in the pre-PBAC response and a price reduction would be required to bring the ICER into an acceptable range. The PBAC considered some changes to the financial estimates were required to align them with the revised patient population for the listing. Given the uncertainty in patient numbers, uptake and duration of treatment, the PBAC considered a risk sharing arrangement would be appropriate.

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PRASUGREL Tablet 5 mg Tablet 10 mg Prasugrel SCP GENERIC HEALTH PTY LTD Early re-entry (New PBS listing)	Acute coronary syndrome (ACS)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing, in combination with aspirin, for the treatment of ACS (myocardial infarction (MI) or unstable angina) managed by percutaneous coronary intervention (PCI).	Recommended	The PBAC recommended prasugrel, in combination with aspirin, for the treatment of ACS i.e., MI or unstable angina, managed by PCI. The PBAC noted that the early re-entry resubmission had satisfactorily addressed the outstanding issues and considered that the cost minimisation approach presented, which was based on 40% clopidogrel and 60% ticagrelor use, and the updated financial impact estimates were reasonable. The PBAC considered that, for the purposes of the cost-minimisation approach, the following doses of prasugrel, ticagrelor and clopidogrel were considered equivalent: Prasugrel 8.07 mg, once daily (61% of patients would receive 10 mg/day and 39% of patients would receive 5 mg/day) Ticagrelor 90 mg, twice daily Clopidogrel 75 mg, once daily
PROGESTERONE Capsule 300 mg Utrogestan® BESINS HEALTHCARE AUSTRALIA PTY LTD Category 4 (New PBS listing)	Luteal phase support	To request a Section 100 (In Vitro Fertilisation Program) Authority Required (STREAMLINED) listing of a new strength for luteal phase support (LPS) as part of an assisted reproductive technology (ART) treatment cycle.	Recommended	The PBAC recommended the Authority Required (STREAMLINED) listing of progesterone capsule 300 mg (Utrogestan), twice daily, under special arrangements covered under the PBS section 100 (IVF Program) for LPS as part of an ART treatment cycle. The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of progesterone 300 mg capsule would be acceptable if it were cost-minimised at an equivalent price per treatment course against the least costly progesterone for LPS currently listed on the PBS. The PBAC accepted the main comparator as progesterone 200 mg, three times daily. The PBAC also considered all other PBS-listed forms of progesterone indicated for LPS as appropriate comparators. The PBAC considered the equi-effective doses as progesterone capsule 300 mg BID for 15 days equivalent to progesterone 200 mg capsule TID for 14 days. The PBAC reaffirmed its July 2016 advice that progesterone 200 mg capsule TID for 14 days was equivalent to progesterone 8% vaginal gel 90 mg (Crinone®) QD (once per day) for 15 days and progesterone tablet 100 mg (Endometrin®) BID or TID for 14 days.

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PROPYLENE GLYCOL Eye drops 60 micrograms per mL, 10 mL Systane Balance® ALCON LABORATORIES (AUSTRALIA) PTY LTD Category 3 (New PBS listing)	Severe dry eye syndrome	To request a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome.	Recommended	The PBAC recommended the listing of propylene glycol on a cost-minimisation basis to the lowest cost PBS-listed ocular lubricant. The PBAC considered that propylene glycol was non-inferior in comparative safety and efficacy to both preservative free and preservative containing ocular lubricants, but the submission had not demonstrated a significant improvement in efficacy or safety over other PBS-listed ocular lubricants.
RAVULIZUMAB Solution concentrate for I.V. infusion 300 mg in 3 mL Solution concentrate for I.V. infusion 1,100 mg in 11 mL Ultomiris® ALEXION PHARMACEUTICALS AUSTRALASIA PTY LTD Category 2 (New PBS listing)	Generalised myasthenia gravis (gMG)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) antibody positive.	Not Recommended	The PBAC did not recommend the listing of ravulizumab for the treatment of patients with gMG who are AChR antibody positive. The PBAC considered that the incremental benefit shown in the trial was modest and that it was difficult to determine whether the incremental benefit would be clinically meaningful in the broad population requested for listing. Further, the PBAC considered the incremental cost-effectiveness ratio presented in the submission was very high and likely to have been underestimated, and the proposed price was very high. The PBAC recognised the high clinical need for effective therapies for gMG, particularly in patients who are not responding to or are unable to use existing therapies, and for those with refractory disease. <u>Sponsor's Comment:</u> Whilst Alexion is disappointed with the current outcome and its impact on patients living with gMG, they extend their sincere gratitude to all healthcare professionals, patient organisations and consumers for their invaluable input and support. Alexion is committed to working with the PBAC to ensure Australians living with gMG can access Ultomiris on the PBS at the earliest opportunity.

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RESPIRATORY SYNCYTIAL VIRUS VACCINE Powder and suspension for injection (0.5 mL) Arexvy® GLAXOSMITHKLINE AUSTRALIA PTY LTD Category 1 (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request a National Immunisation Program (NIP) listing for the prevention of RSV in patients aged 60 years and over.	Not Recommended	The PBAC did not recommend that respiratory syncytial virus vaccine (Arexvy®, RSVpreF3 OA) be a designated vaccine for the purposes of the *National Health Act 1953* for the prevention of lower respiratory tract illness caused by respiratory syncytial virus (RSV). The PBAC noted that the submission had proposed two alternative NIP schedules (i) among adults aged ≥60 years of age (YOA); and (ii) among adults ≥75 YOA. The PBAC noted that ATAGI supported a listing for patients aged 75 years and over; First Nations people aged 60 to 74 years; and people aged 60 to 74 years with conditions that increase their risk of severe disease due to RSV. The PBAC considered that the vaccine was superior to no vaccine in terms of effectiveness with an acceptable safety profile. The PBAC considered that the incremental cost-effectiveness ratio was unacceptably high and uncertain for adults aged ≥60 YOA and for adults aged ≥75 YOA. The PBAC noted that the cost-effectiveness RSVpreF3 OA in First Nations and high risk people aged 60-74 years was unknown as this was not addressed by the submission. <u>Sponsor's Comment:</u> GSK is disappointed by the decision to not recommend Arexvy at the July 2024 meeting but looks forward to working with the PBAC and ATAGI to ensure older adults are protected against lower respiratory tract illness caused by RSV.

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RISDIPLAM Powder for oral solution 750 micrograms per mL, 80 mL Evrysdi® ROCHE PRODUCTS PTY LTD Category 2 (Change to existing listing)	Spinal muscular atrophy (SMA)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of patients with confirmed genetic diagnosis of SMA (*SMA1* deletion or mutation) who have a survival motor neuron 2 (*SMN2*) gene copy number of 3.	Recommended	The PBAC recommended the listing of risdiplam for the pre-symptomatic initiation of treatment in patients aged < 36 months, genetically diagnosed with SMA, who have a *SMN2* gene copy number of 3, on the basis that it should be available only under special arrangements under Section 100. The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of risdiplam would be acceptable if it were cost-minimised against nusinersen. The PBAC's recommendation was based on equi-effective doses of 5 mg of risdiplam daily and nusinersen 12 mg (5 mL) per administration every 4 months (3 per year, i.e. excluding nusinersen loading doses) consistent with its previous advice for the pre-symptomatic initiation of risdiplam in patients with SMA and an SMN2 gene copy number of 1 or 2. The PBAC considered that flow-on changes to the onasemnogene abeparvovec (ONA) restrictions would be required to allow patients with 3 copies of the SMN2 gene to switch from pre-symptomatic treatment with risdiplam to ONA.
SELPERCATINIB Capsule 40 mg Capsule 80 mg Retevmo® ELI LILLY AUSTRALIA PTY LTD Standard re-entry (New PBS listing)	Non-small cell lung cancer (NSCLC)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of advanced or metastatic, rearranged during transfection (RET) fusion-positive NSCLC.	Recommended	The PBAC recommended selpercatinib for the treatment of advanced or metastatic RET fusion-positive NSCLC. The PBAC considered that the additional clinical evidence presented in the resubmission supported the claim that selpercatinib was superior to pembrolizumab plus platinum-based doublet chemotherapy in terms of progression free survival but that the magnitude of any overall survival (OS) benefit remained uncertain. The PBAC considered that applying a more conservative extrapolation function to OS in the economic model would be appropriate. The PBAC considered selpercatinib would be cost effective with an ICER of less than $75,000 per QALY gained (using the effective price of pembrolizumab), consistent with other targeted therapies for NSCLC. The PBAC noted that flow on changes to the PBS listing of pembrolizumab for Stage IV (metastatic) NSCLC would be required to enable its use after selpercatinib.

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TALAZOPARIB Capsule 0.1 mg Capsule 0.25 mg Capsule 0.35 mg Capsule 0.5 mg Talzenna® PFIZER AUSTRALIA PTY LTD Early re-entry (New PBS listing)	Prostate cancer (PC)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing, in combination with enzalutamide, for the treatment of metastatic castration resistant PC (mCRPC) in patients with a *BRCA1* or *BRCA2* mutation who have not received prior treatment with a novel hormonal agent (NHA).	Recommended	The PBAC recommended the listing of talazoparib, for use in combination with enzalutamide for the first line treatment of mCRPC in patients with breast cancer gene *(BRCA)1/2* pathogenic variants who have not received prior treatment with a NHA. The PBAC considered that the early re-entry resubmission appropriately addressed the outstanding economic and financial issues and that talazoparib was cost effective at the price proposed in the pre-PBAC response. The PBAC considered that talazoparib should join the risk sharing arrangement that is in place for olaparib in the mCRPC setting. The PBAC noted flow on changes would be required to the enzalutamide restriction in this setting as the current restriction would not allow a patient who had commenced with abiraterone in the metastatic setting to switch to enzalutamide (in combination with talazoparib) once BRCA1/2 status was confirmed.
VEDOLIZUMAB Powder for injection 300 mg Entyvio® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. Category 2 (Change to existing listing)	Chronic pouchitis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for initial treatment and an Authority Required (Telephone/Online) listing for continuing treatment of chronic pouchitis.	Recommended	The PBAC recommended the Section 100 (Highly Specialised Drugs Program – Public and Private Hospital) listing of vedolizumab for the treatment of patients with chronic pouchitis. The PBAC considered there was a high unmet need for additional treatment options in this small group of patients. The PBAC was satisfied that vedolizumab provides, for some patients, a significant improvement in efficacy over standard of care alone. However, the PBAC considered magnitude of benefit was uncertain and likely modest. The PBAC's recommendation for listing was based on, among other matters, its assessment that, in the context of the high clinical need and small patient population, vedolizumab was likely cost-effective at the price proposed in the pre-PBAC response.

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ZANUBRUTINIB Capsule 80 mg Brukinsa® BEIGENE AUS PTY LTD Category 3 (Change to existing listing)	Waldenström macroglobulinaemia	To request the PBAC consider the previously estimated utilisation of zanubrutinib for the treatment of Waldenström macroglobulinaemia.	Recommended	The PBAC provided advice regarding the subsidisation caps under the current risk sharing arrangement (RSA) for zanubrutinib (Brukinsa®) for the treatment of Waldenström macroglobulinemia (WM). The PBAC considered it was reasonable to make amendments to the financial estimates underpinning the RSA to reflect the proposed changes in incidence and prevalence based on new epidemiological data specific to the WM subset in Australia that had not been previously available. The PBAC was satisfied that the submission provided sufficient evidence to support the requested changes to the assumptions in terms of the incidence and prevalence in the March 2022 financial estimates that were the basis for the current RSA. The PBAC noted that the submission did not propose to change the basis for achieving cost-effectiveness through the RSA, which was intended to limit the treatment duration. The PBAC advised that the cost-effectiveness of zanubrutinib would remain acceptable if the subsidisation caps continue to be determined on the same basis, given that the requested changes affect only the number of patients and not the number of units per patient.

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ZILUCOPLAN Solution for injection 16.6 mg in 0.416 mL (as tetrasodium) pre-filled syringe Solution for injection 23 mg in 0.574 mL (as tetrasodium) pre-filled syringe Solution for injection 32.4 mg in 0.810 mL (as tetrasodium) pre-filled syringe Zilbrysq® UCB AUSTRALIA PROPRIETARY LIMITED Category 1 (New PBS listing)	Generalised myasthenia gravis (gMG)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for initial treatment and a General Schedule Authority Required (Written) listing for continuing treatment of gMG.	Not Recommended	The PBAC did not recommend the listing of zilucoplan for the treatment of patients with gMG who are anti-acetylcholine receptor (AChR) antibody positive. The PBAC considered the incremental cost-effectiveness ratio presented in the submission was very high and was likely to have been underestimated and the proposed price was very high. The PBAC considered the claim of superior comparative effectiveness versus placebo was supported but that the incremental benefit shown in the trial was relatively modest. The PBAC recognised the high clinical need for effective therapies for gMG, particularly in patients who are not responding to or unable to use existing therapies or who have refractory disease. <u>Sponsor's Comment:</u> The sponsor had no comment.

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AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mL Bavencio® MERCK HEALTHCARE PTY LTD	Stage IV clear cell variant renal cell carcinoma	Review of positive PBAC recommendations not accepted by applicants	The PBAC rescinded the March 2021 recommendation for avelumab.
DULAGLUTIDE Injection 3 mg in 0.5 mL single dose pre-filled pen Injection 4.5 mg in 0.5 mL single dose pre-filled pen Trulicity® ELI LILLY AUSTRALIA PTY LTD	Type 2 diabetes mellitus (T2DM)	Review of positive PBAC recommendations not accepted by applicants	The PBAC rescinded the May 2022 recommendation for dulaglutide.
HUMAN MENOPAUSAL GONADOTROPHIN Injection 600 I.U. in 1.92 mL pre-filled multi-dose pen Injection 1,200 I.U. in 1.92 mL pre-filled multi-dose pen Menopur® FERRING PHARMACEUTICALS PTY LIMITED	Assisted reproductive technology	Review of positive PBAC recommendations not accepted by applicants	The PBAC extended the July 2022 recommendation for human menopausal gonadotrophin for an additional 12 months.
IBRUTINIB Capsule 140 mg Imbruvica® JANSSEN-CILAG PTY LTD	Chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma (SLL) with evidence of one or more 17p chromosome deletions	Review of positive PBAC recommendations not accepted by applicants	The PBAC rescinded the November 2019 recommendation for ibrutinib. The PBAC advised that this recommendation had been superseded by the listings of venetoclax + ibrutinib and zanubrutinib.

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PANCREATIC EXTRACT Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity Creon® VIATRIS PTY LTD	Cystic fibrosis	Review of positive PBAC recommendations not accepted by applicants	The PBAC rescinded the November 2020 recommendation for pancreatic extract.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED	Advanced or metastatic gastro-oesophageal cancers	Review of positive PBAC recommendations not accepted by applicants	The PBAC extended the May 2022 recommendation for pembrolizumab for an additional 12 months.
PROGESTERONE Pessary 400 mg Cyclogest® GEDEON RICHTER AUSTRALIA PTY LTD	Assisted reproductive technology	Review of positive PBAC recommendations not accepted by applicants	The PBAC rescinded the July 2022 recommendation for progesterone.
TRIENTINE Tablet 150 mg (as tetrahydrochloride) Cuprior® ORPHALAN	Wilson disease	Review of positive PBAC recommendations not accepted by applicants	The PBAC extended the May 2022 recommendation for trientine for an additional 12 months.

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USTEKINUMAB Injection 90 mg in 1 mL pre-filled syringe Stelara® JANSSEN-CILAG PTY LTD	Crohn disease Severe chronic plaque psoriasis	Review of positive PBAC recommendations not accepted by applicants	The PBAC rescinded the July 2022 recommendation for ustekinumab.

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AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mL Bavencio® DEPARTMENT OF HEALTH AND AGED CARE OBO MERCK HEALTHCARE PTY LTD Other Matters (Change to existing listing)	Stage IV (metastatic) Merkel Cell Carcinoma	To request an amendment to the clinical criteria of the Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of stage IV (metastatic) Merkel Cell Carcinoma to align with the dosing recommendations in the Product Information.	The PBAC recommended the restrictions for avelumab for the treatment of metastatic Merkel Cell Carcinoma should be updated to include 800 mg flat dosing, in addition to the current maximum dose of 10 mg per kg, to align with the dosing instructions in the TGA Product Information and to avoid confusion amongst prescribers.
DUPILUMAB Injection 200 mg in 1.14 mL single dose pre filled syringe Injection 300 mg in 2 mL single dose pre filled syringe Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD Other Matters (Change to existing listing)	Severe atopic dermatitis	To seek the PBAC's advice regarding cost-effectiveness and estimated financial implications.	The PBAC provided further advice regarding the cost-effectiveness, estimated financial implications, and risk sharing arrangement (RSA) for dupilumab for the treatment of severe atopic dermatitis in patients aged 12 years and older, in the context of the sponsor's request to otherwise delist dupilumab for this indication from the PBS. In providing this advice, the PBAC considered the necessity to ensure continued access to dupilumab, acknowledging that dupilumab was an important treatment option for patients with severe atopic dermatitis, and its removal from the PBS would result in an unmet clinical need.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
OCULAR LUBRICANTS FOR THE TREATMENT OF SEVERE DRY EYE SYNDROME All brands and strengths Various sponsors DEPARTMENT OF HEALTH AND AGED CARE (Other Matters)	Severe dry eye syndrome	To provide the PBAC with the findings following a systematic literature review comparing the efficacy and safety of preservative-containing ocular lubricants versus preservative-free ocular lubricants in patients with severe dry eye syndrome.	The PBAC considered the findings of the systematic literature review on the efficacy and safety of preservative-containing (PC) ocular lubricants compared to preservative-free (PF) ocular lubricants in patients with severe dry eye. The PBAC noted the Report was comprehensive, however acknowledged limitations in the available evidence and a lack of consistently defined criteria for 'dry eye disease'. The PBAC considered the Report did not find evidence to support the superior effectiveness or safety of PF products compared to PC products. Despite the findings of the Report, the PBAC noted input from clinicians suggesting there is a subset of patients who may benefit from PF ocular lubricants compared to PC ocular lubricants. The PBAC reaffirmed its May 2023 advice that all PBS-listed ocular lubricants should be considered as relevant comparators, regardless of whether they contain preservatives or hyaluronate. The PBAC advised that future submissions for ocular lubricants be cost minimised to the lowest cost comparator, unless supporting evidence is provided to demonstrate superiority. The PBAC noted comments from consumers and other stakeholders on the Report. The PBAC requested the Department develop an options paper to be considered by the Committee at a future meeting, taking into account current clinical practice and guidelines, while ensuring that PBS-listed ocular lubricants remain cost-effective for the eligible population. The PBAC requested information be prepared on the utilisation of ocular lubricants and associated costs to the PBS to support the Committee's consideration of any potential changes to the PBS listings of these medicines.
OSTEOPOROSIS THERAPY RESTRICTIONS REVIEW ALENDRONATE RISEDRONATE ZOLEDRONIC ACID Various forms and strengths Various brands Various sponsors Matters outstanding (Change to existing listing)	Osteoporosis	To consider the impact of potential broadening of restrictions for osteoporosis therapies. This matter was deferred at the September 2021 PBAC meeting.	The PBAC provided advice on the impact of expanding the current age range for PBS-listed osteoporosis medications (alendronate, risedronate and zoledronic acid) for primary prevention of fractures to those under 70 years of age. The PBAC recalled that it was of a mind to support these changes but deferred making a recommendation pending a review of the Medicare Benefits Schedule (MBS) implications, to ensure that the MBS items for bone mineral density (BMD) testing could be aligned with PBS recommendations (PBAC Meeting Outcomes, September 2021 PBAC meeting). The PBAC noted that the Medical Service Advisory Committee (MSAC) Executive requested that a department contracted assessment report (DCAR) be undertaken to review the economic and financial implications associated with amending MBS items for BMD testing to include patients 60-69 years (MSAC 1758 - Expansion of MBS item numbers 12320 & 12322 for bone mineral density testing to include patients aged 60-69 years). The PBAC noted the DCAR economic evaluation was based on a on a cost-effectiveness analysis (CEA) of universal BMD testing versus no BMD testing in individuals aged 60–69 years, linked to a separate cost-utility analysis (CUA) of early versus delayed osteoporosis treatment. The CUA was based on the risedronate enteric coated (EC) model considered by the PBAC in November 2022 (risedronic acid Public Summary Document (PSD), November 2022 PBAC meeting). The PBAC recalled that it had previously considered the risedronate EC economic model may not be reliable for decision-making, primarily due to concerns regarding the lack of

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			BMD testing costs, assumptions of perfect treatment persistence over the 20-year time horizon, use of alendronate as a proxy for risedronate treatment effects and overestimating the cost of fractures occurring in the younger population (para 7.7, risedronic acid PSD, November 2022 PBAC meeting). The PBAC noted that including BMD testing costs in the CUA yielded an ICER ($ per QALY gained) for risedronate EC that was 12 times higher than previously considered by the Committee. The PBAC agreed with the June 2024 PBAC ESC and MSAC ESC (hereafter 'ESCs') advice that, in addition to including BMD testing costs, the respecified base case relevant for decision making should incorporate imperfect persistence estimates over a 10 year time horizon with the expansion of BMD testing limited to those 65-69 years of age with no repeat BMD testing. The PBAC noted that the ICERs were high for all modelled drug scenarios using the respecified base case and advised that the expansion of restrictions for osteoporosis therapies to include all individuals aged 65-69 years was not cost-effective. However, the PBAC agreed with the ESCs that alternative high-risk subpopulations within the 65-69 years age band, without repeat testing, would likely have improved cost effectiveness due to a reduction in the number needed to test to identify an additional patient with osteoporosis and the number needed to treat to prevent any fracture. These high risk populations could include those identified using the FRAX tool (with a major osteoporotic fracture risk of ≥ 10% over 10 years) and First Nations people, The PBAC noted that these subpopulations were not modelled in the economic evaluation and advised that consideration be given to investigating the cost-effectiveness of restricting use to these high-risk subpopulations within the 65-69 year age band, identified using the FRAX tool and First Nations people, without repeat testing. In terms of the financial estimates, the PBAC noted that MBS costs account for the majority of the budget impact, with the drug cost for osteoporosis treatment being a smaller component. The PBAC noted that the scenarios based on the 65-69 age band with no repeat testing yielded lower financial impacts to the MBS and PBS/ Repatriation Pharmaceutical Benefits Scheme (RPBS) with further restriction to high-risk subpopulations not modelled in the financial estimates. The PBAC advised that consideration be given to investigating the budget impact of restricting use to high-risk subpopulations within the 65-69 years age band, identified using the FRAX tool and First Nations people, without repeat testing.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
JULY 2024 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
REVIEW OF ITEMS FOR NURSE PRACTITIONER AND ENDORSED MIDWIFE PRESCRIBING ON THE PHARMACEUTICAL BENEFITS SCHEME Various forms and strengths Various brands Various sponsors (Other Matters)	Various medicines	To seek the PBAC's consideration of a list of medicines with a Shared Care Model (SCM) administrative note for nurse practitioner prescribing, and advice on whether the SCM note continues to be appropriate for specific listings.	The PBAC reviewed the subset of PBS listings for nurse practitioner prescribing that are subject to an SCM administrative note. In doing so, the PBAC noted the upcoming removal from 1 November 2024 of legislated requirements for nurse practitioners to have specified collaborative arrangements with medical practitioners. The PBAC noted that professional practice standards for nurse practitioners, together with a nurse practitioner's individual scope of practice and setting of care, would largely determine the degree of consultation or collaboration that occurs with a medical practitioner irrespective of the presence of the SCM administrative note. The PBAC recommended that the SCM administrative note be removed without further alteration to the PBS restrictions for most listings. For some medicines the PBAC recommended that the SCM administrative note be replaced by a restriction criterion for PBS prescribing by a nurse practitioner requiring the patient's care to be shared with a medical practitioner or where shared care is intended to occur (e.g. while the patient is waiting to see a specialist). The PBAC made its recommendations with reference to the general guidance principles for determining PBS prescriber eligibility. The PBAC recommended additional PBS restrictions in place of the SCM administrative note mostly for high-risk medicines with a narrow therapeutic index or severe side effects, or where medicines are used for acute conditions with severe consequences.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
JULY 2024 PBAC MEETING

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SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITORS FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS DAPAGLIFLOZIN SAXAGLIPTIN WITH DAPAGLIFLOZIN DAPAGLIFLOZIN WITH METFORMIN All forms and strengths Forxiga® Qtern® 5/10 Xigduo® XR ASTRAZENECA PTY LTD EMPAGLIFLOZIN EMPAGLIFOZIN WITH LINAGLIPTIN EMPAGLIFLOZIN WITH METFORMIN All forms and strengths Jardiance® Glyxambi® Jardiamet® BOEHRINGER INGELHEIM PTY LTD Other Matters (Change to existing listing)	Type 2 diabetes mellitus (T2DM)	To request the PBAC reconsider its March 2022 recommendation and the estimated costs for SGLT2 inhibitors (dapagliflozin and empagliflozin) to be listed as add-on therapy to metformin for the treatment of T2DM patients with cardiovascular disease or high cardiovascular risk	The PBAC confirmed it recommendation from March 2022 that the PBS listings for sodium-glucose cotransporter 2 (SGLT2) inhibitors be expanded to include add-on therapy to metformin for patients with type 2 diabetes mellitus (T2DM) and established cardiovascular disease or high cardiovascular risk, without the requirement to have a specific unmet glycaemic target. The PBAC considered that the cost-effectiveness of expanding the listings for SGLT2 inhibitors was acceptable with a 15% price reduction to the cost of SGLT2 inhibitors for T2DM indications. The PBAC noted the revised inputs and assumptions used to estimate the PBS usage and financial implications for the expanded SGLT2 inhibitor listings and did not specify any changes to the base case model. The PBAC considered that overall, while still uncertain, the revised cost estimates were reasonable. The PBAC recommended that the expanded SGLT2 inhibitor listings were suitable for inclusion in the increased maximum dispensed quantity (MDQ) measure.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TESTOSTERONE Transdermal cream 50 mg per mL, 50 mL AndroForte® 5 LAWLEY PHARMACEUTICALS PTY LTD Other Matters (Change to existing listing)	Androgen deficiency	To seek the PBAC's consideration to amend the current PBS listings of AndroForte 5 cream to allow for non-scrotal application.	The PBAC recommended the proposed amendment to the current PBS listings for testosterone transdermal cream 50 mg per mL, 50 mL (AndroForte 5®), to allow for torso application where scrotal application is not appropriate. The PBAC expressed concern that the changes to the PBS listings for AndroForte 5 recommended in March 2021 led to unintended barriers to access for some people, and considered this change would rectify access issues.

Version 3
Amendments

1. LECANEMAB (Leqembi®) - Withdrawn.

Previous Amendments

2. BLINATUMOMAB (Blincyto®) - added PBAC outcome.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
JULY 2024 PBAC MEETING

Submission category types

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

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.