

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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 style="text-align: center;">ADALIMUMAB</p> <p>Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen</p> <p style="text-align: center;">Humira®</p> <p style="text-align: center;">ABBVIE PTY LTD</p> <p style="text-align: center;">Standard re-entry (Change to existing listing)</p>	<p style="text-align: center;">Vision threatening non-infectious uveitis</p>	<p style="text-align: center;">Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with vision-threatening non-infectious uveitis.</p>	<p style="text-align: center;">Recommended</p>	<p>The PBAC recommended the General Schedule, Authority Required listing of adalimumab for the treatment of vision-threatening non-infectious uveitis, on the basis the listing would be acceptably cost-effective at the price proposed in the pre-PBAC response. The PBAC considered the available evidence supported the effectiveness of adalimumab in reducing uveitis flares, and that whilst the magnitude of the relationship between flares and long-term ocular damage was uncertain, accepted patients would likely experience vision-preserving benefits through improved flare control. The PBAC welcomed the comments from patients (many of whom have accessed adalimumab for this condition), family members, health professionals and organisations, which described the effectiveness of adalimumab in terms of reducing flares, as well as preventing or even reversing ocular damage and the quality-of-life benefits associated with improved vision and reduced side effects associated with being able to reduce or cease high dose corticosteroids. The PBAC considered there was a substantial unmet clinical need on the PBS for adalimumab for non-infectious uveitis and considered an age-agnostic listing was appropriate.</p>

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<p style="text-align: center;">ADALIMUMAB</p> <p>Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen</p> <p style="text-align: center;">Humira®</p> <p style="text-align: center;">ABBVIE PTY LTD</p> <p style="text-align: center;">Category 2 (Change to existing listing)</p>	<p style="text-align: center;">Immune-mediated inflammatory disease (IMID)</p>	<p style="text-align: center;">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of IMID in paediatric patients.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation to list adalimumab (Humira) on the PBS for the treatment of IMID in paediatric patients, to allow further consultation with relevant clinical groups. The PBAC noted that IMID covers a broad range of indications, including rarer conditions. The PBAC noted that adalimumab is not TGA-registered for all these indications, and there are varying levels of evidence available for the use of adalimumab in different IMIDs. On this basis, the PBAC did not accept the request for a broad indication for IMIDs. However, the PBAC advised that for those indications where there was evidence for the use of adalimumab in children, unnecessary barriers to accessing adalimumab on the PBS should be removed. The PBAC noted a range of conditions that were TGA-registered indications for adalimumab and where adalimumab was currently PBS-listed for use in children. The PBAC considered that ankylosing spondylitis was the main indication where there was sufficient evidence for using adalimumab in children however it was not currently PBS-listed for this patient group. The PBAC also noted the current maximum doses for adalimumab on the PBS for Crohn disease and ulcerative colitis in children may not reflect current clinical practice. The PBAC was therefore of a mind to recommend changes to the current listings of adalimumab for these indications to reflect current evidence and practice. The PBAC requested the Department engage with relevant clinical groups to review the current eligibility criteria for the PBS listings of adalimumab for these indications and revise these where necessary so that they reflect current evidence and clinical practice. The PBAC requested the revised listings be brought to the PBAC for consideration.</p> <p><u>Sponsor's Comment:</u> Existing PBS listings for certain immune-mediated inflammatory conditions do not reflect paediatric disease presentations or current clinical practice. AbbVie is disappointed that the PBAC did not accept the request for a broad indication for IMIDs.</p>

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<p style="text-align: center;">ADALIMUMAB</p> <p>Injection 80 mg in 0.8 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe</p> <p style="text-align: center;">Yuflyma®</p> <p>CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p> <p style="text-align: center;">Category 4 (New PBS listing)</p>	<p>Complex refractory fistulising Crohn disease Ulcerative colitis Crohn disease Chronic plaque psoriasis Hidradenitis suppurativa</p>	<p>To request General Schedule Authority Required (Written) listing of Yuflyma 80 mg for initial and first continuing treatment, and Authority Required (STREAMLINED) listing for subsequent continuing treatment under the same conditions as its reference biologic Humira®.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of adalimumab (Yuflyma) in the forms of 80 mg in 0.8 mL pre-filled pen (PFP) and pre-filled syringe (PFS) as biosimilar brands of Humira. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Yuflyma PFP and PFS would be acceptable if it were cost-minimised to Humira PFP and PFS. The PBAC advised the equi-effective doses to be 1 mg of Yuflyma = 1 mg of Humira.</p> <p>The PBAC advised that for the purposes of substitution, Yuflyma and Humira 80 mg in 0.8 mL PFS should be treated as equivalent to each other; and Yuflyma and Humira 80 mg in 0.8 mL PFP should be treated as equivalent to each other (i.e., 'a' flagged in the Schedule). The PBAC advised that Yuflyma PFP should not be considered equivalent for the purposes of substitution with any adalimumab PFS, consistent with its previous considerations of adalimumab.</p>
<p style="text-align: center;">AFLIBERCEPT</p> <p>Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe</p> <p style="text-align: center;">Eylea®</p> <p>BAYER AUSTRALIA LTD</p> <p style="text-align: center;">Category 2 (New PBS listing)</p>	<p>Diabetic macular oedema (DMO)</p>	<p>To request a General Schedule Authority Required (Written) listing for the treatment of patients with visual impairment due to DMO.</p>	<p>Not Applicable</p>	<p>To be considered at a future PBAC meeting</p>

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<p align="center">AFLIBERCEPT</p> <p>Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL)</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</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of visual impairment caused by CNV secondary to age-related macular degeneration.</p>	<p align="center">Not Applicable</p>	<p align="center">To be considered at a future PBAC meeting</p>
<p align="center">AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS</p> <p>Oral powder 400 g (Neocate Syneo)</p> <p align="center">Neocate® Syneo</p> <p align="center">NUTRICIA AUSTRALIA PTY LIMITED</p> <p align="center">Committee secretariat (Other matters)</p>	<p>Cows' milk protein enteropathy Severe cows' milk protein enteropathy with failure to thrive Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Cows' milk anaphylaxis Severe intestinal malabsorption including short bowel syndrome Eosinophilic oesophagitis</p>	<p align="center">To request Neocate Syneo with new formulation continue to be listed on the PBS under the existing conditions.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the new formulation of amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids (Neocate Syneo) continue to be PBS-listed under the same conditions as the current listing. The PBAC noted and supported the Nutritional Products Working Party advice that the new formulation is expected to provide non-inferior clinical effectiveness in comparison to the current formulation. The PBAC considered the new formulation is not expected to have impacts on current utilisation of the product or current costs to Government.</p>

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<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE</p> <p>Oral liquid 125 mL, 30 (PKU Lophlex Select LQ)</p> <p>PKU Lophlex® Select LQ</p> <p>NUTRICIA AUSTRALIA PTY LIMITED</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 vitamins and minerals without phenylalanine (PKU Lophlex Select LQ) be listed on the PBS for the dietary management of phenylketonuria (PKU) under the same circumstances as PKU Lophlex LQ 20, and on a cost-minimisation basis to the lowest cost comparator on a price per gram of protein equivalent basis.</p>
<p>AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE</p> <p>Oral powder 400 g (PKU Start)</p> <p>PKU Start™</p> <p>VITAFLO AUSTRALIA PTY LIMITED</p> <p>Committee secretariat (Other matters)</p>	<p>Phenylketonuria (PKU)</p>	<p>To request PKU Start with new formulation continue to be listed on the PBS under the existing conditions.</p>	<p>Recommended</p>	<p>The PBAC recommended the new formulation of amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine (PKU Start) continue to be PBS-listed under the existing conditions of the current formulation. The PBAC noted and supported the Nutritional Products Working Party advice that the new formulation is expected to provide a non-inferior clinical benefit for the management of PKU.</p>

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<p align="center">ANIFROLUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 2 mL</p> <p align="center">Saphnelo®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Standard re-entry (New PBS listing)</p>	<p align="center">Systemic lupus erythematosus (SLE)</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe SLE with a high level of disease activity despite standard therapy.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended a complex authority required Section 100 Highly Specialised Drugs Authority Required (In Writing/HPOS) listing of anifrolumab for the treatment of patients with severe SLE with high disease activity despite standard of care (SOC). The PBAC was satisfied that anifrolumab provides, for some patients, a significant improvement in efficacy over SOC alone for the management of SLE in the requested population. The PBAC's recommendation for listing was based on, among other matters, its assessment that the resubmission sufficiently addressed the concerns raised with the previous resubmission, and that the cost-effectiveness of anifrolumab would be acceptable at the price proposed in the pre-PBAC response. The PBAC considered that the financial impact estimates were reasonable and that a risk sharing arrangement would mitigate any risks related to variability of patient treatment patterns and use outside of that intended.</p>
<p align="center">ATEZOLIZUMAB</p> <p>Solution for subcutaneous injection containing atezolizumab 1875 mg in 15 mL</p> <p align="center">Tecentriq® SC</p> <p align="center">ROCHE PRODUCTS PTY LTD</p> <p align="center">Category 4 (New PBS listing)</p>	<p>Locally advanced or metastatic non-small cell lung cancer (NSCLC) Stage IV (metastatic) NSCLC Extensive-stage small cell lung cancer (ES-SCLC) Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Resected early stage (Stage II to IIIA) eNSCLC</p>	<p>To request listing of a new form and strength of atezolizumab under the same conditions as the currently listed form and strengths of atezolizumab solution for intravenous (I.V.) infusion.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the dual General Schedule and Section 100 (Efficient Funding of Chemotherapy – Related Benefits) Authority Required listings of subcutaneous (SC) injection of atezolizumab 1875 mg/15 mL (Tecentriq SC) (atezolizumab SC) for locally advanced or metastatic NSCLC, ES-SCLC, advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma and eNSCLC for which atezolizumab 1200 mg/20 mL I.V. infusion (atezolizumab I.V.) is currently listed on the PBS. The PBAC's recommendation for listing was based on, among other matters, its assessment that atezolizumab SC would be cost-effective if it were cost-minimised to the lowest cost comparator. The PBAC advised the equi-effective doses to be 1875 mg/15 mL atezolizumab SC = 1200 mg/20 mL atezolizumab I.V.</p>

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<p align="center">AVACOPAN</p> <p align="center">Capsule 10 mg</p> <p align="center">Tavneos®</p> <p align="center">SEQIRUS (AUSTRALIA) PTY LTD</p> <p align="center">Standard re-entry (New PBS listing)</p>	<p align="center">Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for treatment of severe active GPA and severe active MPA in combination with rituximab or cyclophosphamide.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of avacopan for induction therapy for the treatment of severe active GPA and severe active MPA in combination with a regimen of rituximab or cyclophosphamide. The PBAC acknowledged there was a clinical need for treatments that can be used to reduce exposure to glucocorticoids (GC) in this condition and considered avacopan provided a benefit in reducing GC use along with potential improvements in renal outcomes for patients at high risk of organ damage. Noting the changes to the economic model and the price offered in the pre-PBAC response, the PBAC considered the resulting incremental cost-effectiveness ratio high but acceptable given the clinical need. The PBAC did not accept the resubmissions financial estimates but instead advised that the July 2023 submission financial estimates would be reasonable with appropriate amendments.</p>
<p align="center">BECLOMETASONE WITH FORMOTEROL</p> <p align="center">Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 dose</p> <p align="center">Fostair®</p> <p align="center">CHIESI AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Asthma</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing as a maintenance and reliever treatment (MART) for asthma.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of the fixed dose combination (FDC) of beclometasone 100 µg with formoterol 6 µg (BEC/FOR 100/6) as MART for asthma. The PBAC considered the indirect treatment comparison presented in the submission addressed its July 2020 concerns regarding the adequacy of the data presented for MART. The PBAC's recommendation for listing for this indication was based on, among other matters, its assessment that the cost-effectiveness of BEC/FOR would be acceptable if it were cost-minimised against the lowest price combination of PBS listed inhaled corticosteroid with long-acting beta2 agonist FDC therapy or combination of the individual components that are available for MART at comparable doses.</p>

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<p align="center">BEVACIZUMAB</p> <p>Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL</p> <p align="center">Vegzelma®</p> <p>CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p> <p align="center">Category 3 (New PBS listing)</p>	<p align="center">Cancers</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy) Unrestricted Benefit listing of Vegzelma under the same conditions as the PBS-listed bevacizumab biosimilars.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of a new biosimilar brand of bevacizumab (Vegzelma) in the form of solution for I.V. infusion 100 mg in 4 mL and 400 mg in 16 mL under the same circumstances as the PBS-listed biosimilar brands of bevacizumab (Abevmy®, Bevaciptin®, Mvasi®) on a cost-minimisation basis. The PBAC advised the equi-effective doses were 1 mg of Vegzelma for 1 mg of Avastin (and of the other PBS-listed brands of bevacizumab). The PBAC considered that the listing of Vegzelma on the PBS is not expected to increase the overall use of bevacizumab on the PBS as it is expected that Vegzelma would substitute for the other brands of PBS listed bevacizumab. The PBAC therefore considered that the estimated net cost to the PBS/RPBS would be nil.</p>
<p align="center">BIMEKIZUMAB</p> <p>Injection 160 mg in 1 mL single use pre-filled syringe Injection 160 mg in 1 mL single use pre-filled pen</p> <p align="center">Bimzelx®</p> <p>UCB AUSTRALIA PROPRIETARY LIMITED</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Psoriatic arthritis (PsA)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of PsA.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of bimekizumab for the treatment of severe PsA. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of bimekizumab would be acceptable if it were cost-minimised to the least costly alternative biologic or targeted synthetic disease modifying anti-rheumatic drug (b/tsDMARD) for the treatment of PsA. The PBAC noted the alternative therapies included adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab. The Committee noted the flow-on changes to other PsA b/tsDMARD listings to include bimekizumab in the list of eligible therapies. The PBAC advised the equi-effective doses were: bimekizumab 160 mg subcutaneous injection every four weeks = ixekizumab 160 mg subcutaneous injection at Week 0 then 80 mg subcutaneous injection every four week and doses of alternative b/tsDMARDs derived from the relevant Product Information documents.</p>

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<p align="center">BIMEKIZUMAB</p> <p>Injection 160 mg in 1 mL single use pre-filled syringe Injection 160 mg in 1 mL single use pre-filled pen</p> <p align="center">Bimzelx®</p> <p align="center">UCB AUSTRALIA PROPRIETARY LIMITED</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Ankylosing spondylitis (AS)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of AS.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of bimekizumab for the treatment of AS. The PBAC's recommendation was based on, among other matters, its assessment the cost-effectiveness of bimekizumab would be acceptable if it were cost-minimised to the least costly alternative therapy of adalimumab, etanercept, infliximab, golimumab, certolizumab pegol, ixekizumab, secukinumab, tofacitinib and upadacitinib. The PBAC noted the flow-on changes to other AS listings to include bimekizumab in the list of eligible therapies. The PBAC advised the equi-effective doses were: bimekizumab 160 mg every 4 weeks = secukinumab 150 mg at weeks 0,1,2,3 and 4 then every 4 weeks and doses of alternative b/tsDMARDs derived from the relevant Product Information documents.</p>
<p align="center">BIMEKIZUMAB</p> <p>Injection 160 mg in 1 mL single use pre-filled syringe Injection 160 mg in 1 mL single use pre-filled pen</p> <p align="center">Bimzelx®</p> <p align="center">UCB AUSTRALIA PROPRIETARY LIMITED</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Non-radiographic axial spondyloarthritis (nr-axSpA)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of nr-axSpA.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of bimekizumab for the treatment of nr-axSpA. The PBAC's recommendation was based on, among other matters, its assessment the cost-effectiveness of bimekizumab would be acceptable if it were cost-minimised to the least costly alternative of certolizumab pegol, golimumab, secukinumab or upadacitinib (as well as ixekizumab if listed on the PBS prior to the listing of bimekizumab). The Committee noted the flow-on changes to other nr-axSpA biologic or targeted synthetic disease modifying anti-rheumatic drug (b/tsDMARD) listings to include bimekizumab in the list of eligible therapies. The PBAC advised the equi-effective doses were: bimekizumab 160 mg every 4 weeks = secukinumab 150 mg at weeks 0,1,2,3 and 4 then every 4 weeks and doses of alternative b/tsDMARDs derived from the relevant Product Information documents.</p>

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<p align="center">BRENTUXIMAB VEDOTIN</p> <p align="center">Powder for I.V. infusion 50 mg</p> <p align="center">Adcetris®</p> <p align="center">TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Hodgkin lymphoma</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the first-line treatment of advanced classical Hodgkin lymphoma.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend brentuximab vedotin, in combination with doxorubicin, vinblastine and dacarbazine (A+AVD), for the first line treatment of advanced classical Hodgkin lymphoma. The PBAC considered the availability of alternative treatment options reduced the clinical need for A+AVD. The PBAC advised that the claim of superior effectiveness compared to positron emission tomography (PET)-adapted doxorubicin, bleomycin, vincristine and dacarbazine was highly uncertain due to the indirect evidence presented and the high level of censoring in the key trial evidence, but considered it was likely reasonable. In addition, the PBAC considered the economic model structure used in the submission resulted in an incremental cost-effectiveness ratio that was highly uncertain and advised that the cost-effectiveness of A+AVD was unable to be reliably assessed.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p align="center">BUDESONIDE</p> <p align="center">Capsule (enteric) 3 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">Crohn disease (CD)</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing of a new form of budesonide for the treatment of mild to moderate CD.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of budesonide 3 mg enteric capsules, 50 (Budenofalk) with a maximum quantity of 100 units for treatment of mild to moderately active CD affecting the ileum and/or the ascending colon, on a cost-minimisation basis to budesonide 3 mg modified release capsules, 90 (Entocort®). The PBAC considered that Budenofalk 100 capsules would provide another alternative therapy for the treatment of CD and that the reduced wastage over the comparator may result in a small saving to the PBS. The PBAC advised that the Budenofalk and Entocort brands of budesonide should not be considered equivalent for the purposes of substitution (i.e. not 'a' flagged in the Schedule) as the PBAC noted that the proposed maximum quantity is different (100 versus 90 units of Budenofalk and Entocort, respectively).</p>

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<p style="text-align: center;">BULEVIRTIDE</p> <p style="text-align: center;">Powder for injection 2 mg</p> <p style="text-align: center;">Hepcludex®</p> <p style="text-align: center;">GILEAD SCIENCES PTY LIMITED</p> <p style="text-align: center;">Category 1 (New PBS listing)</p>	<p style="text-align: center;">Chronic hepatitis D (CHD)</p>	<p style="text-align: center;">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of CHD.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of bulevirtide for the treatment of CHD infection. The PBAC considered the available evidence indicates that bulevirtide, for some patients, is effective in terms of reducing or achieving an undetectable viral load and/or normalising some liver enzyme parameters (such as alanine transaminase). However, the PBAC considered the magnitude of long-term benefits in terms of clinical and patient-relevant benefits could not be reliably quantified, which led to major uncertainties with the economic evaluation. The PBAC also considered that the economic model presented likely did not reflect how bulevirtide is used in Australian clinical practice as testing, treatment persistence, and clinical decisions around treatment discontinuation were uncertain. The PBAC considered that the incremental cost-effectiveness ratio was likely underestimated and bulevirtide was not considered cost-effective at the requested price. The PBAC considered the utilisation and financial estimates to be uncertain.</p> <p><u>Sponsor's Comment:</u> Gilead Sciences is disappointed by the decision not to recommend Hepcludex (bulevirtide) be listed on the PBS for the treatment of chronic hepatitis delta (CHD). We are however pleased that the PBAC acknowledged the high clinical need for effective therapies for CHD infection and the long term impacts of CHD infection. We wish to express our sincere thanks to the patient organisations and clinicians who took the time to provide consumer comments in support of the submission.</p>

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<p align="center">CABOZANTINIB</p> <p align="center">Tablet 20 mg Tablet 40 mg</p> <p align="center">Cabometyx®</p> <p align="center">IPSEN PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Renal cell carcinoma (RCC)</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing, in combination with nivolumab, for the first-line treatment of advanced clear cell RCC.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of cabozantinib for use in combination with nivolumab (CBZ+NIVO) for the treatment of advanced (Stage IV) clear cell variant RCC in patients who are classified as intermediate or poor risk using the International Metastatic renal cell carcinoma Database Consortium (IMDC) survival risk classification score. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of CBZ+NIVO would be acceptable if it were cost-minimised against pembrolizumab + lenvatinib (PEM+LEN). The PBAC considered a cost-minimisation approach was reasonable, assuming the same treatment duration and relative dose intensity (RDI) for CBZ as was accepted for LEN and the same treatment duration and RDI for NIVO as was accepted for PEM by the PBAC in its March 2022 consideration of PEM+LEN. The PBAC advised that the cost of CBZ+NIVO should also not be higher than the cost of NIVO+ipilimumab. The PBAC advised that CBZ+NIVO should join the existing risk sharing arrangement with PEM+LEN and other advanced RCC treatments with no increase in expenditure caps. The PBAC recommended flow on changes to the restriction criteria for PEM+LEN, sunitinib and pazopanib.</p>
<p align="center">CABOZANTINIB</p> <p align="center">Tablet 20 mg Tablet 40 mg Tablet 60 mg</p> <p align="center">Cabometyx®</p> <p align="center">IPSEN PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Renal cell carcinoma (RCC)</p>	<p align="center">To request an amendment to the existing General Schedule Authority Required (STREAMLINED) listing to remove the 'clear cell variant' histology requirement to allow treatment in patients with non-clear cell RCC (nccRCC).</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the RCC restriction for cabozantinib be extended to include the treatment of nccRCC. The PBAC considered that there is a high clinical need for treatments in the small subset of RCC patients with nccRCC as there are currently no therapies available on the PBS. The PBAC noted that the evidence is limited but considered that the clinical benefit in patients with nccRCC appears to be similar to that in patients with clear cell RCC (ccRCC), particularly in the first line setting. The PBAC considered that on this basis it was reasonable to accept that cabozantinib would be cost-effective for treatment of nccRCC at the same first-line price as accepted for ccRCC.</p>

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<p align="center">CABOZANTINIB</p> <p>Tablet 20 mg Tablet 40 mg Tablet 60 mg</p> <p align="center">Cabometyx®</p> <p align="center">IPSEN PTY LTD</p> <p align="center">Early re-entry (Change to existing listing)</p>	<p align="center">Differentiated thyroid cancer (DTC)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic DTC in patients who have progressed during or after prior vascular endothelial growth factor (VEGF) targeted therapy.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended cabozantinib for the treatment of locally advanced or metastatic DTC in patients who are radioactive iodine refractory or ineligible, who have progressed following treatment with a tyrosine kinase inhibitor or have developed intolerance to prior VEGF targeted therapy. The PBAC considered that there was a clinical need for additional treatments in this setting. The PBAC noted that the resubmission made the requested changes to the economic model but considered that the approach for including end-of-life costs was inappropriate. However, the PBAC considered that the addition of some post-progression costs would be appropriate, and that cabozantinib would likely be cost-effective at the price proposed in the submission. The PBAC noted that the estimated financial impact was small.</p>
<p align="center">CETUXIMAB</p> <p>Solution for I.V. infusion 100 mg in 20 mL Solution for I.V. infusion 500 mg in 100 mL</p> <p align="center">Erbix®</p> <p align="center">MERCK HEALTHCARE PTY LTD</p> <p align="center">Category 4 (Change to existing listing)</p>	<p align="center">Metastatic colorectal cancer (mCRC)</p>	<p align="center">To request an increase of maximum amount for the existing listings of cetuximab to allow clinician choice of either weekly or fortnightly dosing regimen for the treatment of mCRC.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended increasing the maximum amount for the current listings of cetuximab for mCRC to allow clinicians to prescribe an alternative dosing regimen of 500 mg per m² body surface area once every two weeks, in addition to the currently listed weekly dosing schedule. The PBAC considered that it would be appropriate to amend all current cetuximab listings for mCRC to increase the maximum amount for initial treatment from 880 mg to 1100 mg and for continuing treatment from 550 mg to 1100 mg. The PBAC considered that while the estimated utilisation and financial implications were uncertain, increasing the maximum amount to allow fortnightly dosing of cetuximab would provide patients with greater flexibility and convenience, given the new dosing requires less frequent infusion sessions and hospital visits. Furthermore, it would result in more efficient resource allocation for infusion centres and ease the administrative burden for clinicians.</p>

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<p align="center">DABRAFENIB</p> <p>Capsule 50 mg (as mesilate) Capsule 75 mg (as mesilate) Tablet (dispersible) 10 mg</p> <p align="center">Tafinlar®</p> <p align="center">TRAMETINIB</p> <p>Tablet 500 micrograms Tablet 2 mg Powder for oral solution 5 micrograms per mL (as dimethylsulfoxide), 97 mL</p> <p align="center">Mekinist®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Glioma</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of paediatric patients with BRAF V600E mutation positive low grade glioma (LGG) or high grade glioma (HGG), and to request new forms and strengths of dabrafenib and trametinib.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of dabrafenib in combination with trametinib for the treatment of paediatric patients with BRAF V600E mutation positive LGG and HGG. The PBAC recognised a high clinical need in the proposed LGG and HGG populations and considered that treatment with dabrafenib and trametinib (D+T) offered high added therapeutic value for these patients. The PBAC was satisfied that D+T provides, for some patients, a significant improvement in efficacy over carboplatin and vincristine (C+V) in LGG, and over standard chemotherapy in HGG. The PBAC noted the high incremental cost-effectiveness ratio (ICER) in the LGG population and considered that cost-effectiveness had not been demonstrated at the proposed prices. The PBAC advised that a price reduction would be required to achieve an acceptable ICER in the LGG population. The PBAC considered the ICER for the HGG population was very uncertain due to the underlying clinical evidence base which was an unanchored comparison of single arm studies. The PBAC considered that a lower ICER would be required to demonstrate acceptable cost-effectiveness in the HGG population, compared with the LGG population, in recognition of the high uncertainty of the incremental benefit associated with D+T compared with chemotherapy in HGG.</p>

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<p align="center">DAPAGLIFLOZIN WITH SITAGLIPTIN</p> <p>Tablet containing dapagliflozin 10 mg with sitagliptin 100 mg</p> <p align="center">Sidapvia®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Type 2 diabetes mellitus (T2DM)</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing, for use in combination with metformin, for the treatment of T2DM.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended that dapagliflozin 10 mg with sitagliptin 100 mg (Sidapvia) fixed dose combination (FDC) be listed on the PBS for use in conjunction with metformin, for patients with T2DM with an inadequate response to treatment with dual therapy of metformin and an inhibitor of sodium glucose co-transporter 2 (SGLT2i), or dipeptidyl peptidase 4 (DPP4i). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of dapagliflozin + sitagliptin FDC would be acceptable if it were cost-minimised to the lowest cost PBS-listed SGLT2i+DPP4i FDC. The PBAC advised the equi-effective doses to be: dapagliflozin+sitagliptin FDC (10 mg/100 mg) = empagliflozin+linagliptin FDC (10 mg or 25 mg/5 mg) = dapagliflozin+saxagliptin FDC (10 mg/5 mg).</p> <p>The PBAC considered that insulin should be removed from the current administrative note to allow insulin to be used in combination with metformin and other SGLT2i + DPP4i FDCs. The PBAC recommended that the change to the administrative note be flowed on to other SGLT2i + DPP4i FDCs.</p> <p>The PBAC considered it would be reasonable to include the dapagliflozin+sitagliptin FDC in the 60-day prescription measure as the alternative product combinations that could be used to achieve triple therapy are included in the continuing treatment phase. The PBAC advised the standard clinical criteria for 60-day PBS items as recommended at the December 2022 PBAC meeting should be included in the restriction i.e., "The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient."</p>

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<p>DAUNORUBICIN WITH CYTARABINE</p> <p>Powder for I.V infusion containing daunorubicin 44 mg and cytarabine 100 mg</p> <p>Vyxeos®</p> <p>JAZZ PHARMACEUTICALS ANZ PTY LTD</p> <p>Matters arising (New PBS listing)</p> <p>WITHDRAWN</p>	<p>Acute myeloid leukaemia</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of therapy-related acute myeloid leukaemia (t-AML) or acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC) while system and IT challenges relating to a Section 100 (Efficient Funding of Chemotherapy) listing are resolved.</p>	<p>Not Applicable</p>	<p>This item was withdrawn. <i>Note this item was considered out-of-session between ordinary meetings (March 2024 – July 2024) – outcome provided under out-of-session considerations below.</i></p>

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<p align="center">DUPILUMAB</p> <p>Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe</p> <p align="center">Dupixent®</p> <p>SANOFI-AVENTIS AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Asthma</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of dupilumab for the treatment of patients aged 6 to 11 years of age with uncontrolled severe asthma despite optimised asthma therapy who have total serum immunoglobulin E (IgE) of ≥ 30 IU/mL and evidence of atopy, or blood eosinophils $\geq 150 \times 10^9/L$, or fractional exhaled nitric oxide ≥ 20 parts per billion. For patients with IgE ≥ 30 IU/ mL and evidence of atopy the PBAC considered the claim of non-inferior effectiveness and safety compared to omalizumab was likely reasonable. For patients who had IgE < 30 IU/ mL and no evidence of atopy the PBAC took into consideration that while the clinical evidence presented was limited, there was a clinical need, and that the number of patients and cost was expected to be small. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of dupilumab would be acceptable if it were cost-minimised against omalizumab. The PBAC recommended flow-on changes to the PBS restrictions for omalizumab for uncontrolled severe allergic asthma to ensure eligible patients can switch between omalizumab and dupilumab as part of a treatment cycle. The PBAC considered the equi-effective doses to be dupilumab 300 mg every 4 weeks for patients weighing < 60 kg, or 200 mg every 2 weeks for patients weighing ≥ 30 kg = omalizumab 375 mg given every 4 weeks (either as one dose every 4 weeks or two equal doses every 2 weeks).</p>

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<p align="center">EDARAVONE</p> <p>Solution concentrate for injection I.V. infusion 30 mg in 20 mL</p> <p align="center">Radicava®</p> <p align="center">TEVA PHARMA AUSTRALIA PTY LTD</p> <p align="center">Early re-entry (New PBS listing)</p>	<p align="center">Amyotrophic lateral sclerosis (ALS)</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of ALS.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of edaravone, for treatment of ALS in patients who are independent in activities of daily living and where treatment is initiated within two years of disease onset, on the basis that it should be available only under special arrangements under Section 100. The PBAC recommended Community Access on the HSD program for continuing treatment only. The PBAC acknowledged the high clinical need for effective treatments for ALS, the most common phenotype of motor neuron disease. The PBAC recalled that in November 2023 it did not recommend edaravone for this indication, noting that edaravone was not cost-effective at the price proposed in the submission and that the economic model included a number of optimistic assumptions that were likely to underestimate the incremental cost-effectiveness ratio. The PBAC considered that the majority of the outstanding issues were satisfactorily resolved in the resubmission, including changes to the restriction, economic model and financial estimates and advised that edaravone would be acceptably cost-effective at the price proposed in the resubmission. The PBAC noted that the submission did not reduce the discontinuation rate in the economic model as requested, but considered that the remaining uncertainty regarding treatment duration and the potential for ongoing use in a broader population than the trial could be addressed via a risk sharing arrangement with subsidisation caps.</p>

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<p>ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR</p> <p>Pack containing 56 sachets containing granules elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets containing granules ivacaftor 75 mg</p> <p>Pack containing 56 sachets containing granules elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets containing granules ivacaftor 59.5 mg</p> <p style="text-align: center;">Trikafta®</p> <p style="text-align: center;">VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD.</p> <p style="text-align: center;">Category 2 (New PBS listing)</p>	<p style="text-align: center;">Cystic fibrosis (CF)</p>	<p style="text-align: center;">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of CF in patients who are aged 2 to 5 years and who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (<i>CFTR</i>) gene.</p>	<p style="text-align: center;">Recommended</p>	<p>The PBAC recommended that the restriction for elexacaftor/tezacaftor/ ivacaftor (ELX/TEZ/IVA) be extended to include the treatment of CF in patients who are aged 2 to 5 years and who have at least one F508del mutation on the <i>CFTR</i> gene. The PBAC also recommended that two granule formulations should be made available under Section 100 (Highly Specialised Drugs Program) to facilitate dosing in children aged 2 to < 6 years. The PBAC noted the evidence presented could not accurately quantify the benefit of treating patients with ELX/TEZ/IVA from a younger age but acknowledged treatment from a young age was likely to be beneficial. The PBAC considered ELX/TEZ/IVA was likely to be cost-effective for this population at the same unit price as the current PBS listing (for patients over 6 years of age). The PBAC noted the financial estimates would need to be reduced to account for patients eligible for treatment with ivacaftor (as recommended at the November 2023 PBAC meeting).</p>
<p style="text-align: center;">EMPAGLIFLOZIN</p> <p style="text-align: center;">Tablet 10 mg</p> <p style="text-align: center;">Jardiance®</p> <p style="text-align: center;">BOEHRINGER INGELHEIM PTY LTD</p> <p style="text-align: center;">Category 4 (Change to existing listing)</p>	<p style="text-align: center;">Chronic heart failure</p>	<p style="text-align: center;">To request a change in the General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic heart failure to allow treatment initiation by nurse practitioners.</p>	<p style="text-align: center;">Recommended</p>	<p>The PBAC recommended the amendment of the Nurse Practitioner (NP) prescribing arrangements of empagliflozin for the treatment of chronic heart failure from continuing therapy only to a shared-care model. The PBAC noted the Australian Government commitment to remove the legislated requirement for collaborative arrangements for NPs and endorsed midwives. The PBAC did not recommend the removal of the collaborative arrangements from empagliflozin for chronic heart failure pending implementation of the Government commitment. The PBAC recommended the restriction changes to the NP prescribing arrangements flow-on to dapagliflozin indicated for chronic heart failure.</p>

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<p align="center">ETRASIMOD Tablet 2 mg Velsipity® PFIZER AUSTRALIA PTY LTD Category 2 (New PBS listing)</p>	<p align="center">Ulcerative colitis</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of moderate to severe ulcerative colitis (MSUC).</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of etrasimod for the treatment of MSUC. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of ETR would be acceptable if it were cost-minimised to the least costly alternative biologic or targeted synthetic biologic disease modifying anti-rheumatic drug (b/tsDMARD) therapy out of infliximab, tofacitinib, ozanimod, vedolizumab, ustekinumab and golimumab. The PBAC considered, based on the evidence presented, that etrasimod is likely to be of non-inferior comparative effectiveness and safety to these agents in MSUC and considered the available evidence on balance supports that etrasimod, for some patients, likely provides a significant improvement in effectiveness compared to adalimumab. The PBAC advised the equi-effective doses were: etrasimod 2 mg daily = ozanimod 0.23 mg daily for 4 days, then 0.46 mg daily for 3 days, then 0.92 mg daily thereafter, and doses of alternative b/tsDMARDs derived from the relevant Product Information documents.</p>
<p align="center">EVOLOCUMAB Injection 140 mg in 1 mL single use pre-filled pen Injection 420 mg in 3.5 mL single use pre-filled cartridge Repatha® AMGEN AUSTRALIA PTY LIMITED Category 3 (Change to existing listing)</p>	<p align="center">Hypercholesterolaemia</p>	<p>To request a change to the restriction level of the existing listings for initial treatment from Authority Required (Telephone/Online) to Authority Required (STREAMLINED).</p> <p>The submission also requested a change in the clinical criteria to reduce the minimum treatment duration required with both a statin and ezetimibe prior to initiating evolocumab.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended changing the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the initial treatment listings for evolocumab injection 140 mg in 1 mL single use pre-filled pen and injection 420 mg in 3.5 mL single use pre-filled cartridge for the treatment of homozygous familial hypercholesterolaemia, heterozygous familial hypercholesterolaemia and non-familial hypercholesterolaemia.</p> <p>The PBAC did not recommend a reduction in the minimum treatment duration for both the maximum tolerated dose of statin and ezetimibe, prior to initiating evolocumab in the clinical criteria for the PBS-listings for evolocumab. The PBAC noted that no evidence was provided to demonstrate a clinical benefit to patients if evolocumab is initiated earlier or to justify the resulting increased cost to the PBS.</p>

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<p>GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE</p> <p>Oral liquid 250 mL, 18 (PKU GMPro ULTRA LQ)</p> <p>PKU GMPro® ULTRA LQ</p> <p>NUTRICIA AUSTRALIA PTY LIMITED</p> <p>Category 3 (New PBS listing)</p> <p>WITHDRAWN</p>	<p>Phenylketonuria (PKU)</p>	<p>To request a General Schedule Restricted Benefit listing for the dietary management of PKU in patients who are aged 3 years and over.</p>	<p>Not Applicable</p>	<p>This item was withdrawn.</p>
<p>IBRUTINIB</p> <p>Capsule 140 mg Tablet 280 mg Tablet 420 mg</p> <p>Imbruvica®</p> <p>JANSSEN-CILAG PTY LTD</p> <p>Standard re-entry (New PBS listing)</p>	<p>Chronic lymphocytic leukaemia (CLL) or Small lymphocytic lymphoma (SLL)</p>	<p>Resubmission to request a General Schedule Authority Required (Telephone/Online) listing, for use in combination with venetoclax, for the treatment of previously untreated CLL or SLL.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of ibrutinib for use in combination with venetoclax for the treatment of patients with previously untreated CLL/SLL. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of ibrutinib plus venetoclax would be acceptable if it were cost-minimised against venetoclax in combination with obinutuzumab, with 1.0 initial and 8.67 continuing venetoclax scripts plus 7.355 obinutuzumab scripts being considered equivalent to 12.06 ibrutinib scripts plus 1.0 initial and 9.43 continuing venetoclax scripts. In making its recommendation, the PBAC also considered the clinical need and the equity of access advantages associated with an all-oral therapy. The PBAC recommended flow-on changes to the current venetoclax listing to allow its use in combination with ibrutinib in CLL/SLL.</p>

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<p style="text-align: center;">ICOSAPENT ETHYL</p> <p style="text-align: center;">Capsule 1 g</p> <p style="text-align: center;">Vazkepa®</p> <p style="text-align: center;">SEQIRUS (AUSTRALIA) PTY LTD</p> <p style="text-align: center;">Early re-entry (New PBS listing)</p>	<p style="text-align: center;">Atherosclerotic cardiovascular disease with elevated triglycerides</p>	<p style="text-align: center;">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of atherosclerotic cardiovascular disease with elevated triglycerides.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of icosapent ethyl for the treatment of patients with atherosclerotic cardiovascular disease and elevated triglycerides. The PBAC was satisfied that icosapent ethyl provides, for some patients, a significant improvement in efficacy over standard care of care (consisting of dietary modification, lifestyle interventions, and concomitant optimisation of low-density lipoprotein cholesterol lowering using a statin-based therapeutic regimen). The PBAC acknowledged the proposals to address the substantive outstanding issues identified in November 2023 in this early re-entry resubmission and considered the revised price offer and amendments to the economic model were sufficient if further containment of the overall budget impact was achieved.</p>
<p style="text-align: center;">INFLUENZA VACCINE</p> <p style="text-align: center;">Injection 0.5 mL</p> <p style="text-align: center;">Flucelvax® Quad</p> <p style="text-align: center;">SEQIRUS (AUSTRALIA) PTY LTD</p> <p style="text-align: center;">Category 2 (Change to existing listing)</p>	<p style="text-align: center;">Prevention of influenza</p>	<p style="text-align: center;">To request a National Immunisation Program listing for the prevention of influenza in patients aged 6 months and older.</p>	<p>Recommended</p>	<p>The PBAC recommended that influenza vaccine (Flucelvax Quad, quadrivalent influenza virus vaccine, surface antigen, inactivated, cell-based, QIVc) be a designated vaccine for the purposes of the <i>National Health Act 1953</i>, for vaccination against influenza in children aged ≥6 months to <5 years. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of QIVc would be acceptable at the same price as was previously recommended for QIVc for the current NIP-funded population.</p>

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<p style="text-align: center;">INFLUENZA VACCINE</p> <p style="text-align: center;">Injection 0.5 mL</p> <p style="text-align: center;">Flublok® Quadrivalent</p> <p style="text-align: center;">SANOFI-AVENTIS AUSTRALIA PTY LTD</p> <p style="text-align: center;">Category 2 (New NIP listing)</p>	<p style="text-align: center;">Prevention of influenza</p>	<p style="text-align: center;">To request a National Immunisation Program listing for the prevention of influenza in patients aged 65 years and over.</p>	<p>Recommended</p>	<p>The PBAC recommended that influenza vaccine (Flublok Quadrivalent, RIV4) be a designated vaccine for the purposes of the <i>National Health Act 1953</i> for vaccination against influenza in people aged at least 65 years of age. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of RIV4 would be acceptable if it were cost-minimised against adjuvanted quadrivalent influenza vaccine. The PBAC considered that the equi-effective doses should be one dose of RIV4 0.5 mL and one dose of adjuvanted egg-based quadrivalent influenza vaccine (aQIV) 0.5 mL.</p>
<p style="text-align: center;">IRINOTECAN</p> <p style="text-align: center;">Solution for I.V. infusion containing nanoliposomal irinotecan (as sucrosfate) 43 mg in 10 mL</p> <p style="text-align: center;">Onivyde®</p> <p style="text-align: center;">SERVIER LABORATORIES (AUST.) PTY. LTD.</p> <p style="text-align: center;">Category 2 (New PBS listing)</p>	<p style="text-align: center;">Pancreatic cancer</p>	<p style="text-align: center;">To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, for use in combination with oxaliplatin, 5-fluorouracil and folinic acid/leucovorin, for the first-line treatment of metastatic pancreatic adenocarcinoma (mPAC).</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend nanoliposomal irinotecan (nal-IRI) in combination with oxaliplatin, 5 fluorouracil (5-FU) and leucovorin (LV) for use as a four-drug chemotherapy regimen known as NALIRIFOX, for the first-line treatment of mPAC. The PBAC considered that the combination regimen known as FOLFIRINOX (containing irinotecan, 5-FU, LV and oxaliplatin) was the relevant main comparator in the proposed population, rather than gemcitabine with nanoparticle albumin-bound paclitaxel (Gem+NabP) as nominated by the submission. The PBAC considered that the submission had not established superiority of NALIRIFOX to FOLFIRINOX. The PBAC considered there is a high clinical need for new effective treatments for pancreatic cancer, however the submission's clinical claims were not supported by the clinical evidence.</p> <p><u>Sponsor's Comment:</u> Servier is disappointed by this decision but welcomes the PBAC's recognition of the need for new effective treatment options for patients living with metastatic pancreatic cancer in the first-line setting. Servier will consider options to resolve the issues PBAC have identified, in the hope that Australian patients can access nanoliposomal irinotecan through the PBS for the treatment of pancreatic cancer in a timely way.</p>

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<p align="center">LAROTRECTINIB</p> <p align="center">Capsule 25 mg (as sulfate) Capsule 100 mg (as sulfate) Oral solution 20 mg per mL (as sulfate), 50 mL, 2</p> <p align="center">Vitrakvi®</p> <p align="center">BAYER AUSTRALIA LTD</p> <p align="center">Standard re-entry (Change to existing listing)</p>	<p align="center">Non-small cell lung cancer (NSCLC) or soft tissue sarcoma (STS) harbouring neurotrophic receptor tyrosine kinase (<i>NTRK</i>) gene fusions</p>	<p align="center">Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of locally advanced or metastatic NSCLC or STS harbouring <i>NTRK</i> gene fusions.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of larotrectinib for the treatment of adults with locally advanced or metastatic NSCLC or STS harbouring <i>NTRK</i> gene fusions. The PBAC noted patients with NSCLC and STS have access to gene panel testing that includes <i>NTRK</i> gene fusions on the MBS. The PBAC noted that patients with glioma, glioneuronal tumour or glioblastoma also have access to testing on the MBS and advised it would be reasonable for larotrectinib to be listed on the PBS for these patients harbouring <i>NTRK</i> gene fusions. The PBAC considered the incremental cost-effectiveness ratio was high but acceptable at the price proposed in the pre-PBAC response. The PBAC noted the very small number of patients that would be eligible for treatment and considered the utilisation estimates were reasonable.</p>
<p align="center">LEBRIKIZUMAB</p> <p align="center">Injection 250 mg in 2 mL single use autoinjector</p> <p align="center">Ebglyss®</p> <p align="center">ELI LILLY AUSTRALIA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">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>Recommended</p>	<p>The PBAC recommended the listing of lebrikizumab for adult and adolescent patients (12 years of age and older) with severe AD. The PBAC acknowledged the clinical need for additional systemic treatments for severe AD and considered that lebrikizumab provides an overall clinical benefit similar to the primary comparator dupilumab and the additional comparator upadacitinib. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of lebrikizumab would be acceptable if it were cost-minimised to the lowest cost alternative therapy of dupilumab or upadacitinib. The PBAC considered the equi-effective doses, for adults and adolescents ≥ 60 kg, over a 2 year period, are: lebrikizumab 500 mg at week 0 and 2, followed by 250 mg Q2W until week 16, followed by a maintenance dose of lebrikizumab 250 mg Q4W = dupilumab 600 mg at week 0, followed by a maintenance dose of 300 mg Q2W. The PBAC considered the equi-effective dose for adolescents < 60 kg and slow responders were different and should also be accounted for.</p>

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<p style="text-align: center;">LEVODOPA WITH CARBIDOPA AND ENTACAPONE</p> <p style="text-align: center;">Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg and with entacapone 20 mg per mL, 47 mL</p> <p style="text-align: center;">Lecigon®</p> <p style="text-align: center;">STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p style="text-align: center;">Category 2 (New PBS listing)</p>	<p style="text-align: center;">Parkinson disease</p>	<p style="text-align: center;">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of levodopa with carbidopa and entacapone intestinal gel (LECIg), in patients with advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment. The PBAC was concerned that limitations in the submission’s clinical evidence raised uncertainties about clinical claims vs levodopa with carbidopa intestinal gel (LCIG), but on balance was prepared to accept that the claims of non-inferior efficacy and safety were reasonable. Listing was not recommended because of uncertainty about appropriate equi-effective dosing (that could result in a substantial net financial impact to the PBS). Further, the PBAC considered that there was no clear unmet clinical need for a levodopa-containing intestinal gel formulation, although the use of a smaller infusion pump (with LECIG, relative to the pump used with LCIG) was noted. The PBAC considered that any re-submission should put forward a more conservative equi-effective dose calculation, and that an early re-entry resubmission would be appropriate if sufficiently conservative equi-effective dosing was proposed.</p> <p><u>Sponsor’s Comment:</u> STADA Pharmaceuticals Australia Pty Ltd appreciates the opportunity to resubmit via the early re-entry pathway and is committed to working with the PBAC to bring levodopa with carbidopa and entacapone intestinal gel (LECIg), to Australian patients with advanced idiopathic Parkinson disease, in a timely manner.</p>

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<p align="center">MEPOLIZUMAB</p> <p align="center">Powder for injection 100 mg Injection 100 mg in 1 mL single dose pre-filled pen</p> <p align="center">Nucla®</p> <p align="center">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p align="center">Category 3 (Change to existing listing)</p>	<p align="center">Uncontrolled severe asthma</p>	<p>To request a change to the restriction level of the existing listings for initial treatment from Authority Required (Written) to Authority Required (Telephone/Online), and for continuing treatment from Authority Required (Written) to Authority Required (STREAMLINED) for the treatment of uncontrolled severe asthma.</p> <p>The submission also requested a change to the current requirement for treating with oral corticosteroids as part of optimised asthma therapy for the initial treatment of uncontrolled severe asthma.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the amendment to the clinical criteria of mepolizumab for the treatment of uncontrolled severe asthma to remove the oral corticosteroids (OCS) requirement within the definition of 'optimised asthma therapy' to align with current treatment guidelines. The PBAC did not consider that the change to the OCS clinical criteria would increase the eligible population and therefore considered there to be nil financial impact to the Government. The PBAC recommended flow-on changes of this amendment to the other PBS-listed biologics for uncontrolled severe asthma.</p> <p>The PBAC did not recommend amendments to the authority level for mepolizumab for the treatment of uncontrolled severe asthma. The PBAC considered that, while the available data suggested that the growth of mepolizumab is gradually stabilising, the overall uncontrolled severe asthma market continues to grow. The PBAC therefore considered that it would not be appropriate to amend the circumstances of mepolizumab in isolation, noting the growth of the overall anti-interleukin-5 market for uncontrolled severe asthma.</p>

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<p align="center">MIGALASTAT</p> <p align="center">Capsule containing migalastat hydrochloride 150 mg</p> <p align="center">Galafold®</p> <p align="center">AMICUS THERAPEUTICS PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Fabry disease</p>	<p align="center">To request the PBAC consider its previous recommendation to list migalastat as a General Schedule Authority Required (Written) listing for the treatment of Fabry disease, and to request an amendment to the restriction criteria to be consistent with international clinical guidelines for Fabry disease.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of migalastat for the treatment of Fabry disease in patients aged 12 years of age and older who have an amenable mutation and evidence of organ involvement/injury (including renal disease, cardiac disease, ischaemic and cerebrovascular disease, severe gastrointestinal symptoms, and uncontrolled chronic pain). The PBAC noted the proposed cost of migalastat was substantially higher than recommended in December 2022 but considered that, on balance, noting the high clinical need for ongoing access to funded treatments for Fabry disease, migalastat was likely to be of high but acceptable cost-effectiveness in the recommended population at the cost per patient per year proposed in the resubmission. The PBAC considered the estimated number of patients with Fabry disease who had evidence of organ involvement/injury was likely to be reasonable. The PBAC acknowledged the importance of treating some patients at an earlier stage of disease but considered the clinical effectiveness and cost-effectiveness of this was unknown, and therefore did not recommend extending the listing to patients with classical Fabry disease without evidence of organ involvement/injury.</p>

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<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 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 extend the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of neoadjuvant treatment of resectable NSCLC to allow retreatment.</p>	<p align="center">Not Recommended</p>	<p>At its July 2023 meeting, the PBAC recommended the listing of nivolumab (Opdivo) for the neoadjuvant treatment of surgically-resectable NSCLC. At the March 2024 meeting, the PBAC did not recommend any revisions to its previous advice. Specifically, the PBAC did not recommend retreatment with immunotherapy (IO) in those who relapse with metastatic disease as there was limited evidence to support the effectiveness of IO retreatment following use in surgically-resectable NSCLC, and this resulted in it being unknown if retreatment was cost-effective. The PBAC also did not recommend a price increase for nivolumab for the scenario of no IO retreatment. The PBAC noted the economic model was sensitive to the inputs regarding treatment in the metastatic setting and considered it was unlikely that neoadjuvant nivolumab was cost-effective at the proposed price.</p> <p><u>Sponsor's Comment:</u> The Sponsor would like to reiterate its commitment to finding a pathway forward for immuno-oncology retreatment across early and advanced disease, as evidenced by this submission and a previous submission provided for melanoma which was recommended (Item 6.09, Nov 2022 PBAC Meeting). BMS Australia are looking forward to working with the PBAC to achieve this important change in treatment paradigm for cancer patients.</p>

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<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 100 mg in 10 mL Injection concentrate for I.V. infusion 40 mg in 4 mL</p> <p align="center">Opdivo®</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">Matters outstanding (Change to existing listing)</p>	<p align="center">Muscle invasive urothelial carcinoma (MIUC)</p>	<p align="center">To request reconsideration for a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the adjuvant treatment of high-risk MIUC. This matter was deferred at the November 2023 PBAC meeting.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of nivolumab for the adjuvant treatment of high-risk MIUC in patients who have received prior neoadjuvant platinum-based chemotherapy (NAC). The PBAC considered that there was a moderate clinical need for more effective therapies for this indication and that an improvement in disease free survival was demonstrated in patients who had received prior NAC. The PBAC reaffirmed its view that the clinical criterion allowing use in patients who have a contraindication or intolerance to NAC be removed as there were important cost and quality use of medicines issues arising from use in this patient population with no proven benefit. The PBAC noted the price offered in the revised proposal and considered it addressed the Committee’s previous concerns regarding cost-effectiveness. The PBAC accepted the revised financial estimates with the contraindicated population removed and considered these would be an appropriate basis for a risk sharing arrangement.</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">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Multiple sclerosis</p>	<p align="center">To request separating the current higher efficacy disease modifying therapies (DMT) tier into two distinct efficacy tiers.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend separating the current higher efficacy DMT tier into two distinct efficacy tiers on the basis that the clinical evidence presented did not adequately support the submission’s underlying claim that ofatumumab (proposed as a high-efficacy tier DMT) has superior comparative effectiveness versus fingolimod (as a proxy for the proposed mid-efficacy tier DMTs). In the absence of direct comparative evidence or randomised controlled trials with a common reference arm, the submission included a two-step indirect comparison; however, the PBAC considered there were substantial transitivity issues between the studies included in this comparison. The PBAC further considered the unanchored adjusted comparisons presented were associated with an unknown amount of bias and did not sufficiently address the transitivity issues between the studies. Overall, the PBAC considered the clinical evidence was not sufficiently reliable for the purposes of establishing superiority.</p> <p><u>Sponsor’s Comment:</u> The sponsor had no comment.</p>

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<p align="center">OSILODROSTAT</p> <p align="center">Tablet 1 mg Tablet 5 mg</p> <p align="center">Isturisa®</p> <p align="center">RECORDATI RARE DISEASES AUSTRALIA PTY. LTD.</p> <p align="center">Standard re-entry (New PBS listing)</p>	<p align="center">Cushing syndrome (CS)</p>	<p align="center">Resubmission to request the General Schedule Authority Required (Telephone/Online) listing for the treatment of endogenous CS.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend osilodrostat for the treatment of adult patients with endogenous CS who were not candidates for surgery or for whom surgery was not curative. The PBAC accepted that osilodrostat represented an effective therapy for a disease where high clinical need exists. The PBAC considered that the economic model was not reliable for decision-making as it did not capture the important long-term quality-of-life (QoL) benefits associated with osilodrostat, resulting in an unreliable model and a very high and uncertain incremental cost-effectiveness ratio (ICER). The PBAC considered osilodrostat addresses a high and urgent unmet clinical need and was expected to provide a substantial and clinically relevant improvement in efficacy, over placebo. The PBAC nominated an early resolution pathway for this item.</p> <p>The previous submission was considered in March 2023.</p> <p><u>Comparator: placebo</u> The PBAC reaffirmed its previous consideration that the placebo comparator was the most relevant given that ketoconazole was deregistered by the TGA and metyrapone was used as an off-label therapy.</p> <p><u>Clinical claim: Superior in terms of effectiveness and non-inferior in terms of safety compared to placebo.</u> The PBAC considered that the claim of superior comparative effectiveness was reasonable for the surrogate outcomes of complete or partial response, and acknowledged the important long-term benefits associated with durable response to cortisol level.</p> <p>The PBAC considered that the adverse events were generally manageable, and the claim of non-inferior comparative safety was reasonable, noting regular monitoring of side effects of hypocortisolism was required.</p> <p><u>Economic claim: Cost utility analysis versus placebo</u> The PBAC considered that despite the resubmission’s attempt to model long-term use of osilodrostat, the inputs informing the model, particularly survival and QoL remained uncertain, the</p>

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				<p>base case ICER was too high, and it was unlikely to adequately represent the cost-effectiveness of osilodrostat.</p> <p><u>Sponsor's Comment:</u> Recordati Rare Diseases acknowledges the PBAC's recommendation and will continue to work with the Committee to make Isturisa available on the PBS for all eligible patients with endogenous Cushing's Syndrome.</p>
<p>PEGCETACOPLAN</p> <p>Solution for intravitreal injection 15 mg in 0.1 mL (150 mg per mL)</p> <p>Syfovre®</p> <p>APELLIS AUSTRALIA PTY LTD</p> <p>Category 1 (New PBS listing)</p> <p>WITHDRAWN</p>	<p>Geographic atrophy secondary to age related macular disease</p>	<p>To request a General Schedule Authority Required (Written) listing for the treatment of non-subfoveal geographic atrophy that is secondary to age-related macular degeneration.</p>	<p>Not Applicable</p>	<p>This item was withdrawn.</p>

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<p align="center">PRASUGREL</p> <p align="center">Tablet 5 mg Tablet 10 mg</p> <p align="center">Prasugrel SCP™</p> <p align="center">GENERIC HEALTH PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Acute coronary syndrome (ACS)</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing, in combination with aspirin, for the treatment of ACS (myocardial infarction or unstable angina) managed by percutaneous coronary intervention.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend prasugrel, in combination with aspirin, for the treatment of ACS i.e., myocardial infarction (MI) or unstable angina, managed by percutaneous coronary intervention (PCI). The PBAC considered that there was a low clinical need for prasugrel. The PBAC noted that the submission presented a comparison between prasugrel and ticagrelor, with clopidogrel nominated as a secondary comparator; however, the PBAC considered that both ticagrelor and clopidogrel were relevant comparators. The PBAC considered the clinical claim that prasugrel was superior compared to ticagrelor in terms of efficacy was not reasonable, instead considering that prasugrel was non-inferior compared to ticagrelor, but that the claim of non-inferior safety was reasonable. The PBAC recalled that it had previously considered that the superior comparative clinical benefit of prasugrel over clopidogrel, in terms of reduced non-fatal MI events, marginally outweighed the inferior comparative safety profile in terms of a higher incidence of adverse bleeding events. Given that the claim of superior efficacy compared to ticagrelor was not accepted and noting the numerous errors and issues with the economic evaluation, the PBAC considered that the model comparing prasugrel with ticagrelor was unreliable for decision making. The PBAC recommended the early re-entry resubmission pathway for this item.</p> <p><u>Sponsor's Comment:</u> Generic Health appreciates the opportunity to resubmit via the early re-entry pathway and is committed to working with the PBAC to bring Prasugrel to Australians in a timely manner for the treatment of ACS (myocardial infarction or unstable angina) managed by percutaneous coronary intervention, in combination with aspirin.</p>

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<p align="center">RAVULIZUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 3 mL</p> <p>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 (New PBS listing)</p>	<p align="center">Generalised myasthenia gravis (gMG)</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.</p>	<p align="center">Not Applicable</p>	<p align="center">To be considered at a future PBAC meeting</p>

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<p align="center">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 a General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe pain associated with endometriosis.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended relugolix with estradiol and with norethisterone acetate (Ryeqo), for treatment of moderate to severe pain associated with endometriosis. The PBAC's recommendation for listing was based on its assessment that the cost-effectiveness of Ryeqo would be acceptable if it were no more costly over a 12-month period than 12 months of gonadotropin hormone-releasing hormone (GnRH) therapy (plus add-back therapy) as currently supplied through the PBS. The PBAC noted based on current PBS restrictions that GnRH therapy is available as 6 months of goserelin and 6 months of nafarelin. The PBAC acknowledged that Ryeqo would be used on average for more than 12 months and considered the cost calculated for the first 12 months of therapy provides an appropriate frame of reference for the cost of therapy beyond 12 months. The PBAC noted that based on the proposed price, the cost of Ryeqo, including bone mineral density (BMD) monitoring and goserelin implantation costs, was lower over 12 months than the comparator costs and was therefore considered cost-effective. The PBAC acknowledged the clinical need for new treatments for endometriosis. The PBAC noted that there were significant safety concerns regarding bone mineral density loss, particularly for younger women, and where patients receive ongoing treatment with GnRH therapy, including Ryeqo, for more than 1-2 years. The PBAC noted this could be monitored for at risk patients using BMD testing. The PBAC considered that the listing of Ryeqo, as a fixed dose combination, with the potential for ongoing treatment for 2 years or longer, is likely to result in a net cost to the PBS. The PBAC advised that revisions to prevalence and uptake were required as well as a risk sharing arrangement to manage the uncertainties in the financial estimates.</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 1 (New NIP listing)</p>	<p align="center">Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)</p>	<p align="center">To request National Immunisation Program listing for the prevention of lower respiratory tract illness caused by RSV in infants from birth through to 6 months of age by active immunisation of pregnant individuals.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend recombinant syncytial pre-fusion F protein vaccine (RSVpreF) for the prevention of lower respiratory tract illness (LRTI) caused by RSV in infants from birth through 6 months of age by active immunisation of pregnant women. The PBAC noted the clinical trial evidence presented in the submission showed there was a reduced risk of medically attended lower respiratory tract illness (MA-LRTI) and severe MA-LRTI due to RSV among infants during the first 6 months of life in RSV-vaccinated versus placebo-vaccinated individuals. The PBAC considered that the adverse event profile of RSVpreF was acceptable compared to placebo. The PBAC considered that the incremental cost-effectiveness ratio was high and uncertain. The PBAC considered that a price reduction would be required to ensure the vaccine was cost-effective in the proposed circumstances of use.</p> <p>The PBAC nominated the Early Resolution re-submission pathway for this item.</p> <p><u>Sponsor's Comment:</u> Pfizer welcomes the PBAC's acknowledgement of the high and urgent unmet clinical need for prevention of RSV in infants from birth through 6 months of age and the clinical benefit of Abrysvo compared to placebo. Pfizer will continue to work collaboratively with the PBAC and Department of Health and Aged Care to deliver access to Abrysvo for pregnant individuals via the proposed National Immunisation Program.</p>

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<p style="text-align: center;">RIMEGEPANT</p> <p>Tablet (orally disintegrating) 75 mg</p> <p style="text-align: center;">Nurtec® ODT</p> <p style="text-align: center;">PFIZER AUSTRALIA PTY LTD</p> <p>Early re-entry (New PBS listing)</p>	<p style="text-align: center;">Acute migraine attacks</p>	<p style="text-align: center;">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for adults with migraine who have not responded adequately to treatment of at least two triptans.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend rimegepant for the acute treatment of adults with migraine who have not responded adequately, are intolerant or contraindicated to analgesics and at least two selective 5-hydroxytryptamine receptor agonists (triptans). The PBAC acknowledged that there was a clinical need for new, oral treatments for the acute treatment of migraine and considered that rimegepant provided a benefit over best supportive care (BSC) in terms of efficacy. However, the PBAC considered that the resubmission did not appropriately address the issues raised in July 2023 relating to the economic evaluation and the financial impact estimates. The PBAC noted that a number of the suggested changes from July 2023 were not incorporated into the revised economic model and that the revised model was highly optimistic. Despite this, the PBAC considered that the revised incremental cost-effectiveness ratio (ICER) presented in the resubmission was high and that rimegepant was not cost-effective at the price proposed in the resubmission. Further, the PBAC noted that although it had considered that the utilisation estimates presented in the July 2023 submission were reasonable, the resubmission presented revised utilisation estimates which were substantially higher than the previous submission. This resulted in an estimated financial impact that, despite the lower proposed price, was over 2.5 times higher than in July 2023. The PBAC noted that the patient population was difficult to define and considered that there would likely be broad use of rimegepant. However, the PBAC considered that the proposed Risk Sharing Arrangement (RSA) was not reasonable and did not mitigate the financial risk to Government.</p> <p>The previous submission was considered in July 2023.</p> <p><u>Comparator: Best supportive care (BSC):</u> The PBAC reaffirmed its previous view that the proposed comparator was reasonable.</p> <p><u>Clinical claim: Superior effectiveness and non-inferior safety compared to BSC:</u></p>

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			<p>The PBAC recalled it had previously considered that that a single dose of rimegepant was superior compared to BSC in terms of treating acute migraine but that the long-term treatment effect of rimegepant was uncertain, and that rimegepant was non-inferior compared to BSC in terms of the safety. The PBAC reaffirmed its previous view.</p> <p><u>Economic claim: Cost-utility versus placebo:</u> The PBAC noted that a number of suggested changes were not incorporated into the revised model. The PBAC considered that the revised model presented was optimistic and that the resultant ICER and cost per tablet remained high.</p> <p><u>Sponsor's Comment:</u> While disappointed with the PBAC's decision not to recommend rimegepant for the treatment of acute migraine attacks, Pfizer welcomes the PBAC's continued acknowledgment of the burden of acute migraine and clinical unmet need for novel effective treatments such as rimegepant.</p> <p>Pfizer's resubmission included significant changes intended to address the early re-entry criteria. Pfizer hopes to continue working with the PBAC and the Department of Health and Aged Care to enable access for rimegepant to patients suffering from acute migraine attacks. Pfizer views the PBAC preferred financial estimates as likely underestimating the potential use in clinical practice substantially, for use of rimegepant in acute migraine attacks within the Pfizer proposed restrictions.</p>

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<p align="center">RISPERIDONE</p> <p>I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 75 mg and 1 pre-filled syringe diluent 383 microlitres I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 100 mg and 1 pre-filled syringe diluent 490 microlitres</p> <p align="center">Okedi®</p> <p>SERVIER LABORATORIES (AUST.) PTY. LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Schizophrenia</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of schizophrenia.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of risperidone in-situ microparticles (ISM) 4-weekly long-acting injection (LAI) 75 mg and 100 mg for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone, on a cost-minimisation basis with paliperidone 1-monthly LAI (PP1M) and risperidone 2-weekly LAI Risperdal Consta® (RC). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of risperidone ISM would be acceptable if it were cost-minimised to the lowest cost comparator (RC, paliperidone LAIs, or aripiprazole 4-weekly) for the same indication.</p> <p>The PBAC considered the equi-effective doses to be:</p> <ul style="list-style-type: none"> • Risperidone ISM 75 mg every 4 weeks = RC 37.5 mg every 2 weeks • Risperidone ISM 75 mg every 4 weeks = PP1M 75 mg monthly • Risperidone ISM 100 mg every 4 weeks = RC 50 mg every 2 weeks • Risperidone ISM 100 mg every 4 weeks = PP1M 100 mg monthly.
<p align="center">ROMOSUZUMAB</p> <p>Injection 105 mg in 1.17 mL single use pre-filled syringe</p> <p align="center">Evenity®</p> <p>AMGEN AUSTRALIA PTY LIMITED</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Osteoporosis</p>	<p align="center">To request the PBAC consider its previous recommendation to list romosozumab as a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe osteoporosis in the first-line setting.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of romosozumab for the treatment of severe osteoporosis in the first-line setting. The PBAC considered that romosozumab provides, for some patients a significant improvement in efficacy over alendronate. The PBAC considered that the submission's proposed changes to the economic model inputs resulted in the cost-effectiveness estimate being uncertain, but considered that this could be mitigated through a combined risk sharing arrangement across the first- and second-line settings with first-line expenditure caps based on the price at which it had previously considered romosozumab to be cost-effective. The PBAC further advised that the caps for the second-line setting should be revised to reflect no further growth in this setting (i.e., utilisation remaining at the most recent levels).</p>

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<p align="center">SELUMETINIB</p> <p align="center">Capsule 10 mg Capsule 25 mg</p> <p align="center">Koselugo®</p> <p align="center">ALEXION PHARMACEUTICALS AUSTRALASIA PTY LTD</p> <p align="center">Facilitated resolution (New PBS listing)</p>	<p align="center">Neurofibromatosis type 1 (NF1)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of symptomatic, inoperable plexiform neurofibroma(s) in paediatric patients aged 2 years and over with NF1.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of selumetinib for the treatment of symptomatic inoperable plexiform neurofibroma(s) in paediatric patients with NF1. The PBAC noted the high clinical need for treatments for this condition and considered that selumetinib provided a clinical benefit for patients compared to best supportive care. The PBAC considered that the resubmission had addressed most of the issues raised in the previous submission adequately; however, noted that the incremental cost-effectiveness ratio (ICER) remained high. The PBAC considered that a further reduction in cost would be required to achieve an acceptable ICER. The PBAC considered the estimated number of treated patients would form a reasonable basis for a risk sharing arrangement.</p>
<p align="center">SIPONIMOD</p> <p align="center">Tablet 1 mg (as hemifumarate)</p> <p align="center">Mayzent®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 4 (New PBS listing)</p>	<p align="center">Multiple sclerosis</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing of a new strength of siponimod for the treatment of relapsing-remitting multiple sclerosis.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of siponimod 1 mg tablet under the same circumstances as the current PBS-listed siponimod 0.25 mg tablet 120-unit pack size. The PBAC advised that this recommendation was made on a cost-minimisation basis to siponimod 0.25 mg tablet 120-unit pack size. The PBAC considered the listing of this pack size would reduce the tablet burden for patients on a 1 mg dose.</p>

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<p>SODIUM ZIRCONIUM CYCLOSILICATE</p> <p>Sachet containing powder for oral suspension (as hydrate) 5 g Sachet containing powder for oral suspension (as hydrate) 10 g</p> <p>Lokelma®</p> <p>ASTRAZENECA PTY LTD</p> <p>Category 2 (New PBS listing)</p>	<p>Chronic hyperkalaemia</p>	<p>To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of chronic hyperkalaemia in patients with chronic kidney disease (CKD) Stage 3-4.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of sodium zirconium cyclosilicate (SZC) for the treatment of chronic hyperkalaemia in patients with CKD Stage 3-4. The PBAC accepted that SZC was likely non-inferior in terms of efficacy, and similar in terms of safety, to patiromer. The PBAC considered that a cost-minimisation approach between SZC and patiromer was appropriate and considered that the addition of SZC to the PBS should not result in any additional cost to Government. The PBAC considered that the equi-effective doses were 1 sachet of SZC (either 5 g or 10 g) = 1 sachet of patiromer (either 8.4 g or 16.8 g).</p>
<p>TADALAFIL</p> <p>Tablet 20 mg</p> <p>Tadalafil</p> <p>CIPLA AUSTRALIA PTY LTD</p> <p>Category 4 (New PBS listing)</p>	<p>Pulmonary arterial hypertension (PAH)</p>	<p>To request listing of a new pack size for tadalafil 20 mg of 60 tablets under the same conditions as the existing listings of the 56-pack size for the treatment of PAH.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of a new pack size (60 tablets) of tadalafil 20 mg (Tadalafil 20) on the PBS for the treatment of PAH on a cost-minimisation basis and at the same price per tablet as the currently listed pack size (56 tablets). The PBAC advised that Tadalafil 20 (60-tablet pack) should not be marked as equivalent in the PBS for the purposes of substitution (i.e. 'a' flagged) to Tadalca (tadalafil 20 mg, 56 tablets) and Adcirca® (tadalafil 20 mg, 56 tablets) due to the difference in maximum quantity between these products (i.e., 60 tablets versus 56 tablets).</p>

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<p style="text-align: center;">TALAZOPARIB</p> <p style="text-align: center;">Capsule 0.1 mg Capsule 0.25 mg Capsule 0.35 mg Capsule 0.5 mg</p> <p style="text-align: center;">Talzena®</p> <p style="text-align: center;">PFIZER AUSTRALIA PTY LTD</p> <p style="text-align: center;">Category 2 (New PBS listing)</p>	<p style="text-align: center;">Prostate cancer</p>	<p style="text-align: center;">To request a General Schedule Authority Required (STREAMLINED) listing, in combination with enzalutamide, for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in patients with a 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>Not Recommended</p>	<p>The PBAC did not recommend talazoparib, for use in combination with enzalutamide, for the treatment of mCRPC in patients with <i>BRCA1/2</i> pathogenic variants who have not received prior treatment with a NHA. Although the PBAC considered that talazoparib + enzalutamide was likely superior to enzalutamide alone, it noted that the precise magnitude of the benefit in clinical practice was uncertain given that the results were based on a small, post-hoc subgroup of patients with <i>BRCA1/2</i> pathogenic variants. Additionally, the PBAC considered that the incremental cost-effectiveness ratio presented in the pre-PBAC response was high and uncertain and that utilisation was likely overestimated. The PBAC noted that there is an existing risk sharing arrangement for olaparib monotherapy and considered that it would be appropriate for talazoparib + enzalutamide to join this.</p> <p>The PBAC nominated the Early Re-Entry resubmission pathway for this item.</p> <p><u>Sponsor's Comment:</u> Pfizer welcomes the opportunity to resubmit via the early re-entry pathway. Pfizer looks forward to continuing to work with the PBAC and the Department of Health and Aged Care to provide access to talazoparib for the treatment of mCRPC in patients with <i>BRCA1/2</i> pathogenic variants.</p>

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<p align="center">TIOTROPIUM</p> <p>Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate)</p> <p align="center">Tiotropium Lupin</p> <p align="center">GENERIC HEALTH PTY LTD</p> <p align="center">Category 4 (New PBS listing)</p>	<p align="center">Chronic obstructive pulmonary disease (COPD)</p>	<p align="center">To request a General Schedule Restricted Benefit listing of a new form of tiotropium for the treatment of COPD.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of a new product containing tiotropium, Tiotropium Lupin for use with LupinHaler® as an alternative to the currently PBS-listed Spiriva® for use with Handihaler® for the treatment of COPD. The PBAC recommended the listing on a cost-minimisation basis to the lowest cost PBS-listed tiotropium brand for COPD. The PBAC noted that the TGA considered Tiotropium Lupin to be bioequivalent to Spiriva, and that Braltus® (for use with the Zonda® device) is currently marked as equivalent to Spiriva. The PBAC advised that Tiotropium Lupin, Spiriva, and Braltus should be treated as equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule). The PBAC noted that while the operational steps of the delivery devices for all three brands of tiotropium (Spiriva, Braltus and Tiotropium Lupin) are comparable, each product is intended for use only with its respective delivery device. The PBAC was satisfied that, consistent with its March 2019 consideration for Braltus, the differences in the use of each device for tiotropium inhalation could be managed adequately through regular patient education and counselling on device administration, provided by prescribers and pharmacists.</p>

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<p align="center">TOFACITINIB</p> <p align="center">Tablet (modified release) 11 mg</p> <p align="center">Xeljanz® XR</p> <p align="center">PFIZER AUSTRALIA PTY LTD</p> <p align="center">Category 4 (New PBS listing)</p>	<p align="center">Rheumatoid arthritis (RA) Psoriatic arthritis (PsA)</p>	<p align="center">To request listing of a new form and strength for tofacitinib under the same conditions as the existing listings of tofacitinib 5 mg for the treatment of severe active RA and severe PsA.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of a new form and strength of tofacitinib (tofacitinib tablet (modified release) 11 mg (Xeljanz XR)) under the same circumstances as the current PBS listings for tofacitinib 5 mg tablets for the treatment of severe active RA and severe PsA. The PBAC recommended listing Xeljanz XR on a cost-minimisation basis with the least costly PBS-listed biological disease-modifying anti-rheumatic drug (bDMARD) for severe active RA and severe PsA. The PBAC considered that the submission did not provide evidence to demonstrate that Xeljanz XR provides, for some patients, a significant improvement in efficacy or reduction in toxicity compared to any of the currently listed bDMARDs for severe active RA and severe PsA. The PBAC considered that any of the currently PBS-listed bDMARDs for these conditions could be an alternative therapy to Xeljanz XR. The PBAC advised the equi-effective doses were: Xeljanz XR 11 mg (1 tablet once daily), tofacitinib 5 mg (1 tablet twice daily), and doses of alternative bDMARDs derived from the relevant Product Information documents.</p>
<p align="center">TRASTUZUMAB DERUXTECAN</p> <p align="center">Powder for I.V. infusion 100 mg</p> <p align="center">Enhertu®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Early re-entry (New PBS listing)</p>	<p align="center">Human epidermal growth factor receptor 2 (HER2)-low breast cancer</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the treatment of patients with HER2-low unresectable or metastatic breast cancer.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of trastuzumab deruxtecan (T-DXd) for the treatment of patients with HER2-low unresectable or metastatic breast cancer. The PBAC reiterated its previous consideration that T-DXd was superior to chemotherapy and there was a moderate clinical need for additional treatments in this therapeutic area. The PBAC considered the incremental cost-effectiveness ratio remained high at the price proposed in the pre-PBAC response and a further reduction in treatment cost would be required. The PBAC considered the estimated number of treated patients provided in the pre-PBAC response was reasonable. The PBAC noted the very high financial cost and risk to the Commonwealth and advised a risk share arrangement would be appropriate.</p>

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<p align="center">USTEKINUMAB</p> <p>Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 45 mg in 0.5 mL single use pre-filled pen Injection 90 mg in 1 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled pen</p> <p align="center">Stelara®</p> <p align="center">JANSSEN-CILAG PTY LTD</p> <p align="center">Category 4 (New PBS listing)</p>	<p align="center">Psoriatic arthritis (PsA) Crohn disease (CD) Chronic plaque psoriasis (CPP) Ulcerative colitis (UC) Fistulising Crohn disease</p>	<p align="center">To request Authority Required (Written) listing of new forms, and amendments to the current restrictions for severe CD and severe CPP to align with a change in the quantity required for adult patients resulting from the new listings.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of ustekinumab (UST) 45 mg and 90 mg pre-filled syringe (PFS) and pre-filled pen (PFP) under the same circumstances as the currently listed UST 45 mg injection vial for the treatment of severe PsA, severe CPP, severe CD, moderate to severe UC and complex refractory fistulising CD on the PBS. The PBAC also recommended amendments to the current restrictions for severe CD and severe CPP to align with changes in the quantity required for adult patients following the proposed new listings. The PBAC made its recommendation based on, among other matters, its assessment that the cost-effectiveness of UST would be acceptable if it were cost-minimised to the least costly alternative biological disease modifying anti-rheumatic drug for each of the above-mentioned indications, based on previously advised equi-effective doses.</p> <p>The PBAC considered that equivalent strengths and forms of Stelara and Wezlana (i.e. Stelara PFS and Wezlana PFS; Stelara and Wezlana injection vial) should be treated as equivalent to each other for the purposes of substitution (i.e. 'a' flagged in the schedule).</p> <p>The PBAC considered the equi-effective doses to be as follows:</p> <ul style="list-style-type: none"> • 1 x UST 45 mg PFS and PFP = 1 x UST 45 mg vial • 1 x UST 90 mg PFS and PFP = 2 x UST 45 mg vial • 1 x UST 90 mg PFP = 1 x UST 90 mg PFS

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<p align="center">USTEKINUMAB</p> <p>Injection 45 mg in 0.5 mL Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Solution for I.V. infusion 130 mg in 26 mL</p> <p align="center">Wezlana®</p> <p align="center">AMGEN AUSTRALIA PTY LIMITED</p> <p align="center">Category 3 (New PBS listing)</p>	<p align="center">Psoriatic arthritis (PsA) Crohn disease (CD) Chronic plaque psoriasis (CPP) Ulcerative colitis (UC)</p>	<p align="center">To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings of ustekinumab biosimilar under the same conditions as its reference biologic.</p>	<p align="center">Recommended</p> <p>The PBAC recommended the listing of a new biosimilar brand of ustekinumab (Wezlana) in the forms of injection 45 mg in 0.5 mL, injection 90 mg in 1 mL single use pre-filled syringe (PFS) and solution for I.V. infusion 130 mg in 25 mL under the same circumstances as the PBS-listed reference biologic, Stelara®, for the treatment of adult and paediatric severe CPP, severe CD, moderate to severe UC, complex refractory fistulising CD and severe PsA. The PBAC also recommended injection 45 mg in 0.5 mL single use PFS for adult and paediatric severe CPP and PsA and injection 90 mg in 1 mL single use PFS for severe CD and adult CPP under the same circumstances as Stelara.</p> <p>The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Wezlana would be acceptable if it were cost-minimised to Stelara.</p> <p>The PBAC advised that biosimilar uptake drivers, including the differential authority requirements for subsequent continuing treatment between the reference and biosimilar brand and inclusion of an administrative note encouraging the use of biosimilar brand for treatment naïve patients, should apply to Wezlana. The PBAC advised that equivalent strengths and forms of Stelara PFS and Wezlana PFS should be treated as equivalent to each other; and equivalent strengths and forms of Stelara and Wezlana 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"> • Wezlana 1 x 45 mg injection vial = Stelara 1 x 45 mg injection vial • Wezlana 1 x 45 mg PFS = Stelara 1 x 45 mg PFS • Wezlana 1 x 90 mg PFS = Stelara 2 x 45 mg injection vial • Wezlana 1 x 130 mg injection vial = Stelara 1 x 130 mg injection vial

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<p align="center">VEDOLIZUMAB</p> <p>Injection 108 mg in 0.68 mL single use pre-filled pen Powder for injection 300 mg</p> <p align="center">Entyvio®</p> <p align="center">TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Crohn disease (CD) Ulcerative colitis (UC)</p>	<p>To request a change to the clinical criteria to allow an additional dose of vedolizumab 300 mg at Week 10 for the initial treatment of severe CD.</p> <p>The submission also requested the removal of the requirement to assess the risk of developing progressive multifocal leukoencephalopathy during this treatment from all PBS listings for vedolizumab.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of an additional dose of vedolizumab 300 mg at week 10 for the initial treatment of severe CD for patients who have not responded to therapy after the existing three dose induction therapy. The PBAC also recommended the removal of the requirement to assess the risk of developing progressive multifocal leukoencephalopathy during this treatment from all PBS listings for vedolizumab. The PBAC noted that the additional dose is currently provided to eligible patients through the sponsor's compassionate access program. The PBAC also noted advice from specialists that this approach is being used in clinical practice and hospital settings. The PBAC noted input from Crohn's and Colitis Australia supporting the inclusion of the additional dose. The PBAC recommended that the listing of the additional dose should be cost-neutral to the Government and that the sponsor was supportive of this approach. The PBAC noted minor flow-on restriction changes to the prescribing instructions of the subcutaneous form of vedolizumab indicated for severe CD.</p>
<p align="center">VENETOCLAX</p> <p>Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg</p> <p>Tablet 10 mg Tablet 50 mg Tablet 100 mg</p> <p align="center">Venclexta®</p> <p align="center">ABBVIE PTY LTD</p> <p align="center">Category 3 (Other matters)</p> <p align="center">WITHDRAWN</p>	<p align="center">Chronic lymphocytic leukaemia (CLL)</p>	<p>To request consideration of the current treatment duration and the eligible population being treated with venetoclax in the treatment of CLL.</p>	<p align="center">Not Applicable</p>	<p>This item was withdrawn.</p>

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<p align="center">BECLOMETASONE WITH FORMOTEROL</p> <p>Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 dose</p> <p align="center">Fostair® Chiesi Australia Pty Ltd</p>	<p align="center">Chronic obstructive pulmonary disease</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC rescinded the March 2022 recommendation for beclometasone with formoterol.</p>
<p align="center">BIMEKIZUMAB</p> <p>Solution for injection 160 mg in 1 mL pre-filled pen Solution for injection 160 mg in 1 mL pre-filled syringe</p> <p align="center">Bimzelx® UCB Australia Proprietary Limited</p>	<p align="center">Plaque psoriasis</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC rescinded the March 2022 recommendation for bimekizumab.</p>
<p align="center">DUPILUMAB</p> <p>Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe</p> <p align="center">Dupixent® Sanofi-Aventis Australia Pty Ltd</p>	<p align="center">Atopic dermatitis in children 6 to 11 years of age</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the March 2022 recommendation for dupilumab for an additional 12 months.</p>

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

DRUG NAME, FORM(S), STRENGTH(S) AND SPONSOR	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p align="center">ENOXAPARIN</p> <p>Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL syringe Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL syringe</p> <p align="center">Enoxapo®</p> <p align="center">Apotex Pty Ltd</p>	<p align="center">Antithrombotic</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC rescinded the July 2020 recommendation for enoxaparin.</p>
<p align="center">FREMANEZUMAB</p> <p align="center">Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe</p> <p align="center">Ajovy®</p> <p align="center">Teva Pharma Australia Pty Ltd</p>	<p align="center">Treatment-resistant migraine (change to maximum quantity and number of repeats)</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC rescinded the March 2022 recommendation for fremanezumab.</p>
<p align="center">GALCANEZUMAB</p> <p align="center">Injection 120 mg in 1 mL pre-filled pen</p> <p align="center">Emgality®</p> <p align="center">Eli Lilly Australia Pty Ltd</p>	<p align="center">Treatment-resistant high frequency episodic migraine</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the March 2022 recommendation for galcanezumab for an additional 12 months.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S) AND SPONSOR	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, CARBOHYDRATES, MINERALS AND LOW PHENYLALANINE</p> <p>Sachets containing oral powder 12.5 g, 30 (PKU GMPPro Mix-In)</p> <p>PKU GMPPro Mix-In®</p> <p>Nutricia Australia Pty Limited</p>	<p>Phenylketonuria</p>	<p>Review of positive PBAC recommendations not accepted by applicants</p>	<p>The PBAC extended the March 2022 recommendation for glycomacropeptide formula with amino acids, carbohydrates, minerals and low phenylalanine for an additional 12 months.</p>
<p>GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, VITAMINS, MINERALS, TRACE ELEMENTS, CARBOHYDRATE, FAT AND LOW PHENYLALANINE</p> <p>Sachets containing oral powder 33.4 g, 30 (PKU GMPPro ULTRA)</p> <p>PKU GMPPro ULTRA®</p> <p>Nutricia Australia Pty Limited</p>	<p>Phenylketonuria</p>	<p>Review of positive PBAC recommendations not accepted by applicants</p>	<p>The PBAC extended the March 2022 recommendation for glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine for an additional 12 months.</p>
<p>OZANIMOD</p> <p>Capsule 920 micrograms</p> <p>Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms</p> <p>Zeposia®</p> <p>Celgene Pty Limited</p>	<p>Ulcerative colitis</p>	<p>Review of positive PBAC recommendations not accepted by applicants</p>	<p>The PBAC rescinded the March 2022 recommendation for ozanimod.</p>
<p>RABEPRAZOLE</p> <p>Tablet containing rabeprazole sodium 20 mg (enteric coated)</p> <p>Pariet®</p> <p>Janssen-Cilag Pty Ltd</p>	<p>Gastro-oesophageal reflux disease</p>	<p>Review of positive PBAC recommendations not accepted by applicants</p>	<p>The PBAC rescinded the March 2022 recommendation for rabeprazole.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S) AND SPONSOR	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p align="center">RISANKIZUMAB</p> <p>Injection 150 mg in 1 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen</p> <p align="center">Skyrizi®</p> <p align="center">AbbVie Pty Ltd</p>	<p align="center">Psoriatic arthritis</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the March 2022 recommendation for risankizumab for an additional 12 months.</p>
<p align="center">SECUKINUMAB</p> <p>Solution for injection 300 mg in 2 mL pre-filled pen Solution for injection 300 mg in 2 mL pre-filled syringe</p> <p align="center">Cosentyx®</p> <p align="center">Novartis Pharmaceuticals Australia Pty Limited</p>	<p align="center">New strength for Non-radiographic axial spondyloarthritis Severe active psoriatic arthritis Severe psoriatic arthritis Ankylosing spondylitis Active ankylosing spondylitis Severe chronic plaque psoriasis</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the March 2022 recommendation for secukinumab for an additional 12 months.</p>
<p align="center">SOMAPACITAN</p> <p align="center">Injection 10 mg in 1.5 mL pre-filled pen</p> <p align="center">Sogroya®</p> <p align="center">Novo Nordisk Pharmaceuticals Pty. Limited</p>	<p align="center">Adult-onset growth hormone deficiency</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the March 2022 recommendation for somapacitan for an additional 12 months.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>Access to medicines for people in custodial settings</p> <p>Various medicines</p> <p>Other Matters</p>	<p>Various medicines</p>	<p>The Department seeks to update the PBAC with advice received from the States and Territories concerning access to medicines for people in custodial settings and to seek further PBAC advice.</p>	<p>The PBAC noted the input received from relevant state and territory departments, organisations and consumers on what barriers exist for those in custodial settings in accessing medicines. The PBAC considered the identified barriers relate to health workforce capacity, practical and logistical issues relating to the supply of medicines in custodial settings, and issues experienced by patients in custodial settings in establishing or renewing proof of Medicare eligibility. As these issues fall outside the PBAC’s legislated remit of considering matters relating to the subsidy of medicines and the operation of the Pharmaceutical Benefits Scheme (PBS), the PBAC was unable to provide advice on specifically addressing these access issues.</p> <p>The PBAC noted that state and territory governments are responsible for the delivery of corrective services, including the healthcare of people in custody. The exception is medicines listed on the Section 100 Highly Specialised Drugs (HSD) program, which are funded by the Commonwealth for all patients that meet the eligibility criteria, including people in custodial settings.</p> <p>The PBAC noted the Department had received a proposal from stakeholders to ‘dual list’ certain medicines listed on the general schedule (s85) of the PBS onto the s100 HSD program to enable prisoners to access these medicines. Dual listing means a medicine is included in both s85 and s100 of the PBS, which allows it to be prescribed and dispensed in both a community and hospital setting. The PBAC advised that dual listing certain medicines would unlikely address the identified barriers and may result in increased administrative burden for prisons and public hospitals. For example, prescribing of s100 listings (excluding Community Access listings) must be initiated by prescribers affiliated with a hospital. Dual listing s85 medicines onto the s100 HSD program would require prescribers treating patients in custodial settings to have this affiliation. The PBAC reiterated the need for holistic solutions by governments (Commonwealth, state, and territory) and corrective services providers to ensure equitable access for people in custodial settings to medicines that are available to all other eligible people in the community, such as those medicines listed on the general schedule of the PBS.</p> <p>The PBAC noted the Department has commissioned an independent Review into Health Care in Prisons to consider the provision of healthcare for First Nations people in custodial settings (the Review) which commenced in November 2023. The PBAC noted that the identified issues could be shared with the independent reviewer to inform their findings.</p> <p>The PBAC advised that it would assist the Department by participating in future discussions, should the Department consider further engagement with stakeholders is required to articulate the barriers faced by people in custodial settings in accessing PBS subsidised medicines.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>Access to Opioid Dependence Treatment Medicines</p> <p>BUPRENORPHINE</p> <p>Buvidal® Weekly Buvidal® Monthly CAMURUS PTY LYD</p> <p>Subutex® Sublocade® INDIVIOR PTY LTD</p> <p>BUPRENORPHINE WITH NALOXONE</p> <p>Suboxone® Film 2/0.5 Suboxone® Film 8/2 INDIVIOR PTY LTD</p> <p>METHADONE</p> <p>Aspen Methadone Syrup ASPEN PHARMACARE AUSTRALIA PTY LIMITED</p> <p>Biodone® Forte BIOMED AUST PTY LIMITED</p> <p>Other Matters (Change to existing listing)</p>	<p>Opioid dependence</p>	<p>To provide the PBAC with an update on the transition of the ODT program to the Section 100 Highly Specialised Drugs (HSD) Program (Community Access), including feedback from stakeholders on the impacts of the maximum repeats that was set for these listings.</p> <p>To seek the advice of the PBAC on whether it would be appropriate to amend the circumstances under which ODT medicines are listed on the PBS.</p>	<p>The PBAC noted an update on the transition of the Opioid Dependence Treatment (ODT) program to the Section 100 (S100) Highly Specialised Drugs (HSD) Program (Community Access) of the Pharmaceutical Benefits Scheme (PBS), including feedback from stakeholders on the impacts of the maximum number of repeats that was set for the listings.</p> <p>The PBAC recommended that the maximum repeats for ODT medicines be amended to provide for up to six months' treatment per prescription. In doing this, the PBAC acknowledged that there remain other opioids for chronic conditions listed on the PBS with repeats sufficient for three months' treatment under the general schedule. The PBAC considered that the circumstances of prescribing and supply of ODT medicines under the S100 HSD (Community Access) program provided additional review points with health professionals for patients during treatment that were unique to ODT and did not recommend the changes be extended to non-ODT opioid listings.</p> <p>In making the recommendation, the PBAC was cognisant of the feedback it had received during the Post-Market Review (PMR) of PBS Opiate Dependence Treatment Program medicines, and since the transition of the ODTP to S100 HSD, of the pressure that exists on the limited prescribing workforce providing opioid dependence treatment. The PBAC considered this amendment would reduce the administrative burden for these prescribers and may assist in increasing the number of available appointments for them to provide treatment to additional patients.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>Review of utilisation of ganciclovir and valganciclovir for the management of cytomegalovirus (CMV)</p> <p>GANCICLOVIR</p> <p>Powder for I.V. infusion 500 mg (as sodium) Cymevene® Pharmaco (Australia) Limited</p> <p>Powder for I.V. infusion 500 mg (as sodium) Ganciclovir SXP® Southern Cross Pharma Pty Ltd</p> <p>VALGANCICLOVIR</p> <p>Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL Valcyte® Pharmaco (Australia) Limited</p> <p>Tablet 450 mg (as hydrochloride) VALGANCICLOVIR HETERO® Gem Pharma Pty Ltd</p> <p>Tablet 450 mg (as hydrochloride) Valganciclovir Sandoz® Sandoz Pty Ltd</p> <p>Tablet 450 mg (as hydrochloride) Valganciclovir Viatrix® Alphapharm Pty Ltd</p> <p>Other Matters</p>	<p>Cytomegalovirus (CMV) infection</p>	<p>To request PBAC advice on proposed changes to the PBS restrictions for ganciclovir and valganciclovir for the management of cytomegalovirus (CMV) infection in immunocompromised patients</p>	<p>The PBAC recommended amending the circumstances under which ganciclovir and valganciclovir are listed under the Section 100 Highly Specialised Drug (HSD) Public/Private instrument. The PBAC noted the 2019 guidelines from the American Society of Transplantation Infectious Diseases Community of Practice and the Third International Consensus Guidelines on the Management of cytomegalovirus (CMV) in Solid-organ transplantation (2018) which recommend ganciclovir or valganciclovir as first-line treatment of CMV disease. The PBAC noted the distinction between prophylactic and active treatment phases of CMV is often ambiguous for the immunocompromised patient cohort.</p> <p>The PBAC also noted that the comparison of the epidemiological estimates with current PBS utilisation suggested that valganciclovir is currently being used for both prophylaxis and treatment in CMV and potentially in bone marrow transplant (BMT) recipients in addition to solid organ transplant (SOT) recipients. The PBAC noted the differences in the TGA registered indications between these medicines. However, it also noted that valganciclovir is an oral pro-drug of ganciclovir, and considered subsidised access to both drugs for the management of patients with BMT would provide clinicians additional flexibility in managing patients while aligning with clinical guidelines. The PBAC therefore considered that ganciclovir and valganciclovir would be suitably cost-effective in the expanded population at the existing price on the basis of the evidence presented. The PBAC also considered that it would be appropriate to amend the restrictions to remove reference to the prophylactic treatment phase and align the restrictions between the drugs to provide access to SOT and BMT patients for the management of CMV infection and disease.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>Correspondence from the Australasian Leukaemia & Lymphoma Group (ALLG) and the Haematology Society of Australia and New Zealand (HSANZ)</p> <p align="center">GILTERITINIB</p> <p align="center">Tablet 40 mg (as fumarate)</p> <p align="center">Xospata®</p> <p align="center">ASTELLAS PHARMA AUSTRALIA PTY LTD</p>	<p align="center">Acute Myeloid Leukaemia (AML)</p>	<p>To seek advice from the PBAC on a requested change to the PBS clinical criteria for the gilteritinib 40 mg tablets (Xospata) continuing treatment listing to allow use in patients who have relapsed post-allograft and who have not previously received treatment with gilteritinib.</p>	<p>The PBAC recommended a change in the clinical criteria for the PBS-listings for gilteritinib 40 mg tablets for relapsed or refractory AML to clarify that patients must not be undergoing or have undergone a stem cell transplant since initiating treatment with gilteritinib. This will allow patients who had relapsed after a prior allograft to access gilteritinib through the PBS, provided they met all other PBS criteria and had not used gilteritinib prior to transplant. The PBAC recalled its March 2022 recommendation for gilteritinib did not intend to exclude this patient group.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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The following item was considered out-of-session between ordinary meetings (March 2024 – July 2024)*

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p>DAUNORUBICIN WITH CYTARABINE</p> <p>Powder for I.V infusion containing daunorubicin 44 mg and cytarabine 100 mg</p> <p>Vyxeos®</p> <p>JAZZ PHARMACEUTICALS ANZ PTY LTD</p> <p>Matters arising (New PBS listing)</p>	<p>Acute myeloid leukaemia</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of therapy-related acute myeloid leukaemia (t-AML) or acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC) while system and IT challenges relating to a Section 100 (Efficient Funding of Chemotherapy) listing are resolved.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of liposomal daunorubicin and cytarabine (Vyxeos) under the Section 100 Highly Specialised Drugs (HSD) Program, while implementation issues relating to a Section 100 Efficient Funding of Chemotherapy (EFC) listing are being resolved. The PBAC noted that under Section 100 EFC, patients are not required to pay a co-payment for repeat prescriptions but would be required to do so under Section 100 HSD. The PBAC considered that the proposed approach for an interim Section 100 HSD listing was a pragmatic approach to enable patients’ PBS access to liposomal daunorubicin and cytarabine.</p>

*Note this item was considered prior to the publication date for the March 2024 PBAC meeting outcomes and hence has been included in this document.

Version 2

Amendments

1. BULEVIRTIDE - added PBAC outcome.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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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
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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>