

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 PBAC MEETING**

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

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p align="center">ABEMACICLIB</p> <p align="center">Tablet 50 mg Tablet 100 mg Tablet 150 mg</p> <p align="center">Verzenio®</p> <p align="center">ELI LILLY AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Hormone receptor positive (HR+) human epidermal growth factor receptor 2 negative (HER2-) breast cancer</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HR+ HER2- lymph node positive, invasive, resected early breast cancer at high risk of disease recurrence.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of abemaciclib, in combination with standard adjuvant endocrine therapy (ET), for the treatment of HR+, HER2-, lymph node positive, invasive, resected early breast cancer at high risk of disease recurrence. The PBAC considered the evidence presented demonstrated an invasive disease-free survival benefit over the comparator ('ET alone') but noted that a benefit in terms of overall survival had not been demonstrated and therefore remained uncertain. The PBAC noted that changes to the economic evaluation and financial estimates had partially addressed the Committee's previous concerns. The PBAC advised that revisions should be made to the duration of treatment effect and the patient age assumed in the economic model. While the PBAC acknowledged the remaining uncertainties in the submission, the PBAC considered that with a price reduction abemaciclib would be acceptably cost-effective. The PBAC also considered that the financial estimates remained overestimated and advised the assumed uptake rates should be reduced.</p> <p>The PBAC recommended flow on changes to limit subsidy of CDK4/6i therapy to once per lifetime, irrespective if prescribed for early disease or late stage disease to the current listings of abemaciclib, palbociclib and ribociclib.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">ADALIMUMAB</p> <p>Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen</p> <p align="center">Hadlima®</p> <p align="center">ORGANON PHARMA PTY LTD</p> <p align="center">Category 4 (New listing)</p>	<p>Severe Crohn disease Moderate to severe ulcerative colitis Severe active juvenile idiopathic arthritis Complex refractory fistulising Crohn disease Severe active rheumatoid arthritis Severe psoriatic arthritis Ankylosing spondylitis Severe chronic plaque psoriasis Moderate to severe hidradenitis suppurativa</p>	<p>To request a General Schedule Authority Required (Written) listing of Hadlima 40 mg in 0.4 mL pre-filled syringe and 40 mg in 0.4 mL pre-filled pen under the same circumstances as the PBS-listed reference biologic Humira® for all indications for which Hadlima 40 mg in 0.8 mL pre-filled syringe and 40 mg in 0.8 mL pre-filled pen are currently listed on the PBS.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of adalimumab (Hadlima) in the forms of 40 mg in 0.4 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 Hadlima PFP and PFS would be acceptable if it were cost-minimised to the lowest cost PBS-listed adalimumab brand. The PBAC advised the equi-effective doses to be 1 mg of Hadlima = 1 mg of Humira and all other biosimilar brands and formulations of adalimumab.</p> <p>The PBAC advised that for the purposes of substitution, Hadlima and Humira PFS should be treated as equivalent to each other; and Hadlima and Humira PFP should be treated as equivalent to each other (i.e. 'a' flagged in the Schedule). The PBAC advised that adalimumab 40 mg in 0.4 mL and adalimumab 40 mg in 0.8 mL PFS should be treated as equivalent to each other for the purposes of substitution; and adalimumab 40 mg in 0.4 mL and adalimumab 40 mg in 0.8 mL PFP should be treated as equivalent to each other for the purposes of substitution. The PBAC advised that Hadlima PFP should not be considered equivalent for the purposes of substitution with any adalimumab PFS, consistent with its previous considerations of adalimumab.</p>

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<p align="center">APREMILAST</p> <p align="center">Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg</p> <p align="center">Otezla®</p> <p align="center">AMGEN AUSTRALIA PTY LIMITED</p> <p align="center">Category 3 (Change to existing listing)</p>	<p align="center">Chronic plaque psoriasis (CPP)</p>	<p align="center">To request a change in the General Schedule Authority Required (STREAMLINED) listing for the treatment of severe CPP to allow treatment initiation by additional medical practitioner types.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the following changes to the treatment criteria of apremilast (Otezla) for the treatment of severe CPP in patients who have failed treatment with, or who are contraindicated or intolerant, to methotrexate:</p> <ul style="list-style-type: none"> • To allow rheumatologists and general physicians to initiate treatment (in addition to dermatologists). • To allow rheumatology registrars to initiate treatment in consultation with one of the above practitioner types (in addition to dermatology registrars). <p>The PBAC did not recommend the requested change to allow general practitioners (GPs) to initiate treatment with apremilast. The PBAC considered that the proposed treatment criteria was broad, that the required experience is not ascertainable in a manner that can be verified, and carried a risk of misdiagnosis and inappropriate prescribing. The PBAC noted that GPs are currently able to prescribe continuing treatment with apremilast where there is agreement with one of the initiating practitioner types, and considered that this remained appropriate.</p> <p>The PBAC recommended that the Prescribing Instruction regarding the need for prescribers to complete a Psoriasis Area and Severity Index assessment for patients to move onto biologic treatments should be included in the restriction for apremilast and should flow onto ciclosporin and deucravacitinib. The PBAC recommended that the changes to the initial treatment criteria for apremilast should flow onto ciclosporin for the treatment of CPP, and that all of the recommended changes to the treatment criteria for apremilast should flow onto the listings for deucravacitinib for severe CPP.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">BUDESONIDE WITH FORMOTEROL</p> <p>Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses</p> <p>Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses</p> <p align="center">Bufomix® Easyhaler®</p> <p align="center">ORION PHARMA (AUS) PTY LIMITED</p> <p align="center">Category 4 (New listing)</p>	<p align="center">Asthma Chronic obstructive pulmonary disease (COPD)</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of asthma and COPD on the basis of bioequivalence to Symbicort® Turbuhaler®.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of two new forms of budesonide with formoterol (Bufomix Easyhaler 200/6 and 400/12) under the same circumstances as the currently PBS-listed Symbicort Turbuhaler 200/6 and 400/12 respectively. The PBAC recommended listing Bufomix Easyhaler on a cost-minimisation basis to the lowest cost PBS-listed budesonide with formoterol powder for inhalation 200/6 and 400/12 items respectively. It noted that listing both strengths of Bufomix Easyhaler on the PBS is expected to have no net cost to the PBS. The PBAC noted the TGA considered Bufomix Easyhaler to be bioequivalent to Symbicort Turbuhaler, and advised the equi-effective doses were: Bufomix Easyhaler 200/6 = Symbicort Turbuhaler 200/6, and Bufomix Easyhaler 400/12 = Symbicort Turbuhaler 400/12. The PBAC advised that the equivalent strengths of Bufomix Easyhaler, Symbicort Turbuhaler and other PBS-listed generic brands should be considered equivalent for the purposes of substitution (i.e., ‘a’ flagged in the Schedule).</p> <p>The PBAC noted that Bufomix Easyhaler comes in a 60 dose pack for both strengths, and that a maximum quantity of 2 packs for each listing is required to align with the current PBS-listings of the two strengths of budesonide with formoterol. The PBAC noted this will be addressed in the implementation stage to facilitate the listing of the different pack size for the 200/6 strength.</p> <p>The PBAC recommended the following flow-on changes:</p> <ul style="list-style-type: none"> • The addition of an administration advice to budesonide with formoterol 200/6 for the treatment of asthma in patients who have failed fluticasone propionate with salmeterol to facilitate substitution. The advice will state the PBS listings for the 120 actuations form and 2 x 60 actuations form are equivalent for the purposes of substitution. • Updates to the current administrative note for the other PBS-listings of budesonide with formoterol 200/6 to include Bufomix Easyhaler.

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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">Category 2 (Change to existing listing)</p>	<p align="center">Differentiated thyroid cancer (DTC)</p>	<p align="center">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-targeted therapy (VEGF).</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend cabozantinib for the treatment of patients with locally advanced or metastatic DTC who are radioactive iodine refractory or ineligible and who have progressed following treatment with a tyrosine kinase inhibitor or have developed intolerance to prior VEGF-targeted therapy. The PBAC noted the clinical need for effective treatments in this setting but considered that the economic model was uncertain and that the incremental cost-effectiveness ratio was likely underestimated.</p> <p>The PBAC nominated the Early Re-entry resubmission pathway for this item.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p align="center">CEMIPLIMAB</p> <p>Solution for I.V. infusion 350 mg in 7 mL</p> <p align="center">Libtayo®</p> <p align="center">SANOFI-AVENTIS AUSTRALIA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing to be used with platinum doublet chemotherapy (PDC) as a first line treatment of adult patients with Stage IV (metastatic) NSCLC.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of cemiplimab to be used with PDC as a first-line treatment of adult patients with Stage IV (metastatic) NSCLC with no evidence of epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or c-ROS-proto-oncogene 1 (ROS1) aberrations. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of cemiplimab plus PDC would be acceptable if it were cost-minimised to pembrolizumab plus PDC. The PBAC advised the equi-effective doses were that cemiplimab 350 mg every three weeks is equivalent to pembrolizumab 200 mg every three weeks.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p style="text-align: center;">CHLORMETHINE HYDROCHLORIDE</p> <p style="text-align: center;">Gel 160 micrograms per g, 60 g</p> <p style="text-align: center;">Ledaga®</p> <p style="text-align: center;">JUNIPER BIOLOGICS PTY LTD</p> <p style="text-align: center;">Standard re-entry (New listing)</p>	<p style="text-align: center;">Mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL)</p>	<p style="text-align: center;">To request a General Schedule Authority Required (Telephone/Online) listing for the topical treatment of MF-type CTCL.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of chlormethine gel for the topical treatment of MF-type CTCL in adult patients who have no more than 25% of their body surface area involved. The PBAC acknowledged the clinical need for additional treatment options for patients with MF-type CTCL. The PBAC considered that due to the limited data available for this rare condition the claim of non-inferior effectiveness was highly uncertain but likely reasonable. The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of chlormethine gel would be acceptable if it were cost-minimised to phototherapy. The PBAC considered it would be appropriate for a small price premium to be applied to chlormethine gel over phototherapy due to the potential for improvement in accessibility and suitability for patients unable to be treated with phototherapy due to the areas involved.</p>
<p style="text-align: center;">CLADRIBINE</p> <p style="text-align: center;">Tablet 10 mg</p> <p style="text-align: center;">Mavenclad®</p> <p style="text-align: center;">MERCK HEALTHCARE PTY LTD</p> <p style="text-align: center;">Category 2 (Change to existing listing)</p>	<p style="text-align: center;">Relapsing-remitting multiple sclerosis (RRMS)</p>	<p style="text-align: center;">To request a revision to the equi- effective doses of cladribine versus fingolimod for the treatment of RRMS.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend amending the existing equi-effective doses of cladribine and fingolimod for the treatment of RRMS, on the basis that the evidence presented did not satisfactorily establish that two years of treatment with cladribine (plus two years of no treatment) is non-inferior to four years of treatment with fingolimod. The PBAC considered the key clinical evidence, a propensity score matched analysis of the MSBase registry data (GLIMPSE), was not reliable for the purposes of establishing non-inferiority over four years given the potential for confounding and the small number of patients on treatment for four years.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</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>Early re-entry (New listing)</p>	<p>Acute myeloid leukaemia</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy 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).</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of liposomal daunorubicin and cytarabine for the treatment of t-AML or AML-MRC. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of daunorubicin and cytarabine would be acceptable at the price proposed in the resubmission. The PBAC considered that the revised estimated utilisation and financial estimates were reasonable.</p>
<p>DIFELIKEFALIN</p> <p>Solution for I.V. injection 50 micrograms in 1 mL vial</p> <p>Korsuva®</p> <p>VIFOR PHARMA PTY LIMITED</p> <p>Standard re-entry (New listing)</p>	<p>Chronic kidney disease (CKD) associated pruritus</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of moderate-to-severe pruritus associated with CKD.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of difelikefalin for the treatment of moderate to severe pruritus associated with CKD in patients who are undergoing haemodialysis, on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program). The PBAC is satisfied that difelikefalin provides, for some patients, a significant improvement in efficacy over best supportive care for the management of moderate to severe pruritus in the requested population.</p> <p>The PBAC reaffirmed its March 2023 advice that the claims of superior comparative effectiveness and inferior safety were reasonable. The PBAC considered the resubmission economic model was structurally reliable for decision-making and advised that, with the pre-PBAC response price offer, the listing was acceptably cost - effective in this population with a clinical need for effective treatment options. The PBAC accepted the revised financial estimates presented in the pre-PBAC response and considered that these were an appropriate basis for a risk sharing arrangement.</p>

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<p align="center">DOSTARLIMAB</p> <p>Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p align="center">Jemperli®</p> <p align="center">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p align="center">Category 2 (New listing)</p>	<p align="center">Endometrial cancer</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for use in combination with platinum-containing chemotherapy for the treatment of primary advanced or first recurrent endometrial cancer.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of dostarlimab in combination with platinum-containing chemotherapy, for the treatment of primary advanced or first recurrent endometrial cancer that is mismatch repair deficient (dMMR), on the basis that it should be available only under special arrangements under Section 100 (Efficient Funding of Chemotherapy). The PBAC is satisfied that dostarlimab provides, for some patients, a significant improvement in efficacy over platinum-containing chemotherapy alone, noting a clinical benefit, in terms of progression-free survival, from first line treatment for this population. The PBAC considered that, for the dMMR population, dostarlimab would be acceptably cost-effective with a price reduction to account for the uncertain longer-term outcomes, including the uncertain gain in overall survival.</p> <p>The PBAC did not recommend listing of dostarlimab for the treatment of primary advanced or first recurrent endometrial cancer in the broader population, which includes mismatch repair proficient (pMMR) endometrial cancer. The PBAC noted that there is a high clinical need for effective first-line treatments for endometrial cancer but considered that the clinical benefit in the pMMR population was unclear, noting that it was possible that these patients may benefit more from second-line treatment with pembrolizumab in combination with lenvatinib.</p>

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NOVEMBER 2023 PBAC MEETING**

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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">UPADACITINIB</p> <p>Tablet 15 mg Tablet 30 mg</p> <p align="center">Rinvoq®</p> <p align="center">ABBVIE PTY LTD</p> <p>Matters outstanding (Other matters)</p>	<p align="center">Severe atopic dermatitis (AD) (adults and adolescents)</p>	<p align="center">To request the PBAC consider the cost-effectiveness of dupilumab and upadacitinib for severe AD.</p>	<p align="center">Advice Provided</p>	<p>The PBAC noted that the current utilisation substantially exceeds the estimated utilisation. The PBAC considered that, at the current level of utilisation, dupilumab and upadacitinib would not be considered cost-effective at their current prices. The PBAC noted that the current risk sharing arrangements (RSAs) are formalised under Deeds of Agreement between the Commonwealth and the sponsors of dupilumab and upadacitinib. The PBAC considered that one of the main purposes of RSAs are to manage uncertainties, including those associated with budget impact and appropriate cost-effective use. The PBAC considered that renegotiation of any Deed arrangements was ultimately a matter for the Commonwealth, however provided advice for consideration at the time of negotiation of any future RSA.</p>

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<p style="text-align: center;">EDARAVONE</p> <p style="text-align: center;">Solution concentrate for injection 30 mg in 20 mL</p> <p style="text-align: center;">Radicava®</p> <p style="text-align: center;">TEVA PHARMA AUSTRALIA PTY LTD</p> <p style="text-align: center;">Category 1 (New listing)</p>	<p style="text-align: center;">Amyotrophic lateral sclerosis (ALS)</p>	<p style="text-align: center;">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of ALS.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend edaravone for treatment of ALS. The PBAC considered that edaravone was superior to placebo in slowing the rate of decline in terms of motor impairment and functional deterioration, however the level of long-term benefit and effect on survival is uncertain. The PBAC considered that edaravone was not cost-effective at the price proposed in the submission, noting that the economic model included a number of optimistic assumptions that were likely to underestimate the incremental cost-effectiveness ratio.</p> <p>The PBAC nominated the Early Re-entry resubmission pathway for this item</p> <p><u>Sponsor's Comment:</u> Teva Pharma appreciates the opportunity to resubmit via the early re-entry pathway and is committed to working with the PBAC to bring Radicava to Australian patients with ALS in a timely manner.</p>
<p style="text-align: center;">ELTROMBOPAG</p> <p style="text-align: center;">Tablet 25 mg Tablet 50 mg</p> <p style="text-align: center;">Revolade®</p> <p style="text-align: center;">HAEMATOLOGY SOCIETY OF AUSTRALIA AND NEW ZEALAND (HSANZ)</p> <p style="text-align: center;">Category 2 (Change to existing listing)</p>	<p style="text-align: center;">Aplastic anaemia (AA)</p>	<p style="text-align: center;">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe AA.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of eltrombopag for the treatment of severe AA, as first-line treatment in combination with anti-thymocyte globulin and ciclosporin, and as a second-line treatment in patients with an inadequate response to immunosuppressive therapy. The PBAC considered there is a clinical need for effective treatment options for this rare condition. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of eltrombopag would be acceptable at the effective price currently in place for severe chronic idiopathic thrombocytopenic purpura. The PBAC acknowledged the significant work by HSANZ in bringing this request to the PBAC.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">EMPAGLIFLOZIN</p> <p align="center">Tablet 10 mg</p> <p align="center">Jardiance®</p> <p align="center">BOEHRINGER INGELHEIM PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Chronic kidney disease (CKD)</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for CKD.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of empagliflozin for the treatment of CKD, as an add-on to standard care, for patients with an estimated glomerular filtration rate (eGFR) of ≥ 25 to ≤ 75 mL/min/1.73 m² and a urine albumin-creatinine ratio (UACR) of ≥ 200 to $\leq 5,000$ mg/g. The PBAC's recommendation for listing was based on its assessment that the cost-effectiveness of empagliflozin would be acceptable if it were cost-minimised against dapagliflozin.</p> <p>The PBAC did not recommend the listing of empagliflozin for the proposed incremental CKD population based upon the subgroup analysis in the EMPA-KIDNEY trial which showed little or no improvement from empagliflozin in patients categorised as low, moderate and high-risk (KDIGO staging) or in those patients with UACR < 200 mg/g at baseline. The PBAC did not consider that the EMPA-KIDNEY trial adequately demonstrated a benefit in the broadened indication for CKD. The PBAC noted the modelled treatment effects were not representative of the incremental population, and the overall complexity and uncertainty of the cost-effectiveness analysis made it uninformative.</p>

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<p align="center">FLUTICASONE PROPIONATE WITH SALMETEROL</p> <p>Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses</p> <p>Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses</p> <p align="center">Salflumix® Easyhaler®</p> <p align="center">ORION PHARMA (AUS) PTY LIMITED</p> <p align="center">Category 4 (New listing)</p>	<p align="center">Asthma Chronic obstructive pulmonary disease (COPD)</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of asthma and COPD</p>	<p align="center">Recommended</p> <p>The PBAC recommended the listing of two new forms of fluticasone propionate with salmeterol (Salflumix Easyhaler 250/50 and 500/50) under the same circumstances as the currently PBS-listed Seretide® Accuhaler® 250/50 and 500/50 respectively. The PBAC recommended listing Salflumix Easyhaler on a cost-minimisation basis to the lowest cost PBS-listed fluticasone propionate with salmeterol powder for inhalation items of equivalent strengths. It noted that listing both strengths of Salflumix Easyhaler on the PBS is expected to have no net cost to the PBS. The PBAC noted the TGA considered Salflumix Easyhaler to be bioequivalent to Seretide Accuhaler, and advised the equi-effective doses were: Salflumix Easyhaler 250/50 = Seretide Accuhaler 250/50, and Salflumix Easyhaler 500/50 = Seretide Accuhaler 500/50. The PBAC advised that the equivalent strengths of Salflumix Easyhaler and Seretide Accuhaler and other PBS-listed generic brands should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule).</p> <p>The PBAC noted that Salflumix Easyhaler, and the currently PBS-listed brands of fluticasone propionate with salmeterol 250/50 and 500/50 are currently TGA-registered for use in children aged 12 years of age and older, and adults. The PBAC noted the inconsistencies in the age recommendations between the TGA Product Information, PBS population criteria and Australian Asthma Handbook for these items. The PBAC recommended not including an age restriction for the listings of Salflumix Easyhaler for asthma. The PBAC recommended that this be flowed onto the restrictions for the currently listed fluticasone propionate with salmeterol 250/50 microgram and 500/50 microgram items for asthma by removing the population criteria 'Patient must be aged 4 years or older' from these listings.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 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;">Category 1 (New listing)</p>	<p style="text-align: center;">Atherosclerotic cardiovascular disease (ASCVD) with elevated triglycerides</p>	<p style="text-align: center;">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of ASCVD with elevated triglycerides.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend icosapent ethyl for the treatment of patients with ASCVD with elevated triglycerides. The PBAC considered that there was a low clinical need for icosapent ethyl given current therapies to treat patients with ASCVD are underutilised, while adding icosapent ethyl would complicate the treatment space at a substantial potential cost to Government. Furthermore, the PBAC considered the magnitude of benefit was uncertain given the mechanism of action of icosapent ethyl is poorly understood, there are inconsistent trial results across studies of eicosapentaenoic acid therapies, and the negative impact of the mineral oil used in the placebo arm of the REDUCE-IT trial was not easily quantifiable. The PBAC considered that the revised incremental cost-effectiveness ratio presented in the pre-PBAC response was too high and remained uncertain and that a substantial price reduction was required. In addition, the PBAC considered that the estimated utilisation and the financial impact were very high and uncertain and, in the context of uncertain benefits and low clinical need, could not be justified. The PBAC advised that a risk sharing arrangement based on revised estimates would be required.</p> <p>The PBAC nominated the Early Re-Entry resubmission pathway for this item.</p> <p><u>Sponsor's Comment:</u> Cardiovascular disease remains one of Australia's leading causes of death. CSL Seqirus engaged extensively with cardiologists, endocrinologists, primary care providers and healthcare organisations to guide our PBAC submission, and all agreed that further reimbursed options to manage cardiovascular risk would be welcomed.</p> <p>We are committed to working with the PBAC towards the reimbursement of Vazkepa to further reduce cardiovascular risk in Australian patients as soon as possible.</p>

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<p>IMATINIB, DASATINIB, NILOTINIB, PONATINIB, ASCIMINIB</p> <p>All brands and strengths</p> <p>Various sponsors</p> <p>(Other matters)</p>	<p>Chronic myeloid leukaemia (CML)</p>	<p>For the PBAC to consider updating the restriction wording for tyrosine kinase inhibitors in CML.</p>	<p>Not Applicable</p>	<p>To be considered at a future PBAC meeting</p>

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<p align="center">IVACAFTOR</p> <p>Sachet containing granules 25 mg Sachet containing granules 50 mg Sachet containing granules 75 mg Tablet 150 mg</p> <p align="center">Kalydeco®</p> <p align="center">VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD.</p> <p align="center">Category 2 (New listing)</p>	<p align="center">Cystic fibrosis (CF) with the CF transmembrane conductance regulator (<i>CFTR</i>) gene mutation</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of (i) CF patients aged 4 to 12 months with a gating (Class III) <i>CFTR</i> gene mutation; (ii) CF patients aged 4 months or older with at least one <i>CFTR</i> gene mutation shown to be responsive to ivacaftor potentiation.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended that the listing for ivacaftor granules and tablets be extended to include the treatment of CF in patients aged 4 months and older who have at least one mutation in the <i>CFTR</i> gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. The PBAC also recommended that an additional strength of granules (ivacaftor 25 mg) should be available under Section 100 (Highly Specialised Drugs Program) for use in this population. The PBAC noted that, overall, the evidence supporting the clinical claim in the submission was limited but acknowledged the difficulties in obtaining efficacy data in this population. The PBAC considered ivacaftor was likely to be cost effective at the requested price for 3% of the additional population, noting these patients would be eligible to commence treatment with ivacaftor at 12 months of age. For the remaining additional population, the PBAC considered it was unlikely ivacaftor would be cost-effective at the requested price, given its cost per patient per year was substantially higher than the current CFTR modulators and that most patients will transition to a CFTR modulator at an older age. However, ivacaftor was likely to be cost-effective if it was priced no higher than elexacaftor/tezacaftor/ivacaftor (Trikafta®) for the population who would transition to another CFTR modulator at an older age (52% of the additional population) and for the population for whom there was limited clinical evidence (45% of the additional population).</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">LENACAPAVIR</p> <p align="center">Injection set containing 2 vials lenacapavir sodium solution for injection 463.5 mg in 1.5 mL and 2 disposable syringes</p> <p align="center">Sunlenca®</p> <p align="center">GILEAD SCIENCES PTY LIMITED</p> <p align="center">Standard re-entry (New listing)</p>	<p align="center">Human immunodeficiency virus (HIV)</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of multidrug resistant HIV.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of lenacapavir (LEN), in combination with optimised background regimen (OBR), for the treatment of patients with highly multi-drug resistant (hMDR) HIV infection. In making this recommendation, the PBAC accepted there is a clinical need for new and effective therapies for the treatment of people living with HIV that have a few remaining effective treatment options, and that LEN as add-on therapy to OBR is effective for some patients in terms of achieving viral suppression. The PBAC considered LEN would be cost-effective with a price reduction to achieve an incremental cost-effectiveness ratio in the range of \$45,000 to \$75,000 per quality adjusted life year using the alternative base case economic model as presented in the evaluation. Noting there is likely to be a reluctance to alter treatment regimens for patients with hMRD HIV infection where an acceptable therapeutic outcome is being achieved through currently available combinations of anti-retrovirals, the PBAC considered the uptake of LEN in the resubmission remained overestimated. The PBAC considered there was a risk of leakage to people who do not meet the strict definition of hMDR as per the proposed listing, and that this risk should be managed with a risk sharing arrangement.</p> <p>The PBAC recommended amending the definition of virologic failure from greater than 400 copies per mL to greater than 200 copies per mL for applicable PBS listings – maraviroc, etravirine, darunavir and the combination drugs darunavir with cobicistat, and darunavir with cobicistat, emtricitabine and tenofovir alafenamide.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">LENALIDOMIDE</p> <p align="center">Capsule 20 mg</p> <p align="center">Lenalide®</p> <p align="center">JUNO PHARMACEUTICALS PTY LTD</p> <p align="center">Category 4 (New listing)</p>	<p align="center">Multiple myeloma Myelodysplastic syndromes Mantle cell lymphoma</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing of a new strength under the same conditions and for the same population as the currently listed strengths.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of lenalidomide capsule 20 mg (Lenalide) under the same circumstances as lenalidomide capsule 25 mg (all brands), and cost-minimised on a per mg basis to the listed 25 mg strength of lenalidomide.</p>
<p align="center">MARIBAVIR</p> <p align="center">Tablet 200 mg</p> <p align="center">Livtency®</p> <p align="center">TAKEDA PHARMACEUTICALS AUSTRALIA PTY LTD</p> <p align="center">Category 1 (New listing)</p>	<p align="center">Post-transplant cytomegalovirus (CMV)</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for treatment of post-transplant CMV infection and disease that is refractory, resistant or intolerant to one or more prior therapies.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend listing maribavir for the treatment of post-transplant CMV infection and disease resistant, refractory or intolerant to one or more prior therapies. The PBAC considered that the comparative clinical evidence was subject to uncertainty due to the limitations of the pivotal randomised study. In addition, the incremental cost-effectiveness ratio was subject to a high level of uncertainty given that the economic evaluation was based on multiple assumptions that were not adequately justified.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

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<p align="center">MAVACAMTEN</p> <p align="center">Capsule 2.5 mg Capsule 5 mg Capsule 10 mg Capsule 15 mg</p> <p align="center">Camzyos®</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">Early re-entry (New listing)</p>	<p align="center">Hypertrophic cardiomyopathy (HCM)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adults with symptomatic obstructive HCM.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of mavacamten for the treatment of adults with symptomatic obstructive HCM. The PBAC noted there was an unmet need for treatments in this condition and that mavacamten was the first drug to have proven benefits over placebo in HCM. The PBAC considered mavacamten provided, for some patients, a significant benefit over current standard of care in terms of symptomatic improvement. The PBAC considered that the early re-entry resubmission adequately addressed PBAC’s previous concerns from the July 2023 meeting in terms of the proposed place in therapy and uncertain economic modelling. With revisions to the economic model, including a price reduction, the PBAC considered that mavacamten would be cost-effective for the recommended PBS population.</p>
<p align="center">MEDROXYPROGESTERONE ACETATE</p> <p align="center">Suspension for injection 150 mg in 1 mL pre-filled syringe</p> <p align="center">Depo-Provera®</p> <p align="center">PFIZER AUSTRALIA PTY LTD</p> <p align="center">Category 4 (New listing)</p>	<p align="center">Unrestricted benefit</p>	<p align="center">To request a General Schedule unrestricted listing for a pre-filled syringe (PFS)</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of medroxyprogesterone acetate 150 mg/mL PFS (Depo-Provera) under the same circumstances as the currently listed medroxyprogesterone acetate 150 mg/mL injection, vial forms (Depo-Provera, Depo-Ralovera®). The PBAC advised that the equi-effective doses were medroxyprogesterone acetate 150 mg/mL PFS = medroxyprogesterone acetate 150 mg/mL injection vial.</p> <p>The PBAC advised that the medroxyprogesterone vial and medroxyprogesterone PFS should be considered equivalent for the purposes of substitution (i.e., ‘a’ flagged in the Schedule).</p>

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<p style="text-align: center;">MENINGOCOCCAL VACCINE</p> <p style="text-align: center;">Injection 0.5 mL</p> <p style="text-align: center;">Menveo®</p> <p style="text-align: center;">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p style="text-align: center;">Committee secretariat (New listing)</p>	<p style="text-align: center;">Prevention of invasive meningococcal diseases (IMDs)</p>	<p style="text-align: center;">To request a National Immunisation Program listing for adolescents for the prevention of IMDs caused by Neisseria meningitidis serogroups A, C, W-135 and Y</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of meningococcal serogroup A, C, W-135 and Y oligosaccharides conjugated individually to Corynebacterium diphtheriae CRM197 protein (MenACWY-CRM) vaccine (Menveo solution for injection) as a designated vaccine on the <i>National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)</i> for adolescents for the prevention of IMDs caused by Neisseria meningitidis serogroups A, C, W-135 and Y under the same circumstances as MenACWY-CRM Menveo solution and powder for reconstitution. The PBAC’s recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Menveo solution for injection would be acceptable if it were cost-minimised against the nominated comparators, Menveo solution and powder for reconstitution and Nimenrix. The PBAC advised the equi-effective doses to be 0.5 mL Menveo solution for injection = 0.5 mL Menveo solution and powder for reconstitution = 0.5 mL Nimenrix.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">MIDAZOLAM</p> <p>Oromucosal solution in pre-filled syringe 2.5 mg in 0.25 mL Oromucosal solution in pre-filled syringe 5 mg in 0.5 mL Oromucosal solution in pre-filled syringe 7.5 mg in 0.75 mL Oromucosal solution in pre-filled syringe 10 mg in 1 mL</p> <p align="center">Zyamis®</p> <p align="center">CLINECT PTY LTD</p> <p align="center">Category 3 (Other matters)</p>	<p align="center">Generalised convulsive status epilepticus (GCSE)</p>	<p align="center">To request consideration of revised financial estimates and risk share proposal for a General Schedule Authority required (Telephone/Online) listing for the treatment of GCSE.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of midazolam oromucosal solution in pre-filled syringes (PFS) (2.5 mg, 5 mg, 7.5 mg and 10 mg), for the treatment of GCSE in patients aged over 6 months. The PBAC noted that GCSE presents stressful situations for parents and carers, and considered that the proposed listing, offered clinically meaningful benefits by improved quality use of medicines with easier and more accurate administration. Consistent with its November 2022 advice, the PBAC’s recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of midazolam oromucosal solution in PFS would be acceptable if it were cost-minimised against off-label use of midazolam ampoules. However, the PBAC recognised there were additional health outcome benefits to this formulation associated with the accurate and timely administration of midazolam during an acute health emergency that justified a significant price premium under the specific circumstances of the restriction. The PBAC noted that the submission had presented revised financial estimates and a revised risk sharing arrangement for PBAC consideration. The PBAC considered that a modest increase in the utilisation estimates was justified to account for the utilisation of patients experiencing high-frequency seizures.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">MOLNUPIRAVIR</p> <p align="center">Capsule 200 mg</p> <p align="center">Lagevrio®</p> <p align="center">MERCK SHARP & DOHME (AUSTRALIA) PTY LTD</p> <p align="center">Matters outstanding (Change to existing listing)</p>	<p align="center">Mild to moderate COVID-19</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of high risk patients with mild to moderate SARS-CoV-2 infection.</p>	<p align="center">Advice Provided</p>	<p>The PBAC provided advice regarding molnupiravir (Lagevrio), for the treatment of patients with mild to moderate Coronavirus disease (COVID-19) who are at high risk of severe disease requiring hospitalisation. Consistent with its July 2023 advice, the PBAC considered that molnupiravir may be an appropriate treatment for patients who cannot use nirmatrelvir and ritonavir (Paxlovid®). The PBAC noted that nirmatrelvir and ritonavir is a more effective treatment than molnupiravir, however nirmatrelvir and ritonavir is contraindicated in patients with severe renal or hepatic impairment, and contraindicated for use with certain other drugs, due to the risk of significant drug-drug interactions. The PBAC noted that these contraindications are clinically important for some vulnerable patients and must be managed carefully by prescribers. The PBAC recommended changes to the restriction, and a reduction in the price of molnupiravir consistent with its advice on the cost-effectiveness evaluation. The PBAC noted that the market share for molnupiravir remained higher than nirmatrelvir and ritonavir, which did not reflect clinical guidelines. The PBAC recommended that the sponsor and Department of Health and Aged Care explore initiatives to support the safe and effective use of oral antiviral medicines for COVID-19, consistent with quality use of medicines principles.</p>

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<p style="text-align: center;">NIRMATRELVIR AND RITONAVIR</p> <p>Pack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5</p> <p style="text-align: center;">Paxlovid®</p> <p style="text-align: center;">PFIZER AUSTRALIA PTY LTD</p> <p style="text-align: center;">Category 1 (Change to existing listing)</p>	<p style="text-align: center;">SARS-CoV-2 infection</p>	<p style="text-align: center;">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of SARS-CoV-2 infection in people who are at increased risk of severe disease.</p>	<p>Advice Provided</p>	<p>The PBAC provided advice regarding nirmatrelvir and ritonavir (Paxlovid), for the treatment of patients with mild to moderate Coronavirus disease (COVID-19) who are at high risk of severe disease requiring hospitalisation. The PBAC maintained its previous advice that nirmatrelvir and ritonavir is preferred over molnupiravir in a scenario where both oral antivirals are able to be used based on clinical evidence showing greater efficacy with nirmatrelvir and ritonavir. The PBAC recommended that, at its current price, there should be a change to the restriction for patients aged 50-69 years, which currently allows access for patients with one or more additional risk factors, to revert to the requirement for two or more risk factors, due to reduced cost-effectiveness in this lower risk population. The PBAC noted that a price reduction was offered in the pre-PBAC response however the proposed price remained higher than the current price. The PBAC advised that a price reduction is required from the current price because cost-effectiveness has almost certainly declined since the initial decision to recommend listing on the PBS was made.</p>
<p style="text-align: center;">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL</p> <p>Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p style="text-align: center;">Opdivo®</p> <p style="text-align: center;">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p style="text-align: center;">Standard re-entry (Change to existing listing)</p>	<p style="text-align: center;">Muscle invasive urothelial carcinoma (MIUC)</p>	<p style="text-align: center;">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the adjuvant treatment of high-risk MIUC.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation for nivolumab for the adjuvant treatment of high-risk MIUC to allow for further consultation with the sponsor regarding a cost-effective price for nivolumab. The PBAC agreed with the ESC that despite the use of more reasonable inputs the incremental cost-effectiveness ratio from the multivariate analysis remained uncertain. The PBAC considered a substantial price reduction would be required to achieve cost-effectiveness.</p> <p><u>Sponsor's Comment:</u> Bristol-Myers Squibb looks forward to working with the PBAC to make nivolumab available to Australian patients for the adjuvant treatment of high-risk muscle invasive urothelial carcinoma. We are committed to working closely with the PBAC to ensure that this treatment is made available to patients in a timely manner.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">OLAPARIB</p> <p align="center">Tablet 100 mg Tablet 150 mg Tablet 150 mg</p> <p align="center">Lynparza®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Metastatic castration-resistant prostate cancer (mCRPC)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of mCRPC in patients with a Class 4 or 5 Breast Cancer Gene 1 (<i>BRCA1</i>) or <i>BRCA2</i> mutation who have not received prior treatment with a novel hormonal agent.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend olaparib, for use in combination with abiraterone, for the first line treatment of mCRPC patients with <i>BRCA1/BRCA2</i> pathogenic variants who have not received prior treatment with a novel hormonal agent (NHA). The PBAC considered that the clinical evidence presented in the submission, which was based on a small post-hoc subgroup, was uncertain. The PBAC also considered that the incremental cost-effectiveness ratio was highly uncertain and likely underestimated and that the financial impact estimates were overestimated. Further, the PBAC considered that the clinical place of olaparib in combination with abiraterone was uncertain, noting that olaparib was available as monotherapy in the mCRPC setting following treatment with a NHA and that no evidence was presented to suggest that the combination of olaparib and abiraterone was superior to sequential treatment of a NHA followed by olaparib.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p align="center">OLAPARIB</p> <p align="center">Tablet 100 mg Tablet 150 mg Tablet 150 mg</p> <p align="center">Lynparza®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Standard re-entry (Change to existing listing)</p>	<p align="center">Human epidermal growth factor receptor 2 negative (HER2-) early breast cancer</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for patients with HER2-, high risk early breast cancer with a confirmed germline Breast Cancer Gene 1 (<i>gBRCA1</i>) or <i>gBRCA2</i> mutation.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended olaparib for the treatment of patients with HER2-, high risk early breast cancer with a confirmed <i>gBRCA1</i> or <i>gBRCA2</i> mutation who have previously been treated with neoadjuvant or adjuvant chemotherapy. The PBAC noted there was a high need for effective treatment in this population, which is a small subset of breast cancer patients. The PBAC considered that the revised economic evaluation addressed most of the outstanding issues; however, an additional price reduction was required to account for remaining uncertainty in the modelled benefit of olaparib. The PBAC noted the revised financial estimates and advised that further amendments were necessary to reflect the likely use in practice.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p style="text-align: center;">OSIMERTINIB</p> <p style="text-align: center;">Tablet 40 mg Tablet 80 mg</p> <p style="text-align: center;">Tagrisso®</p> <p style="text-align: center;">ASTRAZENECA PTY LTD</p> <p style="text-align: center;">Category 2 (Change to existing listing)</p>	<p style="text-align: center;">Non-small cell lung cancer (NSCLC)</p>	<p style="text-align: center;">To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of Stage IB to IIIA epidermal growth factor receptor (EGFR) mutation positive NSCLC as adjuvant therapy after surgical resection.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of osimertinib for the treatment of Stage IB to IIIA <i>EGFR</i> mutation positive NSCLC as adjuvant therapy after surgical resection. The PBAC considered that osimertinib provided a substantial benefit in terms of disease free survival compared to standard of care, but the magnitude of overall survival benefit remained uncertain. The PBAC considered osimertinib would be cost-effective at a price lower than offered in the pre-PBAC response. The PBAC advised the net cost of listing osimertinib in the adjuvant treatment setting (accounting for reduced use in the metastatic treatment setting) could be added to the risk sharing arrangement currently in place for osimertinib.</p>
<p style="text-align: center;">OXYBUTYNIN</p> <p style="text-align: center;">Transdermal patches 36 mg, 8</p> <p style="text-align: center;">Oxytrol®</p> <p style="text-align: center;">THERAMEX AUSTRALIA PTY LTD</p> <p style="text-align: center;">Category 4 (Change to existing listing)</p>	<p style="text-align: center;">Detrusor overactivity in patients unable to tolerate or unable to swallow oral oxybutynin</p>	<p style="text-align: center;">To request consideration of whether oxybutynin 3.9 mg transdermal patch satisfies the criteria to be classified an 'exempt item' as described by Section 84AH of the <i>National Health Act 1953</i>.</p>	<p>Advice Provided</p>	<p>The PBAC advised that Oxytrol (oxybutynin 3.9 mg transdermal patch) can be considered as an exempt item under subsection 84AH of the <i>National Health Act 1953</i> on the basis that the transdermal form of oxybutynin is the only option for patients for whom the oral formulation is unsuitable due to adverse events or inability to swallow. The PBAC noted that there are no bioequivalent, biosimilar or 'a' flagged products listed for the same indication, no other non-oral dose forms for the same indication, and no alternative brands of the transdermal patches.</p>

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NOVEMBER 2023 PBAC MEETING**

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<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">MERCK SHARP & DOHME (AUSTRALIA) PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Squamous cell carcinoma (SCC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of metastatic or locally advanced cutaneous SCC that is not curative by surgery or radiation.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of pembrolizumab for the treatment of metastatic or locally advanced cutaneous SCC that it not curable by surgery or radiation. The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of pembrolizumab would be acceptable if it were cost-minimised against cemiplimab, and included in the current risk sharing arrangement for cemiplimab. The PBAC considered the equi-effective doses were:</p> <ul style="list-style-type: none"> • pembrolizumab 200 mg every 3 weeks (Q3W) is equivalent to cemiplimab 350 mg Q3W, and • pembrolizumab 400 mg every 6 weeks is equivalent to 2x cemiplimab 350 mg Q3W. <p>The PBAC recommended the flow-on restriction amendments for cemiplimab (PBS item codes 13125F and 13135H) to restrict the use of subsequent immunotherapy in those who have already received such treatment unless they have experienced a severe intolerance leading to permanent treatment discontinuation.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 style="text-align: center;">PNEUMOCOCCAL CONJUGATE VACCINE, 20-VALENT</p> <p style="text-align: center;">0.5 mL pre-filled syringe</p> <p style="text-align: center;">Prevenar 20®</p> <p style="text-align: center;">PFIZER AUSTRALIA PTY LTD</p> <p style="text-align: center;">Category 2 (New listing)</p>	<p style="text-align: center;">Prevention of pneumococcal disease</p>	<p style="text-align: center;">To request a National Immunisation Program (NIP) listing for paediatric populations.</p>	<p>Recommended</p>	<p>The PBAC recommended that 20-valent pneumococcal conjugate vaccine (20vPCV; Prevenar 20) be a designated vaccine for the purposes of the <i>National Health Act 1953</i>, for the prevention of pneumococcal disease in the following paediatric populations:</p> <ul style="list-style-type: none"> • Children aged 12 months or younger in NSW, VIC, ACT, and TAS and non-Indigenous children aged 12 months or younger in QLD, NT, WA and SA (2+1 schedule). • Aboriginal and Torres Strait Islander children aged 12 months or younger in QLD, NT, WA and SA (3+1 schedule). • Children aged 12 months or younger with currently NIP-funded risk conditions (3+1 schedule). • Children aged more than 12 months with currently NIP-funded risk conditions (single dose). <p>These populations match those recommended for 13-valent pneumococcal conjugate vaccine (13vPCV) and 15-valent pneumococcal conjugate vaccine (15vPCV). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of 20vPCV would be acceptable if it were cost-minimised against the nominated comparators, 13vPCV and 15vPCV.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 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">Category 2 (Change to existing listing)</p>	<p align="center">Chronic plaque psoriasis (CPP)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of severe CPP.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of two new forms of risankizumab, a 150 mg pre-filled syringe (PFS) and a 150 mg pre-filled pen (PFP) for the treatment of severe CPP. The Committee noted it had previously recommended the listing of these forms of risankizumab for CPP in November 2021 and advised the basis of this recommendation differed to that of the previous outcome. The PBAC noted the 150 mg forms and the 75 mg form of risankizumab are bioequivalent, and considered there is sufficient evidence to conclude that the 150 mg forms of risankizumab provides, for some patients, a significant improvement in efficacy compared to adalimumab, etanercept and ustekinumab. The PBAC was also satisfied that risankizumab provides, for some patients, a significant improvement in efficacy or reduction of toxicity over infliximab. The PBAC's recommendation for listing was therefore based on, among other matters, its assessment that the cost-effectiveness of the 150 mg forms of risankizumab would be acceptable if they were cost-minimised to the least costly alternative therapy of risankizumab (2 x 75 mg presentation), bimekizumab, guselkumab, ixekizumab, tildrakizumab and secukinumab.</p>
<p align="center">SACITUZUMAB GOVITECAN</p> <p>Powder for injection 180 mg</p> <p align="center">Trodelvy®</p> <p align="center">GILEAD SCIENCES PTY LIMITED</p> <p align="center">Early re-entry (Change to existing listing)</p>	<p align="center">Hormone receptor-positive (HR+) human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer.</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of adult patients with unresectable locally advanced or metastatic HR+, HER2- breast cancer, who have previously received at least two systemic therapies, one of which may have been in the neoadjuvant/adjuvant setting.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend the listing of sacituzumab govitecan (SG), for the treatment of adult patients with unresectable locally advanced or metastatic HR+, HER2- breast cancer, who have previously received at least two prior chemotherapeutic regimens. In making this recommendation, the PBAC considered that the changes made to the proposed restriction of SG appropriately reflected the inclusion criteria for the TROPiCS-02 trial and accepted that there is a moderate clinical need for new and effective therapies in this indication. The PBAC considered that SG provided a clinical benefit with a significant improvement in progression free survival (PFS) and overall survival (OS) compared with treatment of physician's choice (TPC). However, the PBAC noted that revised economic evaluation had not addressed a number of the Committee's previous concerns. The PBAC considered that the incremental cost-effectiveness ratio (ICER) remained underestimated and</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 PBAC MEETING**

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			<p>SG was not cost-effective at the price proposed in the submission.</p> <p><u>Comparator:</u> Single-agent TPC, consisting of eribulin, capecitabine, gemcitabine or vinorelbine. The PBAC reaffirmed its previous view that the proposed comparator was reasonable.</p> <p><u>Clinical claim:</u> Superior effectiveness and a known and manageable safety compared with TPC. The PBAC recalled it had previously accepted the superior comparative effectiveness claim based on PFS and OS and reaffirmed its previous view that SG was associated with inferior comparative safety.</p> <p><u>Economic claim:</u> Cost-utility versus TPC. The PBAC noted that the revised economic evaluation had not addressed a number of the Committee's previous concerns. The PBAC considered that the ICER remained underestimated and SG was not cost-effective at the price proposed in the submission.</p> <p><u>Sponsor's Comment:</u> Gilead Sciences is disappointed by this decision as we believe Australians living with metastatic breast cancer need new treatment options.</p> <p>We wish to thank the many patient organisations and clinicians who took the time to submit consumer comments in support of our submission.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 align="center">SECUKINUMAB</p> <p>Solution for injection 300 mg in 2 mL pre-filled syringe Solution for injection 150 mg in 1 mL pre-filled syringe Solution for injection 150 mg in 1 mL pre-filled pen Solution for injection 300 mg in 2 mL pre-filled pen</p> <p align="center">Cosentyx®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Early re-entry (Change to existing listing)</p>	<p align="center">Hidradenitis suppurativa (HS)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of HS.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of secukinumab (SEC) for the treatment of moderate to severe HS. The PBAC's recommendation was based on, among other matters, its assessment the cost-effectiveness of SEC would be acceptable if it were cost minimised to adalimumab (ADA) (noting it was the only biologic disease modifying anti-rheumatic drug (bDMARD) currently PBS-listed for HS).</p> <p>The PBAC reaffirmed its view expressed in July 2023 that there was a high clinical need for additional treatment options for patients with moderate to severe HS; and in that context, considered the changes to the cost-minimisation approach, utilisation and financial estimates in the early re-entry submission had satisfactorily addressed the Committee's outstanding concerns expressed at that meeting.</p> <p>The PBAC recommended flow-on restriction changes and noted a re-design would be required for ADA (and be part of the SEC listing) to facilitate the entry of a second bDMARD for the treatment of HS.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 align="center">SEMAGLUTIDE</p> <p>Injection 0.25 mg in 0.5 mL pre-filled single dose pen Injection 0.5 mg in 0.5 mL pre-filled single dose pen Injection 1.0 mg in 0.5 mL pre-filled single dose pen Injection 1.7 mg in 0.75 mL pre-filled single dose pen Injection 2.4 mg in 0.75 mL pre-filled single dose pen</p> <p align="center">Wegovy®</p> <p align="center">NOVO NORDISK PHARMACEUTICALS PTY. LIMITED</p> <p align="center">Standard re-entry (New listing)</p>	<p align="center">Severe obesity</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe obesity despite prior participation in an appropriate lifestyle-based weight management intervention.</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend the listing of semaglutide for the treatment of severe obesity. The PBAC considered that the resubmission did not adequately support access to semaglutide as defined in the proposed PBS population. There was no strong clinical rationale for the obesity comorbidities selected for inclusion in the proposed PBS listing and they did not identify patients most likely to experience relatively large reductions in weight or long-term benefits from weight loss. No new clinical trial evidence was presented in this resubmission to support benefits of longer-term use, although the Committee noted that new randomised controlled trial data highlighting potential benefits in reducing cardiovascular events was announced by the sponsor in a press release after the resubmission was received. The PBAC considered this information would be informative in defining eligible patients who would obtain downstream health benefits of weight loss. The PBAC also considered it would be unreasonable for patients currently eligible for semaglutide 1 mg once-weekly (Ozempic®) for Type 2 diabetes, who had severe obesity, to not be able to access the higher dose of semaglutide 2.4 mg once-weekly (Wegovy) and advised that this patient group be included for future consideration. The PBAC considered semaglutide was not cost-effective at the price proposed, noting although only short-term weight loss benefits were modelled, there were multiple issues with the utility values applied. The PBAC considered a risk sharing arrangement would be required given the extremely high estimated expenditure and the criteria for defining the patient population. The PBAC nominated the facilitated resolution pathway for this item, given the high added therapeutic value of semaglutide and outstanding issues for resolution in defining the patients in whom treatment would reduce downstream consequences of obesity, be cost-effective, and appropriate for the significant Government expenditure.</p> <p>The previous submission was considered in March 2022.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 PBAC MEETING**

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			<p><u>Comparator: placebo in conjunction with diet and exercise:</u> The PBAC reaffirmed its previous view that the proposed comparator was reasonable.</p> <p><u>Clinical claim: Superior effectiveness and inferior safety compared with placebo in conjunction with diet and exercise:</u> The PBAC recalled it had previously accepted the superior comparative effectiveness claim with regards to surrogate markers of weight loss, HbA1c and other biomarkers, but that effectiveness on clinical endpoints remained uncertain. The PBAC reaffirmed its previous view that the claim of inferior comparative safety was reasonable.</p> <p><u>Economic claim: Cost-utility versus placebo in conjunction with diet and exercise:</u> The PBAC noted the new economic model developed for this resubmission. The PBAC considered the model was overly simplistic and unreliable given there were multiple issues with the utility values.</p> <p><u>Sponsor's Comment:</u> Novo Nordisk is disappointed with the outcome and appreciates all submissions from individuals, healthcare professionals and organisations in support of making Wegovy available on the PBS for the treatment of obesity. Novo Nordisk remains committed to continuing to work collaboratively with the PBAC to ensure Australians living with obesity, especially high-risk and vulnerable patients, have government-funded access to Wegovy.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 align="center">TERIPARATIDE</p> <p>Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen</p> <p align="center">Teriparatide Lupin</p> <p align="center">GENERIC HEALTH PTY LTD</p> <p align="center">Category 4 (New listing)</p>	<p align="center">Osteoporosis</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing under the same conditions as the currently listed brand Terrosa®.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of teriparatide injection 250 micrograms per mL, 2.4 mL in multi dose pre-filled pen (PFP) (Teriparatide Lupin) under the same circumstances as the currently listed teriparatide injection 250 micrograms per mL, 2.4 mL in multi dose pre-filled cartridge (PFC) (Terrosa). The recommendation was on a cost-minimisation basis with an equi-effective dose of 250 microgram/mL of Lupin PFP to 250 microgram/mL of Terrosa PFC. The PBAC advised that Teriparatide Lupin PFP and Terrosa in both its PFP and PFC forms should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) as the PBAC considered that Teriparatide Lupin PFP was therapeutically equivalent to Terrosa PFC.</p>
<p align="center">TERIPARATIDE</p> <p>Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen</p> <p align="center">Terrosa®</p> <p align="center">GEDEON RICHTER AUSTRALIA PTY LTD</p> <p align="center">Category 4 (New listing)</p>	<p align="center">Osteoporosis</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for a pre-filled pen (PFP) under the same conditions as the currently listed cartridge presentation.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of the Terrosa brand of teriparatide injection 250 micrograms per mL, 2.4 mL (teriparatide 250 mcg) in multi dose PFP on a cost-minimisation basis and under the same conditions as the Terrosa brand of teriparatide 250 mcg in multi-dose pre-filled cartridge (PFC). The PBAC considered that Terrosa PFP would be equivalent to Terrosa PFC and the Teriparatide Lupin brand of teriparatide 250 mcg in multi-dose PFP.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 style="text-align: center;">TISLELIZUMAB</p> <p style="text-align: center;">Solution concentrate for injection 100 mg in 10 mL</p> <p style="text-align: center;">Tevimbra®</p> <p style="text-align: center;">BEIGENE AUS PTY LTD</p> <p style="text-align: center;">Category 2 (New listing)</p>	<p style="text-align: center;">Non-small cell lung cancer (NSCLC)</p>	<p style="text-align: center;">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with Stage IV (metastatic) NSCLC.</p>	<p style="text-align: center;">Not Applicable</p>	<p style="text-align: center;">This item is to be considered at a future PBAC meeting.</p>
<p style="text-align: center;">TRASTUZUMAB DERUXTECAN</p> <p style="text-align: center;">Powder for I.V. infusion 100 mg</p> <p style="text-align: center;">Enhertu®</p> <p style="text-align: center;">ASTRAZENECA PTY LTD</p> <p style="text-align: center;">Category 1 (New listing)</p>	<p style="text-align: center;">Human epidermal growth factor receptor 2 (HER2)-low breast cancer</p>	<p style="text-align: center;">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of patients with HER2-low unresectable or metastatic breast cancer.</p>	<p style="text-align: center;">Not Recommended</p>	<p>The PBAC did not recommend the listing of trastuzumab deruxtecan (T-DXd) for the treatment of patients with HER2-low unresectable or metastatic breast cancer. The PBAC considered there was a moderate clinical need for additional treatments in this therapeutic area. The PBAC considered T-DXd was superior to chemotherapy based on progression free survival and overall survival. However, the PBAC considered T-DXd was not cost-effective at the price proposed in the submission given optimistic assumptions included in the economic model. The PBAC considered the financial estimates provided in the submission were substantially overestimated.</p> <p>The PBAC nominated the Early Re-entry resubmission pathway for this item.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 align="center">VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE</p> <p align="center">Injection 1 vial & adjuvant substance diluent 0.5 mL vial</p> <p align="center">Shingrix®</p> <p align="center">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p align="center">Matters Outstanding (New listing)</p>	<p align="center">Herpes zoster virus</p>	<p align="center">To request consideration of the population that was deferred at the March 2023 PBAC meeting: broader population of immunocompromised individuals aged ≥ 18 years at increased risk of herpes zoster.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended that varicella zoster virus recombinant vaccine (RZV) be a designated vaccine for the purposes of the <i>National Health Act 1953</i>, for the prevention of herpes zoster and post-herpetic neuralgia for individuals aged 18 years to 64 years at a moderate to high risk of infection, as defined by the Australian Technical Advisory Group on Immunisation (ATAGI). The PBAC noted RZV is currently funded on the National Immunisation Program for all individuals aged over 65 years and Aboriginal and Torres Strait Islander individuals aged over 50 years.</p> <p>The PBAC considered that RZV was likely to be cost-effective at the requested cost per dose in the moderate and high risk populations aged 18 years to 64 years.</p> <p>Individuals at a moderate to high risk of infection (as defined by ATAGI) include:</p> <ul style="list-style-type: none"> • Those with acute or chronic haematological malignancies, HIV infection (with CD4+ cell count < 200/ μL), some inborn errors of immunity (including x-linked agammaglobulinemia, severe combined immunodeficiency, chronic granulomatous disease) and Stage 5 kidney disease or on dialysis. • Those receiving treatment with: cellular therapies, B and T-cell targeted monoclonal antibody therapies, conventional chemotherapy for haematological cancers or solid organ tumours, immunosuppressive therapy to prevent organ rejection, some conventional immunosuppressive agents (including high dose methotrexate, mercaptopurine, azathioprine, mycophenolate, calcineurin inhibitors, mTOR inhibitors, cladribine), some biologic therapies (including TNF-α inhibitors, abatacept, dupilumab, mepolizumab, tocilizumab), immunomodulatory drugs (including sphingosine-1-phosphate inhibitors) and some oral small molecule targeted therapies (including JAK inhibitors, BTK inhibitors, BCR-ABL inhibitors).

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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">ADALIMUMAB</p> <p align="center">Injection 40 mg in 0.8 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe</p> <p align="center">Hulio®</p> <p align="center">Alphapharm Pty Ltd</p>	<p align="center">Severe Crohn disease Ulcerative colitis Juvenile idiopathic arthritis Complex refractory fistulising Crohn disease Rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Chronic plaque psoriasis Hidradenitis suppurativa</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC rescinded the November 2021 recommendation.</p>
<p align="center">BEVACIZUMAB</p> <p align="center">Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL</p> <p align="center">Zirabev®</p> <p align="center">Pfizer Australia Pty Ltd</p>	<p align="center">Metastatic colorectal cancer Advanced, metastatic or recurrent non-squamous non-small cell lung cancer Relapsed or recurrent glioblastoma Epithelial ovarian, fallopian tube or primary peritoneal cancer Cervical cancer</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the July 2020 recommendation for a further 12 months.</p>
<p align="center">ETANERCEPT</p> <p align="center">Injection 50 mg in 1 mL single use pre-filled syringe</p> <p align="center">Rymti®</p> <p align="center">Alphapharm Pty Ltd</p>	<p align="center">Rheumatoid arthritis Plaque psoriasis Ankylosing spondylitis Psoriatic arthritis Juvenile idiopathic arthritis Paediatric plaque psoriasis</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC rescinded the November 2021 recommendation.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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">INSULIN ASPART</p> <p>Injection (human analogue), cartridge 100 units per mL, 3 mL Injection (human analogue), pre-filled pen, 100 units per mL, 3 mL</p> <p align="center">Truvelog® Truvelog Solostar®</p> <p align="center">Sanofi-Aventis Australia Pty Ltd</p>	<p align="center">Diabetes mellitus</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the July 2020 recommendation for a further 6 months.</p>
<p align="center">IXEKIZUMAB</p> <p>Injection 80 mg in 1 mL single dose pre-filled pen</p> <p align="center">Taltz®</p> <p align="center">Eli Lilly Australia Pty Ltd</p>	<p align="center">Non-radiographic axial spondyloarthritis</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the July 2020 recommendation for a further 12 months.</p>
<p align="center">MELATONIN</p> <p>Tablet 1 mg Tablet 5 mg</p> <p align="center">Slenyto®</p> <p align="center">Aspen Pharmacare Australia Pty Ltd</p>	<p align="center">Smith-Magenis syndrome</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC deferred this item. It will be considered at the December 2023 PBAC intracycle meeting.</p>
<p align="center">RISANKIZUMAB</p> <p>Injection 150 mg in 1 mL pre-filled pen Injection 150 mg in 1 mL pre-filled syringe</p> <p align="center">Skyrizi®</p> <p align="center">AbbVie Pty Ltd</p>	<p align="center">Severe chronic plaque psoriasis</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC rescinded the November 2021 recommendation.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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">SECUKINUMAB</p> <p>Injection 75 mg in 0.5 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen Injection 300 mg in 2 mL pre-filled syringe Injection 300 mg in 2 mL pre-filled pen</p> <p align="center">Cosentyx®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p>	<p align="center">Paediatric psoriasis</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC extended the July 2020 recommendation for a further 12 months.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 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 medicines for people in custodial settings</p> <p>Various Medicines</p> <p>Other Matters</p>	<p>Various medicines</p>	<p>For the PBAC to note stakeholders' concerns regarding inequitable access to PBS-listed General Schedule medicines for people in custodial settings.</p>	<p>The PBAC noted the request from the Minister's delegate for advice in response to concerns raised by stakeholders regarding inequitable access to medicines for people in custodial settings. The PBAC noted that state and territory governments fund the provision of healthcare to people in custodial settings, except for medicines listed on the Highly Specialised Drugs program which is funded by the Commonwealth. The PBAC acknowledged barriers preventing people in custody from accessing medicines listed on the PBS General Schedule that are available to people in the community, and the need to improve access to medicines in these settings.</p> <p>The PBAC noted the Department's intention to undertake further work on a proposal from stakeholders to improve access to certain medicines for people in custodial settings. The PBAC noted it would consider further work undertaken by the Department and provide advice if required at a future meeting.</p>
<p>OMALIZUMAB</p> <p>Injection 150 mg in 1 mL single dose pre-filled syringe</p> <p>Xolair®</p> <p>NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p>Systematic literature review to supplement DUSC Analysis</p>	<p>Chronic spontaneous urticaria (CSU)</p>	<p>To consider the findings of a systematic literature review of the most recent comparative clinical evidence for omalizumab and cyclosporin for the treatment of CSU, including the equi-effective dose, for comparison with the evidence previously considered by the PBAC.</p>	<p>The PBAC noted the findings from the Review of clinical evidence for omalizumab versus cyclosporin for the treatment of CSU, and an addendum to the predicted vs actual analyses of omalizumab, which presented an additional analysis of time between prescriptions for omalizumab. The PBAC also noted the DUSC's advice.</p> <p>The PBAC noted that there was no evidence of a significant number of patients increasing dosing intervals to 6-8 weeks in the time to resupply analyses.</p> <p>The PBAC considered that the Review's updated evidence supported the clinical effectiveness of omalizumab at both 300 mg and 600 mg doses. Consistent with the November 2015 submission, both cyclosporin and omalizumab were more effective than placebo, and omalizumab had a better safety profile than cyclosporin.</p> <p>The PBAC considered that there was insufficient evidence presented by the Review on which to base any change of the accepted equi-effective dose of omalizumab 300 mg every four weeks and cyclosporin 4 mg/kg/day for CSU. The PBAC would consider a resubmission for omalizumab, in light of the evidence in this Review, if required.</p>

Version 2

Amendments

1. ABEMACICLIB – added PBAC recommended flow-on statement.
2. BUDESONIDE WITH FORMOTEROL – corrected naming by removing “+” and adding “with”.
3. FLUTICASONE PROPIONATE WITH SALMETEROL – corrected naming by removing “+” and adding “with”.
4. LENACAPAVIR – added PBAC recommended flow-on statement.
5. OXYBUTYNIN – corrected outcome from “Recommended” to “Advice Provided”.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 PBAC MEETING**

Submission category types

Category 1	<p>A request for PBS or NIP listing of one or more of the following:</p> <ul style="list-style-type: none"> • A first in class medicine or vaccine, and/or a medicine or vaccine for a new population. OR • A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC. OR • A drug or designated vaccine with a TGA Provisional determination related to the proposed population.
Category 2	<p>A request for PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication and do not meet the criteria for a Category 1 submission.</p>
Category 3	<p>Requests to change existing listings that do not change the population or cost-effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission.</p>
Category 4	<p>A request for one or more of the following:</p> <ul style="list-style-type: none"> • Listing of a new pharmaceutical item of a listed medicine. • Consideration as an exempt item (Exempt item as per subsection 84AH of the <i>National Health Act 1953</i>). • Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing. • A change/new manner of administration of a listed medicine. • A change to the maximum quantity and/or number of repeats of a listed medicine. • A change or addition to the prescriber type(s) of a listed medicine.
Committee Secretariat	<p>Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following:</p> <ul style="list-style-type: none"> • New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk • Pharmaceutical benefits that can no longer be supplied early • New brand of glucose indicator pharmaceutical item.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2023 PBAC MEETING**

Resubmission pathways

<p>There are four different resubmission pathways available to applicants following a 'not recommended' PBAC outcome. Resubmission pathways are not available for submissions that receive a positive recommendation from the PBAC. The resubmission pathways are classified into the following categories:</p>	
Standard re-entry	<p>The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where:</p> <ul style="list-style-type: none"> • an applicant chooses not to accept the PBAC nominated resubmission pathway; or • an Early Re-entry or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or • an applicant decides to lodge later than the allowable timelines for the other pathways.
Early re-entry pathway	<p>An Early Re-entry Pathway may be nominated by the PBAC where the PBAC considers that the remaining issues could be easily resolved and the medicine or vaccine does not represent High Added Therapeutic Value (HATV) for the proposed population. Applicants who accept this pathway are eligible for PBAC consideration at the immediate next meeting.</p>
Early resolution pathway	<p>For medicines or vaccines deemed by the PBAC to represent HATV AND where the PBAC considers that the remaining issues could be easily resolved, including when:</p> <ul style="list-style-type: none"> • new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and • a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission. <p>Applicants who accept this pathway are eligible for PBAC consideration out-of-session (before the main meeting), unless the department, in consultation with the PBAC Chair, identifies an unexpected issue such that the resubmission needs consideration at the next main PBAC meeting.</p>
Facilitated resolution pathway	<p>A Facilitated Resolution Pathway may be nominated by the PBAC where the PBAC considers the issues for resolution could be explored through a workshop AND where the medicine or vaccine meets the HATV criteria. Applicants who accept this pathway are eligible for a solution-focussed workshop with one or more members of the PBAC. The workshop agenda will be based on the issues for resolution outlined in the PBAC Minutes. This can be further clarified during the post-PBAC meeting with the Chair.</p>