

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 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	
<p align="center">ABROCITINIB</p> <p align="center">Tablet 50 mg Tablet 100 mg Tablet 200 mg</p> <p align="center">Cibinqo®</p> <p align="center">PFIZER AUSTRALIA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Severe atopic dermatitis (AD)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe AD</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule (Authority Required) listing of abrocitinib 200 mg, 100 mg and 50 mg tablets for adult patients with chronic severe AD. The PBAC acknowledged the clinical need for additional systemic treatments for severe AD and recommended the listings (doses) on the basis of the following cost-effectiveness considerations:</p> <p>Abrocitinib 200 mg was recommended on the basis of a cost-minimisation approach compared to dupilumab. The PBAC considered that abrocitinib 200 mg provides similar efficacy and potentially inferior safety compared to dupilumab. The PBAC considered that there was a possible minor added benefit for abrocitinib 200 mg compared with dupilumab in terms of faster onset of response and that this benefit was offset by an increase in treatment related adverse events. The PBAC considered the equi-effective doses were abrocitinib 200 mg orally once daily and dupilumab 600 mg subcutaneously as an initial dose then 300 mg every 2 weeks thereafter assuming equivalent drug costs over a 2-year period. The PBAC considered the that the cost effectiveness of abrocitinib 200 mg would be acceptable if it were cost-minimised to the lowest cost alternative therapy of dupilumab or upadacitinib.</p> <p>Abrocitinib 100 mg was recommended on the basis of a cost-utility analysis compared to dupilumab. The PBAC considered that while abrocitinib 100 mg provides an inferior clinical benefit to dupilumab, it may have a place in therapy for patients not responding to other systemic treatments who cannot be treated with the higher dose for safety reasons, and for patients who are responding to the higher dose who want to down titrate to the lowest effective maintenance dose (as recommended in the abrocitinib Product Information). The PBAC considered abrocitinib 100 mg orally once daily would be cost-effective at a price that resulted in a cost saving per quality-adjusted life year foregone in the range of \$75,000 to < \$95,000 compared to dupilumab.</p>

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				<p>Abrocitinib 50 mg was recommended based on the PBAC's consideration that the cost-effectiveness of abrocitinib 50 mg would be acceptable if it was listed at the same price per mg as abrocitinib 100 mg, noting that the 50 mg dose is recommended for patients with moderate to severe renal impairment, or for those taking strong inhibitors of cytochrome P450 (CYP) 2C19. The PBAC noted that no evidence for the 50 mg abrocitinib dose was presented in the submission.</p>
<p align="center">AFLIBERCEPT</p> <p>Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe</p> <p align="center">Eylea®</p> <p align="center">BAYER AUSTRALIA LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Diabetic macular oedema (DMO)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing of a new form for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of DMO.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Authority Required listing of aflibercept 8 mg pre-filled syringe (PFS) for the treatment of patients with visual impairment due to DMO. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of aflibercept 8 mg would be acceptable if it were cost-minimised to the lowest cost PBS-listed anti-vascular endothelial growth factor (anti-VEGF) treatment for the same indication. The PBAC considered that the equi-effective doses for the aflibercept 8 mg vial remain appropriate for the 8 mg PFS, with these being 12.91 doses of aflibercept 8 mg/faricimab and 11.65 doses of aflibercept 2 mg/ranibizumab over 2 years.</p>
<p align="center">AFLIBERCEPT</p> <p>Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe</p> <p align="center">Eylea®</p> <p align="center">BAYER AUSTRALIA LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (AMD)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing of a new form for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of subfoveal CNV due to AMD.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Authority Required listing of aflibercept 8 mg pre-filled syringe (PFS) for the treatment of patients with sub-foveal CNV secondary to age-related macular degeneration. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of aflibercept 8 mg would be acceptable if it were cost-minimised to the lowest cost PBS-listed anti-vascular endothelial growth factor (anti-VEGF) treatment for the same indication. The PBAC considered that the equi-effective doses for the aflibercept 8 mg vial remain appropriate for the 8 mg PFS, with these being 11.50 doses of aflibercept 8 mg/faricimab and 14.00 doses of aflibercept 2 mg/ranibizumab over 2 years.</p>

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<p>AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS AND MINERALS WITHOUT PHENYLALANINE</p> <p>Tablets (modified release), 54 g protein per 100 g, 100 g, pack of 6 (PKU Easy Microtabs Plus)</p> <p>PKU Easy Microtabs Plus</p> <p>ORPHARMA PTY LTD</p> <p>Category 3 (New PBS listing)</p>	<p>Phenylketonuria (PKU)</p>	<p>To request a General Schedule Restricted Benefit listing for the dietary management of PKU</p>	<p>Recommended</p>	<p>The PBAC recommended that amino acid formula with fat, carbohydrate, vitamins and minerals without phenylalanine tablets (modified release), 54 g protein per 100 g, 100 g, pack of 6 (PKU Easy Microtabs Plus) be listed on the PBS as a General Schedule Restricted Benefit listing for the dietary management of PKU on a cost-minimisation basis to the lowest cost comparator at an equivalent price per gram of protein equivalent, under the same circumstances as PKU Easy Microtabs.</p>
<p>AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES</p> <p>Oral powder 400 g (Essential Care Jr)</p> <p>Essential Care Jr</p> <p>CORTEX HEALTH PTY LTD</p> <p>Committee Secretariat (New PBS listing)</p>	<p>Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Severe intestinal malabsorption including short bowel syndrome Eosinophilic oesophagitis Cows' milk protein enteropathy Severe cows' milk protein enteropathy with failure to thrive Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Cows' milk anaphylaxis</p>	<p>To request a General Schedule Authority Required (Telephone/Online) listing of a new pack size with new formulation for the same indications as the current listing.</p>	<p>Recommended</p>	<p>The PBAC recommended listing the new 400 g pack size of amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder (Essential Care Jr) with the new formulation on a cost-minimisation basis to the lowest cost comparator accepted by the Nutritional Products Working Party at an equivalent cost per kilojoule. The PBAC noted and supported the NPWP advice that the new formulation is expected to provide non-inferior clinical benefits and safety for the listed indications compared to the current formulation of Essential Care Jr. The PBAC considered that listing the new pack size with the new formulation would not have financial implications to the Government.</p>

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<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN</p> <p>Sachets containing oral powder 12.5 g, pack of 30 (GA explore5)</p> <p>GA explore5™</p> <p>VITAFLO AUSTRALIA PTY LIMITED</p> <p>Category 3 (New PBS listing)</p>	<p>Glutaric aciduria type 1 (GA-1) Pyridoxine dependent epilepsy (PDE)</p>	<p>To request a General Schedule Restricted Benefit listing for the dietary management of proven GA-1 and PDE.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of amino acid formula with vitamins and minerals without lysine and low in tryptophan sachets containing oral powder 12.5 g, 30 (GA explore5) on a cost-minimisation basis to GA gel at an equivalent price per gram of protein equivalent, for the dietary management of patients with proven GA-1 or PDE. The PBAC noted and supported the Nutritional Products Working Party advice that GA explore5 is expected to provide non-inferior clinical benefits and safety compared to GA gel.</p>
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE</p> <p>Sachets containing oral powder 12.5 g, pack of 30 (MMA/PA explore5)</p> <p>MMA/PA explore5™</p> <p>VITAFLO AUSTRALIA PTY LIMITED</p> <p>Category 3 (New PBS listing)</p>	<p>Methylmalonic acidaemia (MMA) Propionic acidaemia (PA)</p>	<p>To request a General Schedule Restricted Benefit listing for the dietary management of MMA/PA</p>	<p>Recommended</p>	<p>The PBAC recommended that amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, sachets containing oral powder 12.5 g, 30 (MMA/PA explore5™) be listed on the PBS as a General Schedule Restricted Benefit listing for the dietary management of patients with a proven diagnosis of MMA or PA on a cost-minimisation basis to the lowest cost comparator accepted by the Nutritional Products Working Party at an equivalent price per gram of protein equivalent, under the same circumstances as MMA/PA Anamix Junior and MMA/PA Anamix Infant. The PBAC considered that listing MMA/PA explore5 would not have financial implications to the Government.</p>

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<p align="center">AMIVANTAMAB</p> <p>Solution concentrate for I.V. infusion 350 mg in 7 mL</p> <p align="center">Rybrevant®</p> <p align="center">JANSSEN-CILAG PTY LTD</p> <p align="center">Category 1 (New PBS listing)</p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of epidermal growth factor receptor (EGFR) exon 20 insertion (ex20ins) mutation-positive locally advanced or metastatic (Stage IIIb-IV) NSCLC in treatment naive patients.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of amivantamab, for the treatment of patients with EGFR ex20ins mutation positive locally advanced or metastatic NSCLC. The PBAC considered it was reasonable for amivantamab to be available for patients in the first- and second-line setting. The PBAC recognised there was a high clinical need for additional treatment options for patients with this rare form of EGFR mutation, which has shown to have a limited response to conventional treatments. The PBAC considered the evidence presented demonstrated a progression-free and overall survival (OS) benefit over the comparator (platinum-based chemotherapy) but the magnitude of benefit in terms of OS was uncertain. The PBAC considered amivantamab would be cost-effective with an incremental cost-effectiveness ratio of \$55,000 to < \$75,000 per quality-adjusted life year gained. The PBAC considered the financial estimates remained overestimated and should be revised based on advice provided by the Drug Utilisation Sub-Committee.</p> <p>The PBAC recommended flow-on amendments to the existing initial PBS listings items for gefitinib, erlotinib, afatinib and osimertinib in the first-line setting for Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC. The flow-on amendments are intended to exclude patients with EGFR ex20ins-positive NSCLC with the addition of the clinical criterion: 'Patient must not have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation'.</p>

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<p align="center">BLINATUMOMAB</p> <p align="center">Powder for I.V. infusion 38.5 micrograms</p> <p align="center">Blincyto®</p> <p align="center">AMGEN AUSTRALIA PTY LIMITED</p> <p align="center">Matters outstanding (Change to existing listing)</p>	<p align="center">Measurable residual disease (MRD)-negative B-cell precursor acute lymphoblastic leukaemia (B- ALL)</p>	<p align="center">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. This matter was deferred at the July 2024 PBAC Meeting.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) listing of blinatumomab for the treatment of patients with B-ALL who are MRD negative following induction chemotherapy. At the July 2024 meeting, the PBAC had deferred blinatumomab for this indication, but was of a mind to recommend, pending advice from the TGA Delegate. At the November 2024 meeting, the PBAC noted that the TGA Delegate was supportive of the registration of blinatumomab for MRD-negative B-ALL, although noted the TGA Delegate was yet to finalise the wording of the specific indication. Further, the PBAC considered that the revised financial estimates were reasonable and advised that blinatumomab should join the existing risk sharing arrangement for blinatumomab and inotuzumab ozogamicin. As such, the PBAC was satisfied that the remaining outstanding issues relating to the application were satisfactorily resolved.</p> <p>The PBAC noted that flow-on changes would be required to the blinatumomab restrictions in the relapsed/refractory setting to allow retreatment in patients who have responded to blinatumomab.</p>
<p align="center">BUDESONIDE</p> <p align="center">Suppository 4 mg</p> <p align="center">Budenofalk®</p> <p align="center">DR FALK PHARMA AUSTRALIA PTY LTD</p> <p align="center">Category 4 (New PBS listing)</p>	<p align="center">Ulcerative colitis (UC)</p>	<p align="center">To request a General Schedule Unrestricted Benefit listing of a new form for the short-term treatment of mild to moderate UC limited to the rectum.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule unrestricted benefit listing of budesonide 4 mg suppository (BUS) under the same circumstances as the PBS-listed budesonide foam (rectal foam 2 mg per application, 14 applications, aerosol 16.8 g, 2; BUF). The PBAC noted the submission nominated BUF as the main comparator. The PBAC also noted other PBS-listed rectal corticosteroids (prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL, prednisolone (as sodium phosphate) 5 mg suppository, 10, and hydrocortisone acetate 10% enema, 21.1) and considered these were also relevant comparators. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of BUS would be acceptable if it were cost-minimised to the lowest cost comparator on a cost of treatment per day basis.</p>

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<p align="center">CAPIVASERTIB</p> <p align="center">Tablet 160 mg Tablet 200 mg</p> <p align="center">Truqap®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Category 1 (New PBS listing)</p>	<p align="center">Hormone receptor-positive (HR+) human epidermal growth factor receptor 2-negative (HER2-) locally advanced (unresectable) or metastatic breast cancer</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HR+/HER2- locally advanced unresectable or metastatic breast cancer with evidence of a serine/threonine protein kinase (AKT) pathway alteration, following recurrence or progression on or after endocrine therapy.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend capivasertib for treatment of HR+/ HER2 locally advanced unresectable or metastatic breast cancer with evidence of a AKT pathway alteration, following recurrence or progression on or after endocrine therapy. The PBAC noted that as an integrated codependent submission, the proposed MBS item for AKT pathway testing would be considered at the November 2024 MSAC meeting. The PBAC noted that there was a moderate clinical benefit for capivasertib compared with fulvestrant in terms of progression free survival, but no demonstrated improvement in overall survival. The PBAC considered that the clinical benefit in practice is likely to be further reduced as, for many patients, fulvestrant is not the most appropriate comparator and other more effective treatments would be preferred. The PBAC also noted inferior safety with increased risk of clinically significant grade 1-2 adverse events including hyperglycaemia, rash, and diarrhoea. The PBAC considered that the incremental cost-effectiveness ratio was high at the proposed price, and likely to be underestimated due to optimistic assumptions in the model, particularly the inclusion of an overall survival benefit for capivasertib and due to use of fulvestrant as the comparator.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

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<p align="center">CLOBETASOL</p> <p>Cream containing clobetasol propionate 500 micrograms per g, 30 g Ointment containing clobetasol propionate 500 micrograms per g, 30 g</p> <p align="center">Xobet®</p> <p align="center">ARROTEX PHARMACEUTICALS PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Corticosteroid responsive dermatoses</p>	<p align="center">To request a General Schedule Restricted Benefit listing for the treatment of corticosteroid responsive dermatoses.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule, Restricted Benefit listing of clobetasol propionate 0.05% cream and ointment for the treatment of corticosteroid-responsive dermatoses in patients who have inadequately responded to lower potency topical corticosteroids (TCS). The PBAC recommendation for listing was based on its assessment that the cost-effectiveness of clobetasol would be acceptable if it were cost minimised against betamethasone dipropionate cream and ointment, on the basis of a gram-for-gram equivalence of these therapies.</p> <p>The PBAC noted the submission was supported by a range of older studies of clobetasol and other TCS and considered that most had major methodological shortcomings, however when the totality of the evidence was considered, which included a systematic review in psoriasis, considered the claims of non-inferior comparative effectiveness and safety to betamethasone dipropionate was reasonable.</p> <p>The PBAC recommended the listing should limit supply of clobetasol propionate cream/ointment to 2 weeks at a time, as clobetasol is intended for short-term use and for small areas of affected skin only.</p>
<p align="center">DENOSUMAB</p> <p>Injection 60 mg in 1 mL pre-filled syringe</p> <p align="center">Jubbonti®</p> <p>Injection 120 mg in 1.7 mL</p> <p align="center">Wyost®</p> <p align="center">SANDOZ PTY LTD</p> <p align="center">Category 3 (New PBS listing)</p>	<p align="center">Osteoporosis Giant cell tumour of bone Bone metastases</p>	<p align="center">To request General Schedule Authority Required (STREAMLINED) listings of denosumab biosimilars under the same conditions as their respective reference biologics.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of new biosimilar of denosumab in the form of 60 mg in 1 mL pre-filled syringe (Jubbonti) under the same circumstances as the PBS-listed reference biologic Prolia, and a new listing of the biosimilar of denosumab in the form 120 mg in 1.7 mL injection vial (Wyost) under the same circumstances as the PBS-listed reference biologic Xgeva on a cost-minimisation basis. The PBAC advised the equi-effective doses were 1 mg of Jubbonti to 1 mg of Prolia, and 1 mg of Wyost to 1 mg of Xgeva. The PBAC noted the listing of Jubbonti and Wyost on the PBS was not expected to increase the overall use of denosumab on the PBS as it is expected that Jubbonti and Wyost would substitute for PBS listed Prolia and Xgeva, respectively. The PBAC considered the estimated net cost to the PBS/RPBS would be nil.</p>

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<p align="center">DROSPIRENONE</p> <p>Pack containing 24 tablets 4 mg and 4 inert tablets</p> <p align="center">Slinda®</p> <p>BESINS HEALTHCARE AUSTRALIA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Contraception</p>	<p align="center">To request a General Schedule unrestricted benefit listing.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of drospirenone 4 mg tablets (Slinda) as an Unrestricted Benefit. The PBAC noted comments from clinicians at the oral contraceptives stakeholder meeting, and comments from other health professionals and individuals, highlighting the importance of having a range of contraceptive options available on the PBS so that cost is not a barrier to accessing the most appropriate contraceptive. The PBAC also noted comments from health professionals and individuals stated that drospirenone offers advantages compared to other hormonal contraceptives currently PBS-listed, including having a longer pill-free window compared to other progestogen-only pills, and providing an additional option for patients who cannot use estrogen-containing contraceptives. The PBAC considered that the claim that drospirenone has superior efficacy compared to the progestogen-only pill containing levonorgestrel is plausible, although the magnitude of superior efficacy is uncertain. The PBAC considered that drospirenone provides an additional, different oral contraceptive option for patients and offers benefits in certain clinical situations compared to PBS-listed oral contraceptives. The PBAC therefore recommended listing drospirenone on the PBS at a price consistent with the price recommended for other newer oral contraceptive pills.</p>

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<p align="center">DURVALUMAB</p> <p>Solution concentrate for I.V. infusion 120 mg in 2.4 mL Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p align="center">Imfinzi®</p> <p align="center">OLAPARIB</p> <p>Tablet 100 mg Tablet 150 mg</p> <p align="center">Lynparza®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Advanced, metastatic or recurrent endometrial cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing of durvalumab in combination with platinum-based chemotherapy, followed by maintenance treatment with or without olaparib, for the treatment of advanced, metastatic or recurrent endometrial cancer.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended durvalumab for use in combination with platinum-based chemotherapy for the treatment of deficient mismatch repair (dMMR) endometrial cancer. For the dMMR population the PBAC accepted that durvalumab was non-inferior in terms of efficacy and safety compared to the nominated comparator, dostarlimab. The PBAC considered that the cost minimisation approach and financial impact estimates presented were generally reasonable and advised that durvalumab should join the existing risk sharing arrangement for endometrial cancer. The PBAC considered that over a mean duration of therapy of 20.5 months, durvalumab 32,712 mg was equivalent to dostarlimab 14,550 mg.</p> <p>The PBAC deferred making a recommendation for durvalumab, for use in combination with olaparib and platinum-based chemotherapy, for the treatment of proficient mismatch repair endometrial cancer due to ongoing TGA considerations.</p>
<p align="center">ENFORTUMAB VEDOTIN</p> <p>Powder for I.V. infusion 20 mg Powder for I.V. infusion 30 mg</p> <p align="center">Padcev®</p> <p align="center">ASTELLAS PHARMA AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer (la/mUC)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of la/mUC in combination with pembrolizumab.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of enfortumab vedotin in combination with pembrolizumab (EV+PEM) for the first line treatment of la/mUC. The PBAC was satisfied that EV+PEM would provide, for some patients, a significant improvement in efficacy over platinum based chemotherapy with gemcitabine. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of EV+PEM would be acceptable at the combined EV+PEM cost required to achieve an incremental cost-effectiveness ratio of around \$55,000 to < \$75,000 per quality-adjusted life-year gained and with a risk sharing arrangement that accounts for expenditure on the use of first line and subsequent line therapies.</p> <p>Flow on restriction changes were required to prevent retreatment with enfortumab vedotin in the third-line setting.</p>

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<p align="center">ENZALUTAMIDE</p> <p align="center">Capsule 40 mg</p> <p align="center">Xtandi®</p> <p align="center">ASTELLAS PHARMA AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Non-metastatic hormone-sensitive prostate cancer (mOHSPC)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) for the treatment of mOHSPC with or without concurrent treatment with androgen deprivation therapy.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend enzalutamide, for use with or without androgen deprivation therapy (ADT), for the treatment of patients who have mOHSPC with high-risk biochemical recurrence. Although the PBAC considered that the clinical claims of superior efficacy compared to the nominated comparator of ADT for both enzalutamide monotherapy and combination therapy were reasonable in terms of metastases free survival, the magnitude of benefit and applicability to the clinical practice setting was uncertain. The PBAC noted that the overall survival data were immature. Further, the PBAC considered that enzalutamide should be given in combination with ADT, rather than as monotherapy, due to improved efficacy. The PBAC considered that the economic model for enzalutamide plus ADT was unreliable, noting that the treatment benefit was likely substantially overestimated. In addition, the cost effectiveness relied on treatment being suspended if prostate-specific antigen levels became undetectable and the extent and duration of treatment suspension in clinical practice is unknown. The PBAC considered that the financial estimates were uncertain, noting the treatment duration was likely underestimated, although difficult to estimate given treatment suspensions, and patients currently accessing treatment under the metastatic hormone sensitive prostate cancer (mHSPC) PBS listings were not removed.</p> <p>The PBAC noted given the range of current and potential future PBS listings for novel hormonal agents for prostate cancer (mCRPC, mOCRPC, mHSPC and mOHSPC), as well as the potential overlap in the patient populations, that it may be possible for the restrictions to be combined and simplified.</p> <p><u>Sponsor's Comment:</u> Astellas looks forward to working with the PBAC and the Department, in the near future, to make enzalutamide available on the PBS for patients with mOHSPC as soon as possible.</p>

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<p align="center">EPCORITAMAB</p> <p align="center">Solution concentrate for subcutaneous injection 4 mg in 0.8 mL Solution for subcutaneous injection 48 mg in 0.8 mL</p> <p align="center">Epkiny®</p> <p align="center">ABBVIE PTY LTD</p> <p align="center">Category 1 (New PBS listing)</p>	<p align="center">Relapsed or refractory diffuse large B-cell lymphoma (RR-DLBCL)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of RR-DLBCL.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of epcoritamab for the treatment of patients with RR-DLBCL. The PBAC is satisfied that epcoritamab provides, for some patients, a significant improvement in efficacy over rituximab + gemcitabine + oxaliplatin, as a proxy for rituximab-based chemoimmunotherapy treatments. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of epcoritamab would be acceptable with a price reduction to achieve an acceptable incremental cost-effectiveness ratio using the pre-PBAC response economic model amended to include a revised hazard ratio for overall survival, and with a risk sharing arrangement to address concerns regarding the potential for use outside of the proposed restriction.</p>
<p align="center">ERENUMAB</p> <p align="center">Solution for subcutaneous injection 70 mg in 1 mL single dose pre-filled pen Solution for subcutaneous injection 140 mg in 1 mL single dose pre-filled pen</p> <p align="center">Aimovig®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Standard re-entry (New PBS listing)</p>	<p align="center">Chronic migraine</p>	<p align="center">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the prophylaxis of adults with chronic migraine who have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended erenumab for the prophylaxis of adults with chronic migraine who have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of erenumab would be acceptable if it were cost minimised to the least costly alternative therapy of the nominated comparators, galcanezumab, fremanezumab and eptinezumab. The PBAC considered that erenumab was non-inferior in terms of efficacy and safety compared to the nominated comparators. The PBAC advised that erenumab should join the existing risk sharing arrangement for this class of medicines with no increase to the expenditure caps. The PBAC considered erenumab could be listed for treatment-resistant migraine.</p> <p>The PBAC considered that the equi-effective doses of erenumab and the alternative therapies were:</p> <ul style="list-style-type: none"> • Erenumab 70 mg or 140 mg every 4 weeks • Galcanezumab 240 mg on Day 0, followed by 120 mg every month • Fremanezumab 225 mg every month • Eptinezumab 100 mg every 12 weeks

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<p align="center">ESTRADIOL</p> <p align="center">Transdermal gel (pump pack) 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses</p> <p align="center">Estrogel®</p> <p align="center">PROGESTERONE</p> <p align="center">Capsule 100 mg</p> <p align="center">Prometrium®</p> <p align="center">ESTRADIOL AND PROGESTERONE</p> <p align="center">Pack containing transdermal gel (pump pack) estradiol 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses and 30 capsules progesterone 100 mg (micronised)</p> <p align="center">Estrogel® Pro</p> <p align="center">BESINS HEALTHCARE AUSTRALIA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Menopausal hormone therapy (MHT)</p>	<p align="center">To request General Schedule unrestricted benefit listings.</p>	<p align="center">Recommended</p> <p>The PBAC recommended the listing of estradiol (Estrogel), progesterone (Prometrium) and estradiol and progesterone (Estrogel Pro) as General Schedule unrestricted benefit listings, and corresponding General Schedule restricted benefit listings for 60-day maximum dispensed quantities. The PBAC noted these products are currently available on the private market, however cost is a barrier to access for many women. The PBAC noted consumer comments stating it was important to have a range of MHT options available on the PBS, and that these products were effective in managing symptoms of menopause and provided benefits compared to other PBS-listed MHT products. In the context of limited clinical evidence, the PBAC found the consumer comments particularly useful in articulating patient-relevant outcomes, especially those from people currently supplied these products on the private market. The PBAC considered there was a public health need to have a range of clinically appropriate MHT options listed on the PBS. The PBAC considered there was a need to list both the individual products as well as the combination, to allow options based on individual patient needs.</p> <p>The PBAC considered there was sufficient evidence that Estrogel, Prometrium and Estrogel Pro are at least as effective as comparator products for the primary outcomes, and may offer small differences compared to MHT options currently PBS-listed. However, these differences were difficult to quantify and the PBAC considered these differences to be marginal and/or highly uncertain. The PBAC considered the claim that micronised progesterone has a lower breast cancer risk compared to medroxyprogesterone acetate was uncertain. The PBAC recommended listing of the three products at a price it considered acceptable in the context of uncertainty in the magnitude of benefits.</p>

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<p align="center">FENFLURAMINE</p> <p align="center">Oral solution 2.2 mg (as hydrochloride) per mL, 360 mL</p> <p align="center">Fintepla®</p> <p align="center">UCB AUSTRALIA PROPRIETARY LIMITED</p> <p align="center">Category 1 (New PBS listing)</p>	<p align="center">Seizures associated with Dravet Syndrome</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of seizures associated with Dravet Syndrome.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule, Authority Required listing of fenfluramine for the treatment of seizures associated with Dravet Syndrome, as an additional therapy to be used in combination with at least two other anti-epileptic drugs. In recommending the listing, the PBAC acknowledged the high clinical need for additional therapies for this refractory and severe form of epilepsy. The PBAC considered the available evidence supported a conclusion that fenfluramine is an effective therapy for the treatment of Dravet Syndrome and was satisfied that fenfluramine provides, for some patients, a significant improvement in efficacy over cannabidiol. The Committee considered fenfluramine was acceptably cost-effective at the price proposed in the Pre-PBAC Response, based on a cost per responder approach. The PBAC considered that, on balance, and noting the small, well defined population, the fenfluramine utilisation estimates provided in the submission were reasonable.</p> <p>The Committee also welcomed the input from clinicians, patients, and their parents and caregivers, who described the effectiveness of fenfluramine and highlighted the additional benefits of treatment including improved development, cognitive and physical ability whilst on treatment.</p>

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<p align="center">FINGOLIMOD</p> <p>Capsule 250 micrograms (as hydrochloride) Capsule 500 micrograms (as hydrochloride)</p> <p align="center">Gilenya®</p> <p align="center">OFATUMUMAB</p> <p>Solution for injection 20 mg in 0.4 mL pre-filled pen</p> <p align="center">Kesimpta®</p> <p align="center">SIPONIMOD</p> <p>Tablet 250 micrograms (as hemifumarate) Tablet 2 mg (as hemifumarate)</p> <p align="center">Mayzent®</p> <p>NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 4 (Change to existing listing)</p>	<p align="center">Multiple sclerosis (MS)</p>	<p align="center">To request an amendment to the listings for the treatment of MS to allow prescribing by nurse practitioners (NPs).</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the amendment to the PBS listings of fingolimod, ofatumumab and siponimod to allow NPs to initiate and continue treatment in consultation with a specialist physician for the treatment of MS. The PBAC considered adding NPs as eligible prescribers to the PBS listings would not result in an increased utilisation outside the intended population estimates considered when fingolimod, ofatumumab and siponimod were first PBS-listed for MS. The PBAC therefore considered the change was likely to result in a nil financial impact to the PBS and RPBS.</p> <p>The PBAC recommended the restriction changes to NP prescribing arrangements to flow-on to other disease modifying treatments listed on the PBS indicated for the treatment of MS which include ozanimod, cladribine, teriflunomide, peginterferon beta 1a, interferon beta 1b, glatiramer acetate, dimethyl fumarate and diroximel fumarate.</p>

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<p>FOLLITROPIN ALFA WITH LUTROPIN ALFA</p> <p>Injection 900 I.U. - 450 I.U. in 1.44 mL multi-dose cartridge</p> <p>Pergoveris®</p> <p>MERCK HEALTHCARE PTY LTD</p> <p>Category 3 (Change to existing listing)</p>	<p>Stimulation of follicular development</p>	<p>To request an amendment to the existing Section 100 (In Vitro Fertilisation Program) Authority Required (STREAMLINED) listing for the stimulation of follicular development to remove the requirement for titration of separate follicular stimulating hormone and luteinising hormone therapies after at least one cycle of treatment, and to request an increase to the maximum quantity.</p>	<p>Recommended</p>	<p>The PBAC recommended increasing the current maximum quantity for follitropin alfa 900 IU with lutropin alfa 450 IU in a 1.44 mL multi-dose cartridge (Pergoveris) for the stimulation of follicular development from 2 to 4 pens per prescription, based on evidence showing that most treatment cycles required 2 to 4 pens to complete a cycle. The PBAC also recommended removing the requirement for dose titration of individual follicle-stimulating hormone and luteinising hormone prior to treatment with Pergoveris in the clinical criteria. The PBAC considered the estimated financial implications from the proposed amendments to the Pergoveris restriction were reasonable.</p>
<p>FOSLEVODOPA WITH FOSCARBIDOPA</p> <p>Solution for subcutaneous infusion foslevodopa 2400 mg with foscarnidopa 120 mg in 10 mL</p> <p>Vyalev®</p> <p>ABBVIE PTY LTD</p> <p>Early re-entry (New PBS listing)</p>	<p>Advanced Parkinson disease (PD)</p>	<p>Resubmission to request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings for the treatment of advanced PD with severe disabling motor fluctuations not adequately controlled by oral therapy.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of foslevodopa with foscarnidopa (FosLD/FosCD) for the treatment of advanced PD with severe disabling motor fluctuations not adequately controlled by oral therapy. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of FosLD/FosCD would be acceptable if it were cost-minimised to levodopa/carbidopa intestinal gel (LCIG) and included in a risk sharing arrangement with LCIG to contain the risk of its use in a broader population. The PBAC considered that the re-submission had addressed the substantive outstanding issues identified at the May 2024 PBAC meeting. The PBAC considered the equi-effective doses to be 1.32 vials of FosLD/FosCD and 1.10 cassettes of LCIG per day.</p>

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<p align="center">GARADACIMAB</p> <p>Injection 200 mg in 1.2 mL pre-filled pen</p> <p align="center">TBD</p> <p>CSL BEHRING (AUSTRALIA) PTY LTD</p> <p align="center">Category 1 (New PBS listing)</p>	<p align="center">Hereditary angioedema (HAE)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (Telephone/Online) listing for the continuing treatment of HAE.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule, Authority Required listing of garadacimab for the prophylaxis of recurrent attacks of HAE Types I and II. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of garadacimab would be acceptable if it were cost-minimised against lanadelumab. The PBAC considered the equi-effective doses over 2 years from treatment initiation to be: garadacimab 5,000 mg and lanadelumab 7,821 mg. The PBAC advised that garadacimab should join the existing lanadelumab risk sharing arrangement with a small increase in expenditure caps due to switching of patients from C1-esterase inhibitor deficiency or dysfunction HAE who would not otherwise be treated with lanadelumab.</p> <p>The PBAC advised that flow-on changes would be required to the lanadelumab restriction to allow switching from garadacimab to lanadelumab and to prevent combination use with garadacimab.</p>
<p align="center">GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS</p> <p>Sachets containing oral powder 15 g, 30 (PKU Build 10)</p> <p align="center">PKU Build 10</p> <p>CORTEX HEALTH PTY LTD</p> <p align="center">Committee secretariat (New PBS listing)</p>	<p align="center">Phenylketonuria (PKU)</p>	<p align="center">To request a General Schedule Restricted Benefit listing of a new pack size for the dietary management of PKU.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended listing the 30-pack of glycomacropeptide and essential amino acids with vitamins and minerals sachets containing 15 g of oral powder (PKU Build 10) under the same conditions as the currently listed 60-pack size of PKU Build 10, except for the maximum quantity, for the dietary management of PKU. The PBAC considered that the 30-pack should be cost-minimised to the lowest cost comparator accepted by the Nutritional Products Working Party at an equivalent price per gram of protein equivalent. The PBAC considered that listing the new pack size would not have financial implications to the Government.</p>

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<p align="center">INCLISIRAN</p> <p>Injection 284 mg in 1.5 mL single use pre-filled syringe</p> <p align="center">Leqvio®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 3 (Change to existing listing)</p>	<p align="center">Familial heterozygous hypercholesterolaemia (FHeH) and Non-familial hypercholesterolaemia (non-FH)</p>	<p align="center">To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the initial treatment of FHeH and non-FH.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended a change to the restriction level of inclisiran (injection 284 mg in 1.5 mL single use pre-filled syringe) from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the initial and grandfather listings for treatment of FHeH and non-FH. The PBAC considered this change would reduce administrative burden for prescribers and would not result in an additional cost to the Government.</p>
<p align="center">INCLISIRAN</p> <p>Injection 284 mg in 1.5 mL single use pre-filled syringe</p> <p align="center">Leqvio®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 4 (Change to existing listing)</p>	<p align="center">Familial heterozygous hypercholesterolaemia (FHeH) and Non-familial hypercholesterolaemia (non-FH)</p>	<p align="center">To request an amendment to the listing for the treatment of FHeH and non-FH to allow prescribing by nurse practitioners (NPs).</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the amendment to the PBS listings of inclisiran to allow NPs to initiate and continue treatment of inclisiran, in consultation with a specialist physician for the treatment of HeFH and non-FH. The PBAC considered adding NPs as eligible prescribers to the PBS listings would not result in an increased utilisation outside the intended population estimates considered when inclisiran was first PBS-listed for HeFH and non-FH. The PBAC therefore considered the change was likely to result in a nil financial impact to the PBS and RPBS.</p> <p>The PBAC recommended that the restriction changes to NP prescribing arrangements to flow-on to evolocumab indicated for the treatment of HeFH and non-FH on the PBS.</p>

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<p align="center">INCOBOTULINUMTOXINA</p> <p>Lyophilised powder for injection 100 units</p> <p align="center">Xeomin®</p> <p align="center">MERZ AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Chronic sialorrhea</p>	<p>To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of chronic sialorrhea due to neurological disorders.</p>	<p align="center">Deferred</p>	<p>The PBAC deferred making a recommendation for the listing of incobotulinumtoxinA for the treatment of chronic sialorrhea due to neurological disorders. While the PBAC was of a mind to recommend incobotulinumtoxinA, the PBAC noted that an MSAC application for the administration of incobotulinumtoxinA for chronic sialorrhea was also required to ensure there would be access to the required MBS items. The PBAC considered that the evidence presented demonstrated an improvement in both the severity and frequency of sialorrhea compared with placebo. However, due to short trial durations and the lack of established minimal clinically important differences, the magnitude of this benefit was uncertain. The PBAC considered incobotulinumtoxinA was not cost-effective at the price proposed in the submission given optimistic assumptions included in the economic model. The PBAC advised that a price reduction would be required for incobotulinumtoxinA to be considered cost-effective. The PBAC considered that, on balance, the utilisation estimates provided in the submission were reasonable.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p align="center">INCOBOTULINUMTOXINA</p> <p>Lyophilised powder for injection 100 units</p> <p align="center">Xeomin®</p> <p align="center">MERZ AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p> <p align="center">WITHDRAWN</p>	<p align="center">Moderate to severe spasticity of the upper limb Dynamic equinus foot deformity</p>	<p>To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of moderate to severe spasticity of the upper limb and dynamic equinus foot deformity in patients with cerebral palsy aged 2 to 17 years.</p>	<p align="center">Not Applicable</p>	<p>This item was withdrawn.</p>

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<p align="center">IRINOTECAN</p> <p>Solution for I.V. infusion containing nanoliposomal irinotecan (as sucrosfate) 43 mg in 10 mL</p> <p align="center">Onivyde®</p> <p>SERVIER LABORATORIES (AUST.) PTY. LTD.</p> <p align="center">Standard re-entry (New PBS listing)</p>	<p align="center">Metastatic pancreatic adenocarcinoma (mPAC)</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, for use in combination with oxaliplatin, 5-fluorouracil and folinic acid, for the first-line treatment of mPAC.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend the listing of nanoliposomal irinotecan (nal-IRI), as part of the NALIRIFOX regimen (including oxaliplatin, 5-fluorouracil and folinic acid/leucovorin), for the treatment of mPAC. In not recommending the listing, the Committee considered the resubmission had not substantively addressed its previous concerns relating to the comparator and that the comparative clinical evidence did not adequately support the claims made in the submission. Therefore, the PBAC considered the economic analysis approach taken by the resubmission was not informative.</p> <p>The previous submission was considered in March 2024.</p> <p><u>Comparator: Weighted comparator of 75 % gemcitabine + nanoparticle albumin-bound paclitaxel (Gem+NabP) and 25 % regular irinotecan (as part of the FOLFIRINOX regimen).</u></p> <p>The PBAC considered the weighted comparator approach to be inappropriate, because the population for NALIRIFOX was most aligned with the population for FOLFIRINOX. Therefore, the Committee considered FOLFIRINOX was the appropriate main comparator.</p> <p>In addition to its view on the population in whom NALIRIFOX would likely be used, the PBAC also considered adverse event profiles of NALIRIFOX and Gem+NabP are different, and the gastrointestinal side effects of NALIRIFOX are more likely to require hospitalisation and negatively impact quality of life. The Committee considered, based on the available information, that NALIRIFOX and FOLFIRINOX were likely to have similar toxicities, further supporting its view on the population in whom NALIRIFOX is likely to be used.</p> <p><u>Clinical claim: Superior comparative effectiveness and 'has advantages' in terms of safety over FOLFIRINOX.</u></p> <p>The PBAC noted the claims relied on a one-step indirect treatment comparison using the GENERATE trial, however the Committee considered GENERATE was unlikely to be exchangeable with the pivotal trial evidence, nor applicable to</p>

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			<p>the Australian context and there was inadequate reporting of details such as analysis methodology. The indirect treatment comparison based on the GENERATE trial was therefore considered unreliable for decision-making. The PBAC maintained its view based on the analyses in the March 2024 evaluation and considered the claims of superior comparative effectiveness and ‘has advantages’ over FOLFIRINOX were not adequately supported.</p> <p><u>Economic claim: The resubmission presented a cost utility analysis (CUA) based on a weighted comparator approach which assumed 75 % Gem+NabP and 25 % FOLFIRINOX.</u> The Committee considered the approach was not appropriate, as FOLFIRINOX was the appropriate main comparator, and as the resubmission had not substantiated a claim of superior comparative effectiveness or safety, further considered the appropriate form of economic evaluation was a cost minimisation approach with FOLFIRINOX.</p> <p><u>Sponsor’s Comment:</u> Servier is disappointed by this outcome. Servier thanks the clinical community who had provided advice to inform the two submissions to PBAC, and thanks the patient community for their valuable input to the PBAC. Servier reaffirms its commitment to people living with metastatic pancreatic cancer and will continue to make nal-IRI available for patients via a private script.</p>

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<p align="center">IVOSIDENIB</p> <p align="center">Tablet 250 mg</p> <p align="center">Tibsovo®</p> <p align="center">SERVIER LABORATORIES (AUST.) PTY. LTD.</p> <p align="center">Early re-entry (New PBS listing)</p>	<p align="center">Bile duct cancer (cholangiocarcinoma)</p>	<p align="center">Resubmission 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 isocitrate dehydrogenase-1 (<i>IDH1</i>) mutation.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended ivosidenib, for treatment of locally advanced or metastatic cholangiocarcinoma with an <i>IDH1</i> mutation, in patients 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 reiterated its previous advice that the clinical evidence indicated that ivosidenib had a small progression free survival and overall survival advantage compared with standard treatment, for the small subset of patients with <i>IDH1</i> mutations. The PBAC noted that not all optimistic assumptions in the economic model had been revised as requested. The PBAC considered the incremental cost-effectiveness ratio remained high at the proposed price in the resubmission when the PBAC preferred assumptions are included in the model and a further price reduction would be required.</p>
<p align="center">LANADELUMAB</p> <p align="center">Injection 150 mg in 1 mL single use pre-filled syringe</p> <p align="center">Takhzyro®</p> <p align="center">TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.</p> <p align="center">Category 3 (New PBS listing)</p>	<p align="center">Hereditary angioedema (HAE)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing of a new form for the treatment of HAE Types 1 or 2 in patients aged 2 to 11 years.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of lanadelumab for the preventative treatment of HAE Types 1 or 2 in patients aged less than 12 years. The PBAC was satisfied that lanadelumab provides, for some patients, a substantial clinical benefit in terms of a reduction in HAE attack frequency versus on-demand treatment (ODT) with icatibant or C1 esterase inhibitor (C1-INH). The PBAC considered that the economic model used to support listing in the ≥12 yrs population could be used to support listing in the expanded population.</p> <p>The PBAC recommended that the lanadelumab restriction in the new patient group (patients aged less than 12 years) should be based on the same baseline HAE attack rate as the existing listing in patients aged ≥12 years (≥12 attacks in the preceding six months). While the submission had requested a lower baseline attack frequency for the <12 years population, the PBAC considered this was not adequately justified by the clinical data or economic evidence. As such, the PBAC considered that the 150 mg/1 mL presentation should be listed age agnostically, with a flow on change to the existing restriction for the 300 mg/2 mL presentation to also make that listing age agnostic.</p>

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<p align="center">LEUPRORELIN</p> <p>Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection set</p> <p>Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection set</p> <p>Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 30 mg, injection set</p> <p>Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 45 mg, injection set</p> <p align="center">Eligard®</p> <p>MUNDIPHARMA PTY LIMITED</p> <p align="center">Committee secretariat (Change to existing listing)</p>	<p align="center">Central precocious puberty Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate</p>	<p align="center">To request a modified injection device for the existing listing.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended Eligard 7.5 mg, 22.5 mg, 30 mg and 45 mg with the updated injection device be included in the existing PBS listings for leuprorelin (Eligard) for the respective strengths, alongside Eligard with the current injection device. The PBAC noted the intention was for the updated injection device to replace the currently PBS-listed injection device for Eligard. The PBAC advised the equi-effective doses were: Eligard 7.5 mg (updated injection device) = Eligard 7.5 mg (current injection device); Eligard 22.5 mg (updated injection device) = Eligard 22.5 mg (current injection device); Eligard 30 mg (updated injection device) = Eligard 30 mg (current injection device); Eligard 45 mg (updated injection device) = Eligard 45 mg (current injection device). The PBAC noted the listing of Eligard with the updated injection device is expected to have no net cost to the PBS.</p>

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<p align="center">LEVODOPA WITH CARBIDOPA AND ENTACAPONE</p> <p>Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg and with entacapone 20 mg per mL, 47 mL</p> <p align="center">Lecigon®</p> <p align="center">STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p>Matters arising from the minutes (New PBS listing)</p>	<p align="center">Advanced Parkinson disease</p>	<p align="center">To request the PBAC consider revised equi-effective doses for levodopa with entacapone and carbidopa intestinal gel (LECIG) to the nominated comparator, levodopa with carbidopa monohydrate intestinal gel (LCIG).</p>	<p align="center">Advice Provided</p>	<p>The PBAC provided further advice in regard to its July 2024 recommendation for the listing of LECIG cartridges for the treatment of advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment. While the PBAC did not accept the alternative equi-effective dosing outlined in the sponsor proposal, it did accept revisions to the equi-effective dosing recommended by the Committee in July 2024. As such, the PBAC advised that the cost-effectiveness of LECIG would be acceptable if it were cost-minimised against LCIG using the revised equi-effective doses recommended by the Committee. The PBAC therefore considered the following revised equi-effective dosing appropriate for the cost minimisation approach:</p> <ul style="list-style-type: none"> • 1.0 cartridge of LECIG (each cartridge contains 47 mL with a total of 940 mg of levodopa) • 0.65 cassette of LCIG (each cassette contains 100 mL with a total of 2,000 mg of levodopa). <p>The PBAC reaffirmed its July 2024 advice that LECIG 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.</p>
<p align="center">MACITENTAN WITH TADALAFIL</p> <p>Tablet containing macitentan 10 mg with tadalafil 40 mg</p> <p align="center">Opsynvi®</p> <p align="center">JANSSEN-CILAG PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Pulmonary arterial hypertension (PAH)</p>	<p align="center">To request a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for the continuing treatment of PAH in patients who are on stable doses of macitentan and tadalafil as combination therapy.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing of macitentan 10 mg with tadalafil 40 mg (Opsynvi®) for the continuing treatment of PAH in patients who are on stable doses of macitentan and tadalafil as combination therapy. The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of Opsynvi would be acceptable if it were cost-minimised against the dual therapy components prices of one macitentan 10 mg tablet with two x 20 mg tadalafil tablets.</p>

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<p align="center">MARIBAVIR Tablet 200 mg Livtency® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. Standard re-entry (New PBS listing)</p>	<p align="center">Post-transplant cytomegalovirus (CMV)</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for treatment of post-transplant CMV infection and disease that is refractory, resistant or intolerant to one or more prior therapies.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of maribavir, for the treatment of post-transplant CMV infection and disease that is resistant, refractory or intolerant to one or more prior therapies. The PBAC was satisfied that maribavir provides, for some patients, a significant improvement in efficacy over standard of care (including ganciclovir, valganciclovir, cidofovir and foscarnet). The PBAC recalled that it previously considered the comparative clinical evidence was subject to uncertainty due to the limitations of the pivotal randomised study. The PBAC noted that no additional data were available to address this uncertainty, but notwithstanding its limitations, maintained that the SOLSTICE trial suggests an advantage for maribavir in achieving viral clearance. The PBAC noted that the resubmission addressed some areas of uncertainty in the economic evaluation, though a high level of uncertainty remained, largely due to the lack of long-term data. The PBAC considered that the treatment duration for maribavir appeared to be overestimated in the economic evaluation and noted that the evaluation was sensitive to this value. Although the treatment duration of maribavir in clinical practice is uncertain, additional analyses with reduced treatment duration provided reasonable assurance that maribavir would be cost effective at the price proposed in the pre-PBAC response.</p>

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<p align="center">MOMELOTINIB</p> <p>Tablet 100 mg (as dihydrochloride monohydrate) Tablet 150 mg (as dihydrochloride monohydrate) Tablet 200 mg (as dihydrochloride monohydrate)</p> <p align="center">Ommjara®</p> <p align="center">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p align="center">Category 1 (New PBS listing)</p>	<p align="center">Myelofibrosis with moderate to severe anaemia</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for initial treatment and an Authority Required (STREAMLINED) listing for continuing treatment of intermediate or high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis in patients with moderate to severe anaemia and who are Janus kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of momelotinib, on the basis that it should be available for intermediate or high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis in patients with moderate to severe anaemia and who are JAK inhibitor naïve or have been treated with ruxolitinib. The PBAC's recommendation for listing was based on its assessment that the cost-effectiveness of momelotinib would be acceptable if it were cost-minimised against ruxolitinib. The PBAC accepted the claim of non-inferior effectiveness and overall non-inferior safety compared to ruxolitinib and agreed with the submission that momelotinib provides a clinically meaningful improvement in anaemia-related outcomes and has a safety advantage in lowering the risk of anaemia adverse events compared to ruxolitinib.</p> <p>The PBAC advised the appropriate equi-effective doses were momelotinib at a mean daily dose of 186.2 mg = ruxolitinib at a mean daily dose of 26.2 mg.</p> <p>The PBAC noted the flow-on changes to the listing of ruxolitinib to allow switching between these agents under limited circumstances.</p>
<p align="center">NINTEDANIB</p> <p>Capsule 100 mg Capsule 150 mg</p> <p align="center">Ofev®</p> <p align="center">BOEHRINGER INGELHEIM PTY LTD</p> <p align="center">Category 3 (Change to existing listing)</p>	<p align="center">Idiopathic pulmonary fibrosis (IPF) Progressive fibrosing Interstitial lung disease (PF-ILD)</p>	<p align="center">To request the PBAC consider the combined utilisation and financial estimates for the IPF and PF-ILD indications of nintedanib listed on the PBS.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend that the risk sharing arrangement (RSA) subsidisation caps for nintedanib for IPF and PF-ILD be combined. The PBAC advised that the evidence provided by the submission did not sufficiently justify the requested combination of the subsidisation caps and considered that the proposed arrangements would not adequately manage the risks originally identified in relation to the nintedanib listings. The PBAC considered that the current RSA for IPF has been working as intended to manage the uncertainty around the original financial estimates and cost-effectiveness for IPF, while the financial estimates for PF-ILD appear to have been overestimated.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

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<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the perioperative treatment of NSCLC.</p>	<p align="center">Not Applicable</p>	<p align="center">To be considered at a future PBAC meeting</p>
<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Urothelial carcinoma (UC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the first-line treatment of cisplatin-eligible adult patients with unresectable or metastatic UC.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of nivolumab for the first-line treatment of cisplatin-eligible adult patients with unresectable or metastatic UC. The PBAC was satisfied that nivolumab provides, for some patients, a small improvement in efficacy over standard of care - consisting of gemcitabine-cisplatin chemotherapy. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of nivolumab would be acceptable with a price reduction to achieve an incremental cost-effectiveness ratio of around \$55,000 to < \$75,000 per quality-adjusted life year gained (using the ESC-respecified economic model) and with a risk sharing arrangement that accounts for expenditure on the use of first line and subsequent line therapies.</p>

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<p align="center">OLAPARIB</p> <p align="center">Tablet 100 mg Tablet 150 mg</p> <p align="center">Lynparza®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Standard re-entry (New PBS listing)</p>	<p align="center">Metastatic castration-resistant prostate cancer (mCRPC)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of mCRPC in patients with a Class 4 or 5 Breast Cancer Gene 1 (<i>BRCA1</i>) or <i>BRCA2</i> mutation who have not received prior treatment with a novel hormonal agent (NHA).</p>	<p align="center">Recommended</p>	<p>The PBAC recommended olaparib, for use in combination with abiraterone, for the first line treatment of mCRPC patients with <i>BRCA1/2</i> pathogenic variants who have not received prior treatment with a NHA. The PBAC considered that the economic model comparing olaparib plus abiraterone to NHA monotherapy was unreliable for decision making but noted that olaparib plus abiraterone was non-inferior in terms of effectiveness and safety compared to talazoparib plus enzalutamide, and that therefore the price of olaparib in this setting should be no higher than the price of talazoparib that was considered cost-effective at the July 2024 meeting. The PBAC considered that olaparib 600 mg daily was equivalent to talazoparib 0.5 mg daily. The PBAC considered that it would be appropriate for olaparib to join same risk sharing arrangement as talazoparib, without adjustment to the financial caps.</p> <p>The PBAC noted that flow on changes to the restriction criterion for talazoparib, enzalutamide, olaparib monotherapy, abiraterone and abiraterone with methylprednisolone would be required.</p>

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<p align="center">PALOVAROTENE</p> <p align="center">Capsule 1 mg Capsule 1.5 mg Capsule 2.5 mg Capsule 5 mg Capsule 10 mg</p> <p align="center">Sohonos®</p> <p align="center">IPSEN PTY LTD</p> <p align="center">Category 1 (New PBS listing)</p>	<p align="center">Fibrodysplasia Ossificans Progressiva (FOP)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for chronic treatment of FOP and an Authority Required (STREAMLINED) listing for flare-up treatment of FOP.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of palovarotene for the treatment of FOP. The PBAC recognised the high and urgent clinical need for treatments for FOP, which is an ultra-rare disease with very substantial impacts on quality of life for patients and their carers. The PBAC was satisfied that palovarotene provides, for some patients, a reduction in annualised heterotropic ossification (when bone tissue develops in soft tissues) that may have a clinically relevant benefit. The PBAC considered that the proposed cost was very high and uncertain as it was dependent on age-based dosing and also the frequency and duration of flares (which require higher dosing). The PBAC considered that the economic model presented in the submission was not sufficiently reliable for decision-making in part due to the limited long-term data available on changes in heterotropic ossification volume and patient functioning that were required to inform the model. The PBAC also advised the clinical trial data and uncertain economic modelling meant the rule of rescue claim that palovarotene provided a worthwhile clinical improvement sufficient to qualify as a rescue from the condition, could not be adequately supported. In the context of this ultra-rare and life-limiting disease, and the importance of even small clinical gains in limiting heterotropic ossification, the PBAC considered palovarotene would be acceptably cost-effective with a reduction in cost that resulted in a lower cost per patient per year, in line with that for previously recommended treatments for rare diseases funded on the PBS when accounting for the clinical need, available evidence and size of the patient population. The PBAC noted that the estimated utilisation of palovarotene remains difficult to predict given treatment costs increase when patients experience flares, and as such a risk-sharing arrangement would be an appropriate way to limit costs per patient per year to the agreed amount and contain overall financial expenditure.</p>

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<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">MERCK SHARP & DOHME (AUSTRALIA) PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Renal cell carcinoma (RCC)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the adjuvant treatment of clear cell RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of pembrolizumab for the adjuvant treatment of patients with RCC with clear cell component who are at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. The PBAC considered that pembrolizumab provided a meaningful improvement in disease free survival and overall survival compared with surveillance. The PBAC advised the subsequent therapies included in the economic model presented in the pre-PBAC response should be revised and a price reduction would be required for pembrolizumab to be considered cost effective in the adjuvant treatment setting. The PBAC considered the financial estimates should account for reduced use in the later line treatment setting. The PBAC considered the expenditure for listing pembrolizumab (accounting for reduced later line use) should be included in the current risk sharing arrangement in place for RCC.</p> <p>The PBAC advised flow on changes are required for the pembrolizumab and nivolumab listings in the metastatic treatment setting to restrict limit use of programmed cell death (ligand) 1 inhibitors to once in a lifetime.</p>
<p>PNEUMOCOCCAL (CONJUGATE, 21-VALENT) VACCINE</p> <p align="center">Injection (0.5 mL)</p> <p align="center">Capvaxive®</p> <p align="center">MERCK SHARP & DOHME (AUSTRALIA) PTY LTD</p> <p align="center">Category 2 (New NIP listing)</p> <p align="center">WITHDRAWN</p>	<p align="center">Prevention of pneumococcal disease</p>	<p>To request a National Immunisation Program listing for the prevention of pneumococcal disease in adults.</p>	<p align="center">Not Applicable</p>	<p align="center">This item was withdrawn.</p>

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<p align="center">RAVULIZUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 3 mL Solution concentrate for I.V. infusion 1,100 mg in 11 mL</p> <p align="center">Ultomiris®</p> <p align="center">ALEXION PHARMACEUTICALS AUSTRALASIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Neuromyelitis Optica Spectrum Disorder (NMOSD)</p>	<p align="center">To request a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for the treatment of adult patients with NMOSD.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of ravulizumab for the treatment of NMOSD on the basis that it should be available only under special arrangements under Section 100. The PBAC recognised the very high unmet need for treatments for NMOSD which is a rare condition with substantial impacts on quality of life. The PBAC was satisfied that ravulizumab provides, for some patients, a significant improvement in efficacy over best supportive care. The PBAC considered that the economic model presented in the submission was not sufficiently reliable for decision-making in part due to the limited long-term data available and the complex and unpredictable nature of the condition. Overall, the PBAC considered that in the context of this rare and severe condition, ravulizumab would be considered acceptably cost-effective with a reduction in treatment costs that would result in an acceptable cost-per-relapse avoided. The PBAC considered that any remaining uncertainties should be managed by a risk sharing arrangement.</p>
<p>RELUGOLIX WITH ESTRADIOL AND WITH NORETHISTERONE ACETATE</p> <p>Tablet containing relugolix 40 mg with estradiol (as hemihydrate) 1 mg and with norethisterone acetate 0.5 mg</p> <p align="center">Ryeqo®</p> <p align="center">GEDEON RICHTER AUSTRALIA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Endometriosis</p>	<p align="center">To request reconsideration of the utilisation and financial estimates of the General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe pain associated with endometriosis.</p>	<p align="center">Advice provided</p>	<p>The PBAC did not revise its March 2024 advice in relation to the utilisation estimates of relugolix with estradiol and with norethisterone. The PBAC considered that the submission did not provide sufficient justification to support the proposed financial estimates and risk sharing arrangement. The PBAC noted that the difference in financial estimates was largely due to the increased uptake rates applied. The PBAC reiterated that there was a high level of uncertainty in relation to the prevalence and uptakes estimates, and that the submission's proposed estimates appeared to be substantially overestimated. The PBAC accepted the submission's proposal for an additional clinical criterion for the PBS restriction to limit treatment to a lifetime maximum of 24 months. This is to be applied to the March 2024 recommended listing.</p>

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<p align="center">RESPIRATORY SYNCYTIAL VIRUS VACCINE</p> <p align="center">Injection (0.5 mL)</p> <p align="center">Abrysvo®</p> <p align="center">PFIZER AUSTRALIA PTY LTD</p> <p align="center">Category 2 (New NIP listing)</p>	<p align="center">Respiratory syncytial virus (RSV)</p>	<p align="center">To request a National Immunisation Program (NIP) listing for the prevention of RSV lower respiratory tract disease in individuals 60 years of age and above who meet certain criteria.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended that respiratory syncytial virus vaccine (Abrysvo, RSVpreF) be a designated vaccine for the purposes of the <i>National Health Act 1953</i> for the prevention of lower respiratory tract illness (LRTI) caused by RSV for adults 75 years of age and above, and for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years. The PBAC considered that the vaccine was superior to no vaccine in terms of effectiveness with an acceptable safety profile, however the duration and magnitude of protection in the requested populations was uncertain. The PBAC advised that inputs for the economic evaluation relating to the duration of protection, and the incidence of hospitalisations due to RSV and associated mortality should be revised, and that RSVpreF would be cost-effective with an incremental cost-effectiveness ratio of no more than \$5,000 to < \$15,000 per quality-adjusted life year gained. The PBAC did not recommend NIP listing for adults aged 60 to 74 years with at least one risk factor for severe RSV disease (the third population that was supported by the Australian Technical Advisory Group on Immunisation [ATAGI]) because it considered that the economic evaluation did not provide a robust estimate of cost-effectiveness for this population, with the baseline risks and benefits unclear, but likely overestimated; with uncertainty around the total financial implications in this group. The PBAC advised that a new submission would be required to assess this population.</p>

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<p align="center">RIBOCICLIB Tablet 200 mg Kisqali® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 2 (Change to existing listing)</p>	<p align="center">Hormone receptor-positive (HR+) human epidermal growth factor receptor 2-negative (HER2-) breast cancer</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the adjuvant treatment of HR+/HER2- lymph node positive, invasive, resected early breast cancer at high risk of disease recurrence.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule Authority Required listing of ribociclib, in combination with standard adjuvant endocrine therapy (ET), for the treatment of HR+, HER2-, lymph node positive, invasive, resected early breast cancer (eBC) at high risk of disease recurrence. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of ribociclib would be acceptable if it were cost-minimised to abemaciclib.</p> <p>The PBAC considered that there was acceptable clinical evidence to support the non-inferiority of ribociclib to abemaciclib, and a moderate unmet clinical need for those patients for whom abemaciclib is unsuitable. The PBAC considered the equi-effective doses to be ribociclib 366.0 mg once daily on days 1 to 21 of a 28-day cycle for 114.84 weeks and abemaciclib 121.34 mg twice daily for 76.56 weeks.</p> <p>The PBAC considered it would be appropriate for ribociclib to join the existing risk-sharing arrangement for abemaciclib.</p> <p>The PBAC recommended that eBC patients who experience intolerance to a CDK4/6 inhibitor of a severity necessitating permanent treatment withdrawal should be able to switch to another CDK4/6 inhibitor and noted that flow-on changes to the restriction criteria for abemaciclib would be required to allow this.</p>

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<p align="center">RIVAROXABAN</p> <p align="center">Tablet 2.5 mg Tablet 10 mg</p> <p align="center">Xarelto®</p> <p align="center">ALPHAPHARM PTY LTD Category 4 (New PBS listing)</p>	<p align="center">Prevention of venous thromboembolism Chronic stable atherosclerotic disease (CSAD)</p>	<p align="center">To request General Schedule Authority Required (STREAMLINED) listings of new pack sizes with amended maximum quantities and number of repeats for the treatment of chronic stable atherosclerotic disease and the prevention of recurrent venous thromboembolism (VTE).</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of rivaroxaban (Xarelto®) tablets 2.5 mg 98-pack (for treatment of CSAD, chronic coronary artery disease and/or peripheral artery disease) and 10 mg 14-pack (for prevention of VTE in total hip or knee replacement), as a General Schedule Authority Required (Streamlined) listing, as per the currently listed rivaroxaban 2.5 mg 60-pack and 10 mg 15-pack, for the same indications. The PBAC recommendation was, among other matters, made on a cost-minimisation basis with equivalent price per tablet.</p>
<p align="center">SACUBITRIL WITH VALSARTAN</p> <p>Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg</p> <p align="center">Entresto®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 4 (Change to existing listing)</p>	<p align="center">Chronic heart failure (CHF)</p>	<p align="center">To request an amendment to the General Schedule Authority Required (STREAMLINED) listings for the treatment of chronic heart failure to allow treatment initiation by nurse practitioners (NPs).</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the amendment to the PBS listings of sacubitril + valsartan (Entresto) to allow NPs to initiate Entresto for the treatment of CHF. The PBAC considered that allowing NPs to initiate treatment with Entresto on the PBS would not result in an increased utilisation outside the intended population estimates considered when Entresto was first PBS-listed for CHF. The PBAC therefore considered the change was likely to result in a nil financial impact to the PBS and RPBS.</p>

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<p align="center">SEMAGLUTIDE</p> <p>Solution for injection 2 mg in 3 mL pre-filled pen</p> <p align="center">Ozempic®</p> <p>NOVO NORDISK PHARMACEUTICALS PTY. LIMITED</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Diabetes mellitus type 2 (T2DM)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing of a new strength for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of T2DM.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of semaglutide (Ozempic) 2 mg in 3 mL pre-filled injector pen, under the same circumstances as the current PBS-listed semaglutide 2 mg in 1.5 mL in pre-filled injector pen, for the treatment of type 2 diabetes. The PBAC noted the applicant's intention to replace the current PBS listed semaglutide 2 mg in 1.5 mL pre-filled injector pen with the 2 mg in 3 mL pre-filled injector pen.</p> <p>The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of semaglutide 2 mg in 3 mL would be acceptable if it were cost-minimised against semaglutide 2 mg in 1.5 mL. The PBAC advised that the equi-effective doses were semaglutide 2 mg in 3 mL (0.68 mg/mL) pen device = semaglutide 2 mg in 1.5 mL (1.34 mg/mL) pen device.</p>
<p align="center">TIOTROPIUM WITH OLODATEROL</p> <p>Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses, pack of 2</p> <p align="center">Spiolto® Respimat®</p> <p>BOEHRINGER INGELHEIM PTY LTD</p> <p align="center">Committee secretariat (New PBS listing)</p>	<p align="center">Chronic obstructive pulmonary disease (COPD)</p>	<p align="center">To request listing of a new pack size for 60-day prescribing for the treatment of COPD.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule Authority Required (STREAMLINED) listing of a new pack size of tiotropium with olodaterol (Spiolto Respimat) with 2 cartridges x 60 actuations for the treatment of COPD under the same circumstances as the currently listed Spiolto Respimat with corresponding 60-day maximum dispensed quantities (MDQ). The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of 1 x double pack of Spiolto Respimat would be acceptable if it were cost-minimised against 2 x single packs of Spiolto Respimat.</p> <p>The PBAC advised that the double pack should be the only listed pack size for the 60-day MDQ listing, while the single pack should remain listed against only the 30-day prescription listings. The PBAC noted that the single pack would be removed from the 60-day MDQ listing by the Department when implementing the double pack listing. The PBAC requested the Department work with the sponsor to minimise impacts on patients with existing MDQ prescriptions for the single packs who require a new prescription for the double pack, such as through the application of a Supply Only period.</p>

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<p align="center">TIOTROPIUM</p> <p>Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (2 x 60 actuations), pack of 2</p> <p align="center">Spiriva® Respimat®</p> <p align="center">BOEHRINGER INGELHEIM PTY LTD</p> <p align="center">Committee secretariat (New PBS listing)</p>	<p align="center">Severe asthma Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease (COPD)</p>	<p align="center">To request listing of a new pack size for 60-day prescribing for the treatment of severe asthma and for bronchospasm and dyspnoea associated with COPD.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule Authority Required (STREAMLINED) listing of a new pack size of tiotropium (Spiriva Respimat) with 2 cartridges x 60 actuations for the treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease (COPD) and for the treatment of severe asthma under the same circumstances as the currently listed Spiriva Respimat with corresponding 60-day maximum dispensed quantities (MDQ). The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of 1 x double pack of Spiriva Respimat would be acceptable if it were cost-minimised against 2 x single packs of Spiriva Respimat.</p> <p>The PBAC advised that the double pack should be the only listed pack size for the 60-day MDQ listing, while the single pack should remain listed against only the 30-day prescription listings. The PBAC noted that the single pack would be removed from the 60-day MDQ listing by the Department when implementing the double pack listing. The PBAC requested the Department work with the sponsor to minimise impacts on patients with existing MDQ prescriptions for the single packs who require a new prescription for the double pack, such as through the application of a Supply Only period.</p>
<p align="center">TIRZEPATIDE</p> <p>Solution for injection 2.5 mg in 0.5 mL vial/pre-filled pen</p> <p>Solution for injection 5 mg in 0.5 mL vial/pre-filled pen</p> <p>Solution for injection 7.5 mg in 0.5 mL vial/pre-filled pen</p> <p>Solution for injection 10 mg in 0.5 mL vial/pre-filled pen</p> <p>Solution for injection 12.5 mg in 0.5 mL vial/pre-filled pen</p> <p>Solution for injection 15 mg in 0.5 mL vial/pre-filled pen</p>	<p align="center">Diabetes mellitus type 2 (T2DM)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (Written) listing as dual therapy in combination with metformin for the treatment of adult patients with inadequately controlled T2DM who (i) have comorbid severe obesity or (ii) identify as Aboriginal and Torres Strait Islander.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend tirzepatide for the treatment of adult patients with inadequately controlled T2DM who (i) have comorbid severe obesity or (ii) identify as Aboriginal and Torres Strait Islander. The PBAC considered that tirzepatide 10 mg once weekly and tirzepatide 15 mg once weekly were superior in terms of effectiveness for glycaemic benefits and short term weight loss compared to semaglutide 1 mg once weekly in the target subgroup with severe obesity, but advised this claim was not supported for tirzepatide 5 mg once weekly compared to semaglutide 1 mg once weekly. The PBAC considered the non-inferior safety claim was not adequately supported for any of the comparisons. The PBAC noted the resubmission provided a revised economic model with further amendments to the model provided in the pre-PBAC response along with a price reduction. The PBAC considered the pre-PBAC response economic model did not</p>

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<p align="center">Mounjaro®</p> <p>Injection 4.17 milligrams per mL (2.5 mg per dose) in multi-dose pre-filled pen, 4 doses</p> <p>Injection 8.33 milligrams per mL (5 mg per dose) in multi-dose pre-filled pen, 4 doses</p> <p>Injection 12.5 milligrams per mL (7.5 mg per dose) in multi-dose pre-filled pen, 4 doses</p> <p>Injection 16.67 milligrams per mL (10 mg per dose) in multi-dose pre-filled pen, 4 doses</p> <p>Injection 20.83 milligrams per mL (12.5 mg per dose) in multi-dose pre-filled pen, 4 doses</p> <p>Injection 25 milligrams per mL (15 mg per dose) in multi-dose pre-filled pen, 4 doses</p> <p align="center">Mounjaro® KwikPen®</p> <p align="center">ELI LILLY AUSTRALIA PTY LTD</p> <p align="center">Standard re-entry (New PBS listing)</p>			<p>adequately address the concerns raised by the Committee in July 2023 or the subsequent concerns raised by the Economics Sub-Committee (ESC) in this consideration. The PBAC considered that the incremental cost-effectiveness ratio was high, inadequately justified, and uncertain. The PBAC advised that a revised economic model including a price reduction would be required for the proposed listing to be considered cost-effective. The PBAC noted the financial impact was extremely high at the prices proposed in the pre-PBAC response, although considered it likely overestimated. The PBAC considered the risk sharing arrangements proposed in the pre-PBAC response were unlikely to satisfactorily mitigate the risk to government of use outside of the proposed restriction.</p> <p>The previous submission was considered in July 2023.</p> <p><u>Comparator: semaglutide</u> The PBAC considered that the nomination of semaglutide as the main comparator was appropriate.</p> <p><u>Clinical claim: Tirzepatide is superior in terms of efficacy and non-inferior in terms of safety compared to semaglutide.</u> The PBAC reaffirmed its July 2023 advice that the claim of superior comparative effectiveness was reasonable for tirzepatide 5 mg once weekly compared to semaglutide 0.5 mg once weekly and for tirzepatide 10 mg once weekly and tirzepatide 15 mg once weekly compared to semaglutide 1 mg once weekly. The PBAC considered results for 10 mg and 15 mg tirzepatide in the subgroup with BMI ≥ 35 kg/m² appeared consistent with results in the whole trial population. The PBAC considered the claim of superior comparative efficacy for tirzepatide 5 mg once weekly compared to semaglutide 0.5 mg once weekly in the subgroup with BMI ≥ 35 kg/m² was uncertain but likely reasonable.</p> <p>The PBAC also reaffirmed its July 2023 advice that the comparison of tirzepatide 5 mg and semaglutide 1 mg remained relevant, and noted that this comparison did not</p>

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			<p>support a clinically meaningful difference in either the whole trial population or the subgroup with BMI ≥ 35 kg/m².</p> <p>The PBAC reaffirmed its July 2023 advice that the claim of non-inferior comparative safety was not adequately supported by the data for any of the comparisons.</p> <p><u>Economic claim: Cost utility analysis of tirzepatide versus semaglutide</u></p> <p>The PBAC considered the pre-PBAC response economic model did not adequately address the concerns raised by the Committee in July 2023 or the subsequent concerns raised by the ESC in this consideration. The PBAC also reaffirmed its July 2023 advice that an ICER in the order of \$25,000 to < \$35,000 per QALY would be appropriate.</p> <p><u>Sponsor's Comment:</u></p> <p>Eli Lilly wishes to thank all of the healthcare professionals, professional societies, leadership bodies, patient organisations and consumers for their support of the tirzepatide (Mounjaro®) submission. We are disappointed by the PBAC's decision not to recommend the PBS listing of tirzepatide for the treatment of adult patients with inadequately controlled T2D who have comorbid severe obesity or identify as Aboriginal and Torres Strait Islander. Eli Lilly remains committed to making this medicine accessible for adult patients living with T2D.</p>

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<p align="center">TISLELIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Tevimbra®</p> <p align="center">BEIGENE AUS PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Oesophageal squamous cell carcinoma (OSCC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of patients with unresectable advanced, recurrent, or metastatic OSCC.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Authority Required (Streamlined) listing of tislelizumab under the Section 100 (Efficient Funding of Chemotherapy) Program for advanced or metastatic gastro-oesophageal cancer. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of tislelizumab in this population would be acceptable if it were cost-minimised to nivolumab. The PBAC considered the equi-effective doses to be tislelizumab 200 mg 3-weekly and nivolumab 360 mg 3-weekly. The PBAC considered it was appropriate for tislelizumab to be included in the risk sharing arrangement currently in place for gastro-oesophageal cancers without an increase in the expenditure caps.</p> <p>The PBAC considered it would be preferable, and clinically appropriate for the listing for tislelizumab (and nivolumab) to not be restricted to the advanced and metastatic settings but to include all stages of the disease with a listing for 'gastro-oesophageal cancers'. However, financial estimates would be required to support this listing change, and as such the PBAC requested sponsors provide these estimates to facilitate the broader listing.</p>
<p align="center">TRIGLYCERIDES, LONG CHAIN WITH GLUCOSE POLYMER</p> <p align="center">Oral liquid 1 L, 6 (ProZero)</p> <p align="center">ProZero®</p> <p align="center">VITAFLO AUSTRALIA PTY LIMITED</p> <p align="center">Category 3 (Change to existing listing)</p>	<p align="center">Proven inborn errors of protein metabolism</p>	<p align="center">To request an amendment to the restriction level from Restricted Benefit to Authority Required (STREAMLINED) for the treatment of proven inborn errors of protein metabolism. The submission also requested amendments to the clinical criteria.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended reducing the maximum quantity packs of triglycerides, long chain with glucose polymer 6 x 1 L cartons (ProZero®) for the treatment of proven inborn errors of protein metabolism from 4 (24 L) to 3 (18 L), consistent with the usual dosing.</p> <p>The PBAC did not recommend the request to increase the authority level of ProZero 1 L for the treatment of proven inborn errors of protein metabolism from Restricted Benefit to Authority Required (STREAMLINED), nor did it recommend the inclusion of new population criteria (children aged 1 year or older, pre-conception/pregnant women, elderly ≥65 years) for the existing ProZero 1 L listing. The PBAC advised that the revised target population, particularly by age, could not be clinically justified and advised that these proposed changes may result in an unmet clinical need for some patients who are currently receiving PBS-subsidised access to ProZero 1 L.</p>

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<p align="center">USTEKINUMAB</p> <p>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</p> <p align="center">Steqeyma®</p> <p>CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p> <p align="center">Category 3 (New PBS listing)</p>	<p>Severe chronic plaque psoriasis Severe psoriatic arthritis Severe Crohn disease Complex refractory fistulising Crohn disease Moderate to severe ulcerative colitis</p>	<p>To request General Schedule and Section 100 (Highly Specialised Drugs Program) listings of an ustekinumab biosimilar 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.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of a new biosimilar brand of ustekinumab (Steqeyma) in the forms of injection 45 mg in 0.5 mL in 0.5 mg pre-filled syringe (PFS), injection 90 mg in 1 mL PFS, and solution for I.V. infusion 130 mg in 26 mL under the same circumstances as the PBS-listed reference biologic, Stelara®.</p> <p>The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Steqeyma would be acceptable if it were cost-minimised to Stelara.</p> <p>The PBAC advised that biosimilar uptake drivers should apply to Steqeyma, that is, to have an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Steqeyma listings encouraging use of the biosimilar brand for treatment naïve patients.</p> <p>The PBAC advised that equivalent strengths and forms of Stelara PFS and Steqeyma PFS should be treated as equivalent to each other; and equivalent strengths and forms of Stelara and Steqeyma injection vial should be treated as equivalent for the purposes of substitution (i.e. 'a' flagged in the schedule). The PBAC advised the equi-effective doses to be the following:</p> <ul style="list-style-type: none"> • Steqeyma 1 x 45 mg PFS = Stelara 1 x 45 mg PFS • Steqeyma 1 x 45 mg PFS = Stelara 1 x 45 mg injection vial • Steqeyma 1 x 90 mg PFS = Stelara 1 x 90 mg PFS • Steqeyma 1 x 90 mg PFS = Stelara 2 x 45 mg injection vial • Steqeyma 1 x 130 mg injection vial = Stelara 1 x 130 mg injection vial

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<p align="center">VUTRISIRAN</p> <p>Injection 25 mg (as sodium) in 0.5 mL pre-filled syringe</p> <p align="center">Amvuttra®</p> <p align="center">MEDISON PHARMA AUSTRALIA PTY LIMITED</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Hereditary transthyretin-mediated (hATTR) amyloidosis</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of hATTR amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program - Public and Private Hospitals), Authority Required listing of vutrisiran for the treatment of hATTR amyloidosis in patients with stage 1 or 2 polyneuropathy. In making this recommendation, the PBAC considered that the available evidence supported a claim that vutrisiran is of comparable effectiveness and safety to patisiran, however uncertainties remained regarding the long-term benefits and risks of both medicines. The PBAC recalled that when recommending patisiran for listing in December 2023, it had considered long term cost-effectiveness of patisiran was uncertain due to limitations of the available trial evidence, and advised that a review of cost-effectiveness should be conducted three years after PBS listing of patisiran. The PBAC advised that a reassessment of vutrisiran should be conducted at the same time as the scheduled patisiran review, no later than three years after PBS listing of patisiran. The PBAC considered, given the comparable effectiveness and safety to patisiran, that the listing should not result in any additional net cost to Government.</p> <p>The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of vutrisiran would be acceptable if it were cost-minimised against patisiran. The Committee advised the equi-effective doses were vutrisiran 25 mg given once every 12 weeks and patisiran at a dose of 0.3 mg/kg body weight (maximum 30 mg) given once every 3 weeks (assuming an average of 2.38 vials of patisiran per administration).</p>

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<p align="center">DUPILUMAB</p> <p>Injection 300 mg in 2 mL single dose autoinjector Injection 200 mg in 1.14 mL single dose autoinjector</p> <p align="center">Dupixent®</p> <p align="center">SANOFI-AVENTIS AUSTRALIA PTY LTD</p>	<p align="center">Chronic severe atopic dermatitis Uncontrolled severe asthma</p>	<p align="center">To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.</p>	<p align="center">The PBAC extended the November 2022 recommendation for an additional 12 months.</p>
<p align="center">ETANERCEPT</p> <p>Injection 50 mg in 1 mL single use auto-injector, 4</p> <p align="center">Nepexto®</p> <p align="center">ALPHAPHARM PTY LTD</p>	<p align="center">Rheumatoid arthritis Juvenile idiopathic arthritis Psoriatic arthritis Plaque psoriasis Ankylosing spondylitis</p>	<p align="center">To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.</p>	<p align="center">The PBAC extended the November 2022 recommendation for an additional 12 months.</p>
<p align="center">HYDROCORTISONE</p> <p>Capsule containing granules 0.5 mg Capsule containing granules 1 mg Capsule containing granules 2 mg Capsule containing granules 5 mg</p> <p align="center">Alkindi®</p> <p align="center">CHIESI AUSTRALIA PTY LTD</p>	<p align="center">Adrenal insufficiency</p>	<p align="center">To request the PBAC review its July 2021 recommendation that has not yet been accepted by the applicant.</p>	<p align="center">The PBAC rescinded the July 2021 recommendation.</p>

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<p align="center">INFLIXIMAB</p> <p>Solution for injection 120 mg in 1 mL pre-filled pen Solution for injection 120 mg in 1 mL pre-filled syringe</p> <p align="center">Remsima® SC</p> <p align="center">CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p>	<p align="center">Rheumatoid arthritis</p>	<p align="center">To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.</p>	<p align="center">The PBAC rescinded the November 2022 recommendation.</p>
<p align="center">INSULIN ASPART</p> <p>Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5</p> <p align="center">Truvelog®</p> <p>Injections (human analogue), prefilled pen, 100 units per mL, 3 mL, 5</p> <p align="center">Truvelog® Solostar</p> <p align="center">SANOFI-AVENTIS AUSTRALIA PTY LTD</p>	<p align="center">Diabetes mellitus</p>	<p align="center">To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.</p>	<p align="center">The PBAC rescinded the November 2021 recommendation.</p>
<p align="center">RISANKIZUMAB</p> <p>Solution concentrate for I.V. infusion 600 mg in 10 mL Injection 360 mg in 2.4 mL in prefilled cartridge</p> <p align="center">Skyrizi®</p> <p align="center">ABBVIE PTY LTD</p>	<p align="center">Crohn disease</p>	<p align="center">To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.</p>	<p align="center">The PBAC rescinded the November 2022 recommendation.</p>

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NOVEMBER 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
<p>Review of PBS items for Nurse Practitioner prescribing subject to a 'Continuing Therapy Only' administrative note</p> <p>Various forms and strengths</p> <p>Various brands</p> <p>Various sponsors</p> <p>(Other matters)</p>	<p>Various</p>	<p>To request the PBAC consider a list of medicines with a Continuing Therapy Only (CTO) administrative note for nurse practitioner prescribing, and seek PBAC advice on whether the CTO note continues to be appropriate for specific listings.</p>	<p>The PBAC recommended removing the CTO administrative note from all PBS listings to which it currently applies and provided advice on further PBS restrictions that should apply for certain listings regarding nurse practitioner prescribing. For most listings, the PBAC recommended removing the CTO note to allow nurse practitioners to initiate treatment, without further requirements beyond those already specified in the restriction. For a subset of medicines, the PBAC recommended that the PBS listings be amended to permit nurse practitioner initiation where patient care is being shared with a medical practitioner. The PBAC considered the conditions being treated by this subset of medicines are complex and management of these conditions is likely to require specialist medical practitioner oversight. The PBAC recognised that nurse practitioners managing these conditions may already be working in collaboration with a medical practitioner and/or specialist and that allowing nurse practitioners to initiate treatment under shared care arrangements may provide greater accessibility to treatment and more efficient healthcare delivery. For a smaller number of medicines, including those where the restriction already limits treatment initiation to specialist medical practitioners, the PBAC recommended that CTO requirements continue for nurse practitioner prescribing, but that these requirements be expressed in the PBS restriction criteria rather than as an administrative note. The PBAC considered these medicines are used to treat complex conditions where medical practitioners or specialists are likely to establish the diagnosis and treatment.</p>
<p>OSTEOPOROSIS THERAPY RESTRICTIONS REVIEW</p> <p>ALENDRONATE RISEDRONATE ZOLEDRONIC ACID</p> <p>Various forms and strengths</p> <p>Various brands</p> <p>Various sponsors</p> <p>Matters outstanding (Change to existing listing)</p>	<p>Osteoporosis</p>	<p>To consider the outcomes of the MSAC August 2024 consideration of Application 1758 – Expansion of MBS item numbers 12320 & 12322 for bone mineral density (BMD) testing to include patients aged 60-69 years.</p>	<p>The PBAC did not recommend changes to the current age range for the PBS listings of alendronate, risedronate, and zoledronic acid to allow use in patients aged under 70 who have not had a prior fracture due to minimal trauma. The PBAC recalled that in September 2021 it had been of a mind to support such changes but had 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 recalled, that in July 2024, the Committee had considered a department contracted assessment report (DCAR) undertaken to review the MBS implications associated with amending BMD testing to include patients 60-69 years (PBAC Meeting Outcomes, July 2024 PBAC Meeting). The PBAC recalled that including BMD testing costs in the cost-utility analysis had yielded ICERs (\$ per QALY gained) that were high for all modelled drug scenarios and the Committee had advised that the expansion of restrictions for osteoporosis therapies to include all individuals aged 65-69 years was not cost-effective (PBAC Meeting Outcomes, July 2024 PBAC Meeting). The PBAC noted that the Medical Service Advisory Committee (MSAC) had considered the DCAR at their August 2024 meeting. The PBAC noted that MSAC did not support amending MBS items 12320 & 12322 for BMD testing to include all individuals aged 60-69 years. The PBAC noted that MSAC considered the proposed expansion to BMD testing, and all alternative scenarios, such as narrowing the expanded use to individuals aged 65-69 years without repeat testing, was not cost-effective. With the additional available evidence from the DCAR and advice from MSAC, the PBAC concluded that the proposed changes to the current age range for the PBS listings of alendronate, risedronate, and zoledronic acid were not appropriate.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 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
<p>DROSPIRENONE WITH ETHINYLESTRADIOL</p> <p>Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol (as betadex clathrate) and 4 inert tablets</p> <p align="center">Yaz®</p> <p>Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets</p> <p align="center">Yasmin®</p> <p>BAYER AUSTRALIA LTD.</p> <p>Other Matters (New PBS Listing)</p>	<p align="center">Contraception</p>	<p align="center">To request the PBAC to reconsider its July 2024 cost-minimisation recommendation for Yaz and Yasmin.</p>	<p>The PBAC provided further advice to its July 2024 recommendation to list the combined oral contraceptives (COCs) 3 mg drospirenone with 20 micrograms ethinylestradiol (Yaz) and 3 mg drospirenone with 30 micrograms ethinylestradiol (Yasmin) on the PBS as Unrestricted Benefit listings. Bayer Australia Ltd, requested the PBAC to reconsider its July 2024 cost-minimisation recommendation for Yaz and Yasmin in light of the outcomes from a stakeholder meeting on oral contraceptives held in October 2024. The PBAC noted the outcomes of the stakeholder meeting, including that access to a range of subsidised hormonal contraceptive options is consistent with public health aims and that newer oral contraceptives are more appropriate in particular clinical situations. The PBAC considered Yaz and Yasmin may provide a different option for some people than the currently PBS-listed COCs and that it was important to have a range of COC options on the PBS. The PBAC considered that Yaz and Yasmin offer benefits in certain clinical situations compared to other COCs and accepted the sponsor's proposed price.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2024 PBAC MEETING**

Submission category types

Category 1	<p>A request for PBS or NIP listing of one or more of the following:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
Category 3	<p>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.</p>
Category 4	<p>A request for one or more of the following:</p> <ul style="list-style-type: none"> • Listing of a new pharmaceutical item of a listed medicine. • Consideration as an exempt item (Exempt item as per subsection 84AH of the <i>National Health Act 1953</i>). • 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	<p>Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following:</p> <ul style="list-style-type: none"> • New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk • Pharmaceutical benefits that can no longer be supplied early • New brand of glucose indicator pharmaceutical item.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2024 PBAC MEETING**

Resubmission pathways

<p>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:</p>	
Standard re-entry	<p>The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
Early resolution pathway	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>
Facilitated resolution pathway	<p>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.</p>