

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">Standard re-entry submission (Change to PBS listing)</p>	<p align="center">Breast cancer</p>	<p align="center">Resubmission to request a General Schedule Authority Required (telephone/online) listing for use in combination with standard adjuvant endocrine therapy (ET) for the treatment of hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-), lymph node-positive, invasive, resected early breast cancer (EBC) at high risk of disease recurrence.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule Authority Required listing of abemaciclib, in combination with standard adjuvant ET, for the treatment of HR+, HER2-, lymph node positive, invasive, resected EBC at high risk of disease recurrence. The PBAC considered the evidence presented in the resubmission demonstrated a meaningful difference in invasive disease-free survival and distant relapse free survival over the comparator (ET alone) but noted that a benefit in terms of overall survival had not been demonstrated in the clinical trial and therefore remained uncertain. The PBAC considered that the incremental cost-effectiveness ratio was likely underestimated and that a price reduction would be required for abemaciclib to be considered cost-effective. The PBAC considered that the financial estimates were overestimated due to optimistic assumptions regarding uptake, compliance and treatment duration. The PBAC also considered that a risk sharing arrangement would be required due to risk of utilisation in patients at lower risk of disease recurrence than defined by the proposed restriction.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">ACALABRUTINIB</p> <p style="text-align: center;">Capsule 100 mg</p> <p style="text-align: center;">Calquence®</p> <p style="text-align: center;">AstraZeneca Pty Ltd</p> <p style="text-align: center;">Category 3 submission (Other matters)</p>	<p style="text-align: center;">Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL).</p>	<p style="text-align: center;">To request the PBAC consider the previously estimated utilisation for relapsed or refractory CLL or SLL.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend that the estimated utilisation of acalabrutinib for relapsed/refractory CLL SLL be amended. The PBS noted that the analysis of the 100% PBS data comparing the last 12 months to 30 November 2022 versus the same period to 30 November 2021 demonstrated that the number of first initiators to relapsed or refractory PBS listings had declined by 7%. The PBAC further considered that while changes to the utilisation estimates due to sequential use may be clinically reasonable, the data are too immature to see a significant difference in patient numbers in sequential treatments.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p style="text-align: center;">ALIROCUMAB</p> <p style="text-align: center;">Injection 300 mg in 2 mL single dose autoinjector</p> <p style="text-align: center;">Praluent®</p> <p style="text-align: center;">Sanofi-Aventis Australia Pty Ltd</p> <p style="text-align: center;">Category 4 submission (New PBS listing)</p>	<p style="text-align: center;">Familial heterozygous hypercholesterolaemia (he-FH) and non-familial hypercholesterolaemia (non-FH).</p>	<p style="text-align: center;">To request listing of a new form and strength under the same conditions as the currently listed form and strengths of alirocumab for the treatment of he-FH and non-FH.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of alirocumab 300 mg in 2 mL single dose autoinjector (AI) under the same circumstances as the PBS-listed alirocumab 75 mg in 1 mL and 150 mg in 1 mL subcutaneous injection pre-filled pens (PFPs) for the treatment of he-FH and non-FH. The PBAC noted that there would be no additional cost to the PBS/RPBS from listing alirocumab AI as it is expected to substitute for alirocumab PFP and will be cost-minimised to the lowest-cost comparator. The PBAC considered that alirocumab PFP and evolocumab are relevant comparators.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID</p> <p>Sachets containing oral powder 12.5 g, 30 (HCU explore5)</p> <p>HCU explore5™</p> <p>Vitaflo Australia Pty Limited</p> <p>Category 3 submission (New PBS listing)</p>	<p>Pyridoxine non-responsive homocystinuria (HCU)</p>	<p>To request a General Schedule Restricted Benefit listing for the dietary management of HCU.</p>	<p>Recommended</p>	<p>The PBAC recommended the General Schedule Restricted Benefit listing of amino acid formula with vitamins and minerals without methionine and supplemented with arachidonic acid and docosahexaenoic acid (HCU explore5™) for the dietary management of pyridoxine non-responsive homocystinuria under the same circumstances as HCU gel, 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 AND MINERALS, WITHOUT PHENYLALANINE AND TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID</p> <p>Sachets containing oral powder 12.5 g, 30 (TYR explore5)</p> <p>TYR explore5™</p> <p>Vitaflo Australia Pty Limited</p> <p>Category 3 submission (New PBS listing)</p>	<p>Tyrosinaemia</p>	<p>To request a General Schedule Restricted Benefit listing for the dietary management of tyrosinaemia.</p>	<p>Recommended</p>	<p>The PBAC recommended the General Schedule Restricted Benefit listing of amino acid formula with vitamins and minerals, without phenylalanine and tyrosine and supplemented with arachidonic acid and docosahexaenoic acid (TYR explore5™), for the dietary management of tyrosinaemia under the same circumstances as TYR gel, and on a cost-minimisation basis to the lowest cost comparator on a price per gram of protein equivalent basis.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID</p> <p>Sachets containing oral powder 12.5 g, 30 (MSUD explore5)</p> <p>MSUD explore5™</p> <p>Vitaflo Australia Pty Limited</p> <p>Category 3 submission (New PBS listing)</p>	<p>Maple syrup urine disease (MSUD)</p>	<p>To request a General Schedule Restricted Benefit listing for the dietary management of patients with MSUD.</p>	<p>Recommended</p>	<p>The PBAC recommended the General Schedule Restricted Benefit listing of amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid (MSUD explore5™) under the same conditions as MSUD gel, and on a cost-minimisation basis to the lowest cost comparator on a price per gram of protein equivalent basis.</p>
<p>AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS</p> <p>Oral powder 400 g (EleCare LCP)</p> <p>EleCare® LCP</p> <p>Abbott Australasia Pty Ltd</p> <p>Category 3 submission (Change to PBS listing)</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 Cows' milk anaphylaxis Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Severe intestinal malabsorption including short bowel syndrome</p>	<p>To request that EleCare® LCP with new source of docosahexaenoic acid (DHA) continue to be listed on the PBS under the current conditions.</p>	<p>Recommended</p>	<p>The PBAC recommended that amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids (EleCare® LCP) continue to be PBS-listed under the same conditions as the current listing. The PBAC considered that the new source of DHA, <i>Schizochytrium</i> sp.oil, was unlikely to change the clinical effectiveness or safety profile of the product nor its market utilisation.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">ANIFROLUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 2 mL vial</p> <p style="text-align: center;">Saphnelo®</p> <p style="text-align: center;">AstraZeneca Pty Ltd</p> <p>Standard re-entry submission (New PBS listing)</p>	<p style="text-align: center;">Systemic lupus erythematosus (SLE)</p>	<p style="text-align: center;">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe SLE with a high degree of disease activity despite standard therapy.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of anifrolumab for the treatment of SLE with high disease activity despite standard therapy.</p> <p>The previous submission was considered in July 2022.</p> <p><u>Comparator: Standard of care (SOC) alone.</u></p> <p>The PBAC considered SOC alone was the appropriate comparator.</p> <p><u>Clinical claim: Superior effectiveness and inferior safety compared with SOC alone.</u></p> <p>The data to support the clinical claim was drawn from three head-to-head randomised controlled trials comparing anifrolumab to SOC alone in adults with moderate to severe SLE (TULIP 1, TULIP 2, and MUSE); and two treatment extension studies (MUSE LTE and TULIP LTE).</p> <p>The PBAC considered the claim of superiority to SOC alone in terms of effectiveness was supported based on improvement in disease activity for some patients, however the magnitude of benefit was modest and uncertain. The PBAC considered the claim of inferior safety to SOC alone was reasonable.</p> <p><u>Economic claim: Cost-effectiveness versus SOC alone</u></p> <p>The economic model remained highly uncertain and was unreliable for decision making.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>The PBAC acknowledged that the low level of certainty in the evidence likely reflects, in part, the complex and variable nature of the condition and the challenges associated with assessing outcomes in SLE. The PBAC expressed a desire for a simpler, more robust model for SLE that was based on conservative assumptions and would provide more reliable estimates of cost-effectiveness for this population.</p> <p>The PBAC considered that the utilisation estimates for anifrolumab remained high despite the revised inputs in the pre-PBAC response.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p style="text-align: center;">APREMILAST</p> <p style="text-align: center;">Tablet 30 mg Pack containing 4 tablets of 10 mg, 4 tablets of 20 mg and 19 tablets of 30 mg</p> <p style="text-align: center;">Otezla®</p> <p style="text-align: center;">Amgen Australia Pty Limited</p> <p style="text-align: center;">Standard re-entry submission (Change to PBS listing)</p>	<p style="text-align: center;">Psoriatic arthritis (PsA)</p>	<p style="text-align: center;">To request a General schedule Authority Required (STREAMLINED) listing for the treatment of severe active PsA.</p>	<p style="text-align: center;">Not Recommended</p>	<p>The PBAC did not recommend the listing of apremilast for the treatment of PsA, in patients who have previously failed to achieve an adequate response to, or are clinically inappropriate for, conventional synthetic disease modifying anti-rheumatic drugs (csDMARDs) (i.e., methotrexate, sulfasalazine and/or leflunomide), and who are ineligible or clinically inappropriate for treatment with a biologic or targeted synthetic disease modifying anti-rheumatic drug (bDMARD/tsDMARD). The PBAC acknowledged there was likely to be a cohort of patients with severe PsA who are unable to be treated with the available treatment options who would benefit from the availability of an additional treatment option. However, the PBAC considered the proposed restriction criteria did not adequately identify the appropriate cohort of patients.</p> <p>Submissions for a different clinical place in PsA were not recommended by the PBAC in March 2015 and November 2015.</p> <p><u>Comparator:</u> Placebo and best supportive care (BSC)</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>The PBAC considered the proposed comparator of placebo and BSC was reasonable for the requested population, as this cohort of patients had either failed or were not eligible for alternative treatment options.</p> <p><u>Clinical claim: Superior comparative effectiveness and inferior comparative safety to placebo and BSC</u></p> <p>The PBAC considered that while there were applicability issues as the clinical trial evidence was not reflective of the requested PBS population, overall, the PBAC considered the clinical claims of superior comparative effectiveness and inferior comparative safety to placebo + BSC were adequately supported.</p> <p><u>Economic claim: Cost-effectiveness</u></p> <p>The PBAC noted the range of issues raised by the Economics Sub-Committee (ESC) that related to the model structure and approach for determining the model inputs which were not able to be adequately addressed through sensitivity analyses. Overall, the PBAC considered the cost-effectiveness of apremilast for the treatment of severe PSA was unable to be determined.</p> <p><u>Sponsor's Comment:</u> Amgen is disappointed with this outcome and will continue to work with the PBAC to improve patient access to apremilast. Amgen would like to thank all of the healthcare professionals, professional societies, patient organisations and consumers for their support of the apremilast submission.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">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 submission (New PBS 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 CPP.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Authority Required listing of bimekizumab (BKZ) for the treatment of severe CPP. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of BKZ would be acceptable if it were cost minimised to the least costly alternative therapy of infliximab, guselkumab, ixekizumab, risankizumab, tildrakizumab and secukinumab. The PBAC considered there is sufficient evidence to conclude that BKZ provides, for some patients, a significant improvement in efficacy compared to adalimumab, etanercept and ustekinumab.</p> <p>The PBAC recommended that flow-on changes to the currently listed biologic disease modifying anti-rheumatic drugs will be required to include BKZ in the list of eligible treatments as part of a treatment cycle.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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"> BUDESONIDE Tablet 500 micrograms (orally disintegrating) Tablet 1 mg (orally disintegrating) Jorveza® Dr Falk Pharma Australia Pty Ltd Category 3 submission (Change to PBS listing) </p>	<p align="center">Eosinophilic oesophagitis (EoE)</p>	<p align="center"> To request PBAC advice regarding the number of biopsies to confirm eligibility for initial treatment; removal of the histological assessment to determine eligibility for continuing treatment; and an expansion to the treatment criteria to include physicians or surgeons experienced in the diagnosis and management of EoE. </p>	<p align="center">Recommended</p>	<p>The PBAC recommended expanding the list of eligible prescribers in the PBS treatment criteria for budesonide orally disintegrating tablets (BOT) 500 micrograms and 1 mg to include physicians or surgeons experienced in the diagnosis and management of EoE. The PBAC noted concerns raised in the submission and input from organisations that non-gastroenterologist specialists may be responsible for the care of individuals with EoE and that patients living in rural and remote areas may not have access to a gastroenterologist.</p> <p>The PBAC noted the submission’s concerns about confusion caused by the current Prescribing Instruction regarding the optimal number of biopsies in the PBS restriction criteria for BOT. The PBAC recommended amending the Prescribing Instruction to provide additional clarity for prescribers.</p> <p>The PBAC deferred making a recommendation regarding the request to remove the PBS criteria requiring a histological assessment (endoscopy) to determine treatment response/eligibility for continuing treatment for BOT for the treatment of EoE. The PBAC noted concerns raised by the submission and healthcare professionals regarding access to second endoscopy within the required timeframe. The PBAC requested further advice from relevant experts on the appropriateness and safety of removing this restriction criteria and requested that the Drug Utilisation Sub-Committee review the utilisation of BOT after 12 months of listing, noting that BOT for the treatment of EoE was listed on the PBS in May 2022.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>CARMELLOSE WITH GLYCERIN AND WITH HYALURONIC ACID</p> <p>Eye drops containing carmellose sodium 5 mg with glycerin 9 mg and with hyaluronic acid 1 mg per mL, 10 mL</p> <p>Optive Fusion®</p> <p>Allergan Australia Pty Limited</p> <p>Category 3 submission (New PBS listing)</p>	<p>Severe dry eye syndrome</p>	<p>To request a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation to list carmellose with glycerol and hyaluronic acid (CGH) as a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome to undertake further analysis of the cost effectiveness of ocular lubricants. The PBAC advised that the listings of all ocular lubricants used for severe dry eye syndrome be revised to remove any references to Sjogren's syndrome in the indication.</p> <p><u>Sponsor's Comment:</u> Allergan is disappointed by the PBAC's decision to defer making a recommendation on CGH until a cost effectiveness review of all ocular lubricants has been conducted.</p>
<p>CHLORMETHINE HYDROCHLORIDE</p> <p>0.016% (160 microgram/g) gel</p> <p>Ledaga®</p> <p>Juniper Biologics Pty Ltd</p> <p>Category 1 submission (New PBS listing)</p>	<p>Mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL)</p>	<p>To request a General Schedule Authority Required (telephone/electronic) listing for the treatment of adults with MF-type CTCL.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of chlormethine hydrochloride gel (hereafter chlormethine gel) for the treatment of MF-type CTCL in adult patients who have no more than 25% of their body surface area involved, have failed, are intolerant of or have a contraindication to treatment with topical corticosteroids. The PBAC acknowledged the clinical need for additional treatment options for patients with MF-type CTCL. However, the PBAC considered that the clinical evidence presented did not adequately support the claim that chlormethine gel provides improved effectiveness compared to phototherapy with respect to health-related quality of life and hence the cost-utility analysis based on this claim did not support that chlormethine gel was cost-effective.</p> <p><u>Sponsor's Comment:</u> The Sponsor will continue to work with the PBAC to make Ledaga® available to Australian patients.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">DARATUMUMAB</p> <p>Solution for I.V. infusion 100 mg in 5 mL vial Solution for I.V. infusion 400 mg in 20 mL vial Solution for S.C. injection 1,800 mg in 15 mL vial</p> <p style="text-align: center;">Darzalex®</p> <p style="text-align: center;">Janssen-Cilag Pty Ltd</p> <p>Category 2 submission (Change to PBS listing)</p>	<p>Multiple myeloma</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (telephone/online) listing for the I.V. and S.C. formulations and a General Schedule Authority Required (telephone/online) listing for the S.C. formulation for use in combination with lenalidomide and dexamethasone for the treatment of transplant ineligible, newly diagnosed multiple myeloma (NDMM).</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend daratumumab, for use in combination with lenalidomide and dexamethasone (DLd) for the treatment of patients with transplant ineligible NDMM. The PBAC noted the benefits of treatment with DLd compared with lenalidomide plus dexamethasone (Ld) and the strong consumer support for this item but considered there were numerous issues that had not been addressed in the submission. These included, but were not limited to, the definition of the proposed patient population, concerns regarding the assumed efficacy of the proposed comparators, the unreasonably high and uncertain incremental cost-effectiveness ratio and the very high and uncertain estimated financial impact estimates. The PBAC considered that a substantial price reduction would be required to ensure daratumumab was cost-effective and that a risk sharing arrangement would be required to mitigate the high likelihood of use in the transplant eligible population, especially given that a patient's eligibility for transplantation may change over time based on many factors, including the alternative treatments available.</p> <p><u>Sponsor's Comment:</u> Janssen are disappointed with the outcome, and remain committed to equitable and sustainable patient access for Australians. Janssen will now review the PBAC's feedback to understand the requirements for the PBS listing of DLd for people with transplant ineligible NDMM.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">DEUCRAVACITINIB</p> <p align="center">Tablet 6 mg</p> <p align="center">Sotyktu®</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">Matters outstanding (New PBS listing)</p>	<p align="center">Plaque psoriasis</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe chronic plaque psoriasis (CPP), in patients who have not responded to, or have a contraindication or demonstrated intolerance to methotrexate.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of deucravacitinib for the treatment of severe CPP. The PBAC’s recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of deucravacitinib would be acceptable with a price reduction to achieve an incremental cost-effectiveness ratio consistent with that previously accepted for this condition.</p> <p>The PBAC recommended flow-on changes to the apemilast criteria to preclude concurrent treatment with deucravacitinib and flow-on changes to the biologic disease modifying anti-rheumatic drug criteria for severe CPP to add deucravacitinib to the list of prior therapies that patients may trial before being eligible for PBS-subsidised biologics.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">DIFELIKEFALIN</p> <p>Solution for I.V. injection 50 mcg in 1 mL vial</p> <p style="text-align: center;">Korsuva®</p> <p style="text-align: center;">Vifor Pharma Pty Limited</p> <p style="text-align: center;">Category 1 submission (New PBS listing)</p>	<p style="text-align: center;">Chronic kidney disease (CKD) associated pruritus</p>	<p style="text-align: center;">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 in adult patients on haemodialysis.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of difelikefalin for the treatment of moderate to severe pruritus (itching) associated with CKD in adult patients who are receiving haemodialysis. The PBAC acknowledged there was a clinical need for effective treatment options as current alternatives were of limited effectiveness and/or prescribed off-label with limited evidence to support their use. The PBAC considered that based on the evidence presented, difelikefalin is likely to be effective for some patients, but noted limited longer-term data were available. However, the PBAC considered the incremental cost-effectiveness ratio for difelikefalin was high and underestimated with the economic model incorporating optimistic assumptions, and that a price reduction would be required for difelikefalin to be considered cost-effective. The PBAC considered that a risk sharing arrangement would be required to address any residual uncertainty with the potential for use outside of the proposed restriction, including in patients with mild pruritus.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p style="text-align: center;">DOSTARLIMAB</p> <p>Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p style="text-align: center;">Jemperli®</p> <p style="text-align: center;">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p style="text-align: center;">Matters outstanding (New PBS listing)</p>	<p style="text-align: center;">Endometrial cancer</p>	<p style="text-align: center;">To seek the PBAC's advice regarding whether the cost of dostarlimab in the revised pricing proposal for the treatment of endometrial cancer is acceptably cost-effective.</p>	<p>Advice Provided</p>	<p>At its November 2022 meeting, the PBAC did not recommend the listing of dostarlimab for the treatment of patients with recurrent or advanced mismatch repair deficient endometrial cancer who have disease progression following prior systemic therapy. The PBAC considered a revised pricing proposal for dostarlimab. On the basis of this proposal, the PBAC did not change its recommendation regarding dostarlimab from the November 2022 meeting.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">DURVALUMAB</p> <p>Solution concentrate for I.V. infusion 120 mg in 2.4 mL vial Solution concentrate for I.V. infusion 500 mg in 10 mL vial</p> <p align="center">Imfinzi®</p> <p align="center">AstraZeneca Pty Ltd</p> <p>Category 1 submission (Change to PBS listing)</p>	<p align="center">Biliary tract cancer</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy program) Authority Required (STREAMLINED) listing for the treatment of advanced biliary tract cancer (BTC).</p>	<p align="center">Not Recommended</p>	<p>The PBAC did not recommend the listing of durvalumab for the treatment of advanced BTC. The PBAC considered that durvalumab in combination with chemotherapy provided a moderate added benefit in progression free survival and overall survival. The PBAC considered the base case incremental cost effectiveness ratio was high and underestimated. The PBAC considered the utilisation of durvalumab was overestimated. The PBAC considered there is a moderate to high clinical need for more effective treatments in this patient population who generally have a poor prognosis.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p>ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR</p> <p>Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg</p> <p align="center">Trikafta®</p> <p align="center">VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD.</p> <p>Matters arising (New PBS listing)</p>	<p align="center">Cystic fibrosis</p>	<p align="center">To request reconsideration of the financial estimates for Trikafta® for the treatment of cystic fibrosis in patients who are aged 6 to 11 years and who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene.</p>	<p align="center">Recommended</p>	<p>The PBAC revised its previous advice regarding the recommendation of Trikafta® for the treatment of cystic fibrosis in patients who are aged 6 to 11 years and who have at least one F508del mutation on the CFTR gene, taking into consideration the additional information provided by the sponsor.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">ENZALUTAMIDE</p> <p align="center">Capsule 40 mg</p> <p align="center">Xtandi®</p> <p align="center">Astellas Pharma Australia Pty Ltd</p> <p align="center">Category 2 submission (Change to PBS listing)</p>	<p align="center">Prostate cancer</p>	<p>To request a General Schedule Authority Required (telephone/online) listing for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in patients with low volume disease, and in high volume disease where the patient is unsuitable for docetaxel due to poor Eastern Cooperative Oncology Group status, comorbidities, or contraindications.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of enzalutamide for the treatment of mHSPC irrespective of disease volume or suitability for docetaxel. The PBAC considered that enzalutamide, in combination with androgen deprivation therapy (ADT), provides a moderate clinical benefit compared to ADT alone. The PBAC advised that changes should be made to the economic model and that for enzalutamide to be considered cost effective, the price should be reduced to achieve an incremental cost-effectiveness ratio consistent with that previously accepted for this condition. Further, the PBAC considered that as enzalutamide does not provide a significant improvement in efficacy and/or reduction in toxicity compared to apalutamide, it should be priced no higher than apalutamide, based on the daily cost at recommended doses, should apalutamide be PBS listed for mHSPC. The PBAC considered that the utilisation estimates were reasonable and that a risk sharing arrangement would mitigate the risks that patients would remain on enzalutamide for longer than estimated and that enzalutamide use in patients with high volume disease suitable for docetaxel may not be cost effective.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">FINERENONE</p> <p align="center">Tablet 10 mg Tablet 20 mg</p> <p align="center">Kerendia®</p> <p align="center">Bayer Australia Ltd</p> <p align="center">Standard re-entry submission (New PBS listing)</p>	<p align="center">Chronic kidney disease (CKD) in Type 2 diabetes</p>	<p align="center">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of CKD in patients with type 2 diabetes mellitus.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule Authority Required listing of finerenone for the treatment of CKD in patients with type 2 diabetes mellitus (diabetic kidney disease). The PBAC was satisfied that finerenone in combination with standard of care provides, for some patients, a significant improvement in efficacy over standard of care alone. The PBAC considered that finerenone has a limited place in therapy given a small and uncertain reduction in clinical events in CKD and cardiovascular disease with use in combination with standard of care, including a sodium-glucose cotransporter-2 inhibitor therapy, and the complication of hyperkalaemia. The PBAC considered finerenone would be cost-effective based on the revised economic model assumptions and the price reduction offered in the pre-PBAC response. However, the PBAC considered that the utilisation estimates remained overestimated and should be revised to include parameters aligned with those recently accepted in the CKD setting.</p>
<p align="center">FOSNETUPITANT (AS CHLORIDE HYDROCHLORIDE)/PALONOSETRON (AS HYDROCHLORIDE)</p> <p align="center">Solution concentrate for I.V. infusion containing fosnetupitant 235 mg and palonosetron 0.25 mg in 20 mL vial</p> <p align="center">Akynzeo®IV</p> <p align="center">Juniper Biologics Pty Ltd</p> <p align="center">Category 2 submission (New PBS listing)</p>	<p align="center">Nausea and vomiting</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) and a General Schedule Authority Required (STREAMLINED) listing for the treatment of nausea and vomiting in patients receiving highly, or moderately, emetogenic chemotherapy.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule and Section 100 (Efficient Funding of Chemotherapy – Related Benefits) listing of intravenous fosnetupitant with palonosetron (NEPA IV) for the treatment and/or prophylaxis of nausea and vomiting in patients receiving highly or moderately emetogenic chemotherapy who are unable to swallow or are contraindicated to an oral anti-emetic regimen.</p> <p>The recommendation was based upon, among other matters, the PBAC's view the cost-effectiveness of NEPA IV was acceptable if it were listed on a cost minimisation basis with IV fosaprepitant and IV palonosetron, with additional restrictions to address the risk of use in patients who would otherwise be eligible for an oral anti-emetic regimen.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS</p> <p>Oral liquid 250 mL, 30 (Tylactin RTD)</p> <p align="center">Tylactin RTD</p> <p align="center">Cortex Health Pty Ltd</p> <p>Committee secretariat submission (Other matters)</p>	<p align="center">Tyrosinaemia</p>	<p align="center">To request Tylactin RTD with new formulation continue to be listed on the PBS under the existing conditions.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended that new formulation of glycomacropeptide and essential amino acids with vitamins and minerals (Tylactin RTD) continue to be listed on the PBS under the existing conditions for the current formulation. The PBAC noted and supported the Nutritional Products Working Party advice that the new formulation is expected to provide non-inferior clinical benefit for the management of tyrosinaemia.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS</p> <p>Sachets containing oral powder 40 g, 30 (Camino Pro Bettermilk)</p> <p>Oral liquid 250 mL, 30 (PKU Glytactin RTD 15)</p> <p>Camino Pro Bettermilk PKU Glytactin RTD 15</p> <p>Cortex Health Pty Ltd</p> <p>Category 3 submission (New PBS listing)</p>	<p align="center">Phenylketonuria</p>	<p>To request Camino Pro Bettermilk and PKU Glytactin RTD 15 with new formulation continue to be listed on the PBS under the existing conditions. The submission also requested a new pack size for Camino Pro Bettermilk of 30 x 40 g sachets.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended a new formulation of glycomacropeptide and essential amino acids with vitamins and minerals (PKU Glytactin RTD 15) continue to be listed on the PBS under the same conditions as the current formulations. The PBAC noted and supported the Nutritional Products Working Party (NPWP) advice that the new formulation is expected to provide a non-inferior clinical benefit for the management of phenylketonuria.</p> <p>The PBAC also recommended the listing of a new 30 x 40 g pack size with new formulation of glycomacropeptide and essential amino acids with vitamins and minerals (Camino Pro Bettermilk) on the PBS under the same conditions as the current 30 x 49 g pack size and formulation. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Camino Pro Bettermilk in pack size 30 x 40 g would be acceptable if it were cost-minimised to the currently listed Camino Pro Bettermilk in pack size 30 x 49 g comparators on a cost per gram of protein equivalent basis. The PBAC noted and supported the NPWP advice that the new pack size and formulation is expected to provide a non-inferior clinical benefit for the management of phenylketonuria.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE</p> <p>Oral liquid 250 mL, 30 (KetoVie 3:1) Oral liquid 250 mL, 30 (KetoVie 4:1) Oral liquid 250 mL, 30 (KetoVie Peptide 4:1)</p> <p>KetoVie 3:1 KetoVie 4:1 KetoVie Peptide 4:1</p> <p>Cortex Health Pty Ltd</p> <p>Committee secretariat submission (Other matters)</p>	<p style="text-align: center;">Ketogenic diet</p>	<p>To request KetoVie 3:1, KetoVie 4:1, and KetoVie Peptide 4:1 with new formulation continue to be listed on the PBS under the existing conditions.</p>	<p>Recommended</p>	<p>The PBAC recommended that new formulations of high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (KetoVie 3:1, KetoVie 4:1, KetoVie Peptide 4:1) continue to be listed on the PBS under the same conditions as the current formulations. The PBAC noted and supported the Nutritional Products Working Party advice that the new formulations are expected to provide non-inferior clinical benefit for the management of a ketogenic diet.</p>
<p>HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR</p> <p>Eye drops containing sodium hyaluronate 1.5 mg per mL with polyethylene glycol 400, propylene glycol and hydroxypropyl guar, 10 mL</p> <p>Systane® Hydration</p> <p>Alcon Laboratories (Australia) Pty Ltd</p> <p>Category 3 submission (New PBS listing)</p>	<p style="text-align: center;">Severe dry eye syndrome</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation to list hyaluronic acid with polyethylene glycol 400 with propylene glycol with hydroxypropyl guar as a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops in order to undertake further analysis of the cost effectiveness of ocular lubricants in Australia.</p> <p><u>Sponsor's Comment:</u> Alcon is disappointed with the outcome but will work with the PBAC to make Systane multi-dose preservative-free eye drops available through the PBS as soon as possible.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">INCLISIRAN</p> <p>Injection 284 mg in 1.5 mL single use pre-filled syringe</p> <p style="text-align: center;">Leqvio®</p> <p style="text-align: center;">Novartis Pharmaceuticals Australia Pty Limited</p> <p style="text-align: center;">Category 2 submission (New PBS listing)</p>	<p style="text-align: center;">Hypercholesterolaemia</p>	<p style="text-align: center;">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia and atherosclerotic cardiovascular disease (ASCVD).</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend inclisiran for the treatment of hypercholesterolaemia and ASCVD. The PBAC considered the proposed positioning of inclisiran as a second-line alternative to ezetimibe was not justified. The PBAC considered inclisiran would be most appropriately positioned as an alternative to the proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors in the third-line setting. The PBAC noted the submission presented supporting indirect treatment comparisons between inclisiran and the PCSK9 inhibitors; however, it considered that, non-inferiority to the PCSK9 inhibitors was uncertain. To address the uncertainty in the non-inferiority claim, an early re-entry resubmission with a lower price than evolocumab would be required to support PBS listing in the same treatment setting as evolocumab for non-familial hypercholesterolaemia and heterozygous familial hypercholesterolaemia. The PBAC considered that revised PBS restrictions and financial estimates would also be required to align with the updated cost-minimisation analysis.</p> <p>The PBAC nominated the early re-entry resubmission pathway for inclisiran.</p> <p><u>Sponsor's Comment:</u> Novartis is working with the PBAC to bring Leqvio® to Australians with high-risk cardiovascular disease as soon as possible. Novartis is fully committed to enabling broad access to treatment for Australians with established cardiovascular disease who are not able to reduce LDL-cholesterol to target levels.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">LAROTRECTINIB</p> <p>Oral solution 20 mg per mL, 50 mL, 2</p> <p align="center">Vitrakvi®</p> <p align="center">Bayer Australia Ltd</p> <p>Committee secretariat submission (New PBS listing)</p> <p align="center">WITHDRAWN</p>	<p align="center">Solid tumours harbouring neurotrophic receptor tyrosine kinase (NTRK) gene fusions</p>	<p align="center">To request listing a new form and formulation of oral solution under the existing conditions to replace the currently listed oral solution of larotrectinib.</p>	<p align="center">Not Applicable</p>	<p align="center">This item was withdrawn.</p>
<p align="center">MIFEPRISTONE AND MISOPROSTOL</p> <p>Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms</p> <p align="center">MS-2 Step®</p> <p align="center">MS Health Pty Ltd</p> <p>Category 3 submission (Change to PBS listing)</p>	<p align="center">Termination of an intrauterine pregnancy</p>	<p align="center">To request a change to the restriction level of the existing listing from Authority Required to Authority Required (STREAMLINED) for termination of an intrauterine pregnancy.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended a change to the restriction level of mifepristone and misoprostol (MS-2 Step®) for the termination of intrauterine pregnancy from Authority Required to Authority Required (STREAMLINED). The PBAC considered that there are adequate resources available to prescribers on the safe prescribing of MS-2 Step®. While the PBAC considered that the change in authority level is unlikely to increase utilisation of MS-2 Step®, it considered that any increase in utilisation may signal improved access for those currently experiencing access challenges, such as people in remote communities.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">NATALIZUMAB</p> <p>Injection 150 mg in 1 mL single dose pre-filled syringe</p> <p align="center">Tysabri®</p> <p align="center">Biogen Australia Pty Ltd</p> <p align="center">Category 4 submission (New PBS listing)</p>	<p align="center">Relapsing-remitting multiple sclerosis (RRMS)</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a new form of natalizumab for the treatment of RRMS.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of natalizumab 150 mg in 1 mL pre-filled syringe for subcutaneous (SC) injection under the same circumstances as the PBS-listed natalizumab 300 mg in 15 mL vial for intravenous (IV) infusion. The PBAC advised that the equi-effective doses were natalizumab SC 300 mg once every 4 weeks (Q4W) and natalizumab IV:300 mg Q4W.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">NETUPITANT WITH PALONOSETRON</p> <p>Capsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride)</p> <p style="text-align: center;">Akynzeo®</p> <p style="text-align: center;">Juniper Biologics Pty Ltd</p> <p style="text-align: center;">Category 4 submission (Change to PBS listing)</p>	<p style="text-align: center;">Nausea and vomiting</p>	<p style="text-align: center;">To request a change to the clinical criteria to align restrictions with the National Comprehensive Cancer Network Guidelines for the treatment of nausea and vomiting.</p>	<p>Recommended</p>	<p>The PBAC recommended an amendment to the restriction criteria of netupitant with palonosetron (NEPA), to align with the Therapeutic Goods Administration indication ‘Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly and moderately emetogenic cancer chemotherapy’ rather than referencing specific chemotherapy drugs. The PBAC considered that the change would address unmet clinical need and inequities for patients receiving new chemotherapy regimens that are not covered in the existing clinical criteria. The PBAC noted that the recommended restriction change would have the effect of lowering the cost-effectiveness of the NEPA PBS listing, as it would broaden the restriction and allow more first line use. The PBAC considered a price reduction would be required for NEPA to be acceptably cost-effective in the expanded population. The PBAC noted that uncertainties in the utilisation and financial impact would also be partly mitigated by a price reduction. The PBAC recommended that the changes to the PBS restrictions for NEPA flow-on to the other neurokinin 1 (NK1) inhibitors on the PBS [fosaprepitant (Emend® IV) and aprepitant oral (Aprepitant SCP® and Aprepitant Apotex®)]. The PBAC noted that the Secretariat had received feedback that the NEPA restrictions are unaligned with current clinical practice with regard to multi-day chemotherapy regimens. The PBAC considered that the relevant prescribing instruction could be removed, as it created confusion due to differing definitions of a ‘cycle’ of chemotherapy and was unnecessary as clinicians are familiar with prescribing NK1s for primary and secondary prophylaxis of chemotherapy-induced nausea and vomiting.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">NIRAPARIB Capsule 100 mg Zejula® GlaxoSmithKline Australia Pty Ltd Category 1 submission (Change to PBS listing)</p>	<p align="center">Epithelial ovarian, fallopian tube, or primary peritoneal cancer</p>	<p align="center">To request an expanded General Schedule Authority Required (telephone/online) listing for the treatment of newly diagnosed, homologous recombination deficiency (HRD) positive, BRCA wild type (BRCAwt) advanced (FIGO Stage III-IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.</p>	<p align="center">Deferred</p>	<p>The PBAC deferred making a recommendation regarding niraparib for maintenance therapy in patients with newly diagnosed HRD positive BRCAwt advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. The PBAC noted that the integrated codependent submission sought Medicare Benefits Schedule funding of HRD testing to determine eligibility for niraparib under the proposed PBS listing. The PBAC considered niraparib was superior to standard medical management in terms of progression free survival in the proposed population of patients with HRD positive BRCAwt tumours, though overall survival data were immature. Consistent with previous advice, the PBAC considered that the benefit of niraparib treatment in the HRD-negative subgroup was uncertain and on this basis it was appropriate to require HRD testing to determine PBS eligibility for niraparib. The PBAC considered that the economic model presented was not reliable for decision-making. However, the PBAC considered that niraparib is likely to be non-inferior to olaparib in the HRD positive BRCAwt setting, as previously accepted in the BRCAm setting, and therefore could be recommended on the basis of cost-minimisation versus olaparib in the event that olaparib is listed on the PBS for patients with HRD positive BRCAwt ovarian cancer.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">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 align="center">Opdivo®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p align="center">Category 3 submission (Other matters)</p>	<p align="center">Gastro-oesophageal cancers</p>	<p align="center">To request that first-line oesophageal squamous cell carcinoma (OSCC) patients are included in the financial estimates for the treatment of advanced or metastatic gastro-oesophageal cancers.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended amending the current risk sharing arrangement expenditure caps for nivolumab for the treatment of advanced or metastatic gastro-oesophageal cancers. The PBAC advised that it was supportive of the requested increase to the expenditure caps to account for the expected additional use of nivolumab should the first line treatment of advanced or metastatic OSCC in patients with tumour cell programmed death-ligand 1 expression \geq 1%, either in combination with fluoropyrimidine and platinum-based chemotherapy or in combination with ipilimumab, be included in the approved Australian Product Information for nivolumab.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">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>Bristol-Myers Squibb Australia Pty Ltd</p> <p style="text-align: center;">Category 2 submission (Change to PBS 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) Authority Required (STREAMLINED) listing for the neoadjuvant treatment of resectable NSCLC.</p>	<p style="text-align: center;">Not Recommended</p>	<p>The PBAC did not recommend the Authority Required (STREAMLINED) listing of nivolumab for the neoadjuvant treatment of patients with resectable NSCLC. The PBAC considered that nivolumab provided a moderate clinical benefit with an improvement in event-free survival and immature overall survival data indicated a trend towards improvement. The PBAC considered the incremental cost-effectiveness ratio was highly uncertain given the extent of extrapolation and issues with the model structure and some inputs. The PBAC considered that revised model inputs would be required to address these issues and that a price-reduction would be required for nivolumab to be considered cost-effective in the neoadjuvant NSCLC setting. The PBAC considered that revised financial estimates should account for offsets for current use of immunotherapy, and considered it would be appropriate for nivolumab use to be included in the current risk sharing arrangement in place for immunotherapies for NSCLC.</p> <p>The PBAC nominated the early re-entry resubmission pathway for nivolumab.</p> <p><u>Sponsor's Comment:</u> The Sponsor is committed to working with the PBAC to bring nivolumab for the neoadjuvant treatment of patients with resectable NSCLC to Australian patients in a timely manner.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">OLAPARIB</p> <p style="text-align: center;">Tablet 100 mg Tablet 150 mg</p> <p style="text-align: center;">Lynparza®</p> <p style="text-align: center;">AstraZeneca Pty Ltd</p> <p style="text-align: center;">Category 2 submission (New PBS listing)</p>	<p style="text-align: center;">Breast cancer</p>	<p style="text-align: center;">To request a General Schedule Authority Required (telephone/online) listing for the treatment of human epidermal growth factor 2 (HER2)-negative high risk early breast cancer with a confirmed germline BRCA1 or BRCA2 mutation who have previously been treated with neoadjuvant or adjuvant chemotherapy.</p>	<p style="text-align: center;">Not Recommended</p>	<p>The PBAC did not recommend olaparib for the treatment of HER2- high-risk early breast cancer with a confirmed germline BRCA1 or BRCA2 mutation in patients who have previously been treated with neoadjuvant or adjuvant chemotherapy. The PBAC noted that a statistically significant result for the pre-specified primary endpoint of invasive disease-free survival (IDFS) was reported from the pivotal registration study, but that the IDFS and overall survival data remained immature. Olaparib was inferior to placebo in terms of safety. The PBAC considered that the incremental cost-effectiveness ratio was highly uncertain and unacceptably high. The PBAC considered that revisions were also required to the financial estimates.</p> <p>The PBAC nominated the early re-entry re-submission pathway for this item.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">OSILODROSTAT</p> <p style="text-align: center;">Tablet 1 mg Tablet 5 mg Tablet 10 mg</p> <p style="text-align: center;">Isturisa®</p> <p style="text-align: center;">Recordati Rare Diseases Australia Pty. Ltd.</p> <p style="text-align: center;">Category 1 submission (New PBS listing)</p>	<p style="text-align: center;">Cushing syndrome (CS)</p>	<p style="text-align: center;">To request a General Schedule Authority Required (telephone/online) listing for the treatment of adult patients with endogenous CS who are not candidates for surgery or for whom surgery was not curative.</p>	<p>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 acknowledged the high mortality and the morbidity associated with the disease, and the lack of a PBS listed medicine for this condition. The PBAC considered that, although there was evidence that osilodrostat was effective in the short term and response would likely be maintained for longer periods, the magnitude of the benefit of this therapy and its cost-effectiveness was highly uncertain. The PBAC considered that the economic analysis of incremental cost per extra responder as presented was not informative as it did not capture the costs and value of the long-term use and improvement in quality of life that may result from treatment with osilodrostat.</p> <p><u>Sponsor's Comment:</u> Recordati Rare Diseases is disappointed in the outcome of the PBAC. We look forward to continuing working closely with the PBAC to address their concerns and ensure that patients with endogenous CS can access medical treatment on the PBS for this rare and severe condition.</p>
<p style="text-align: center;">PATIROMER</p> <p style="text-align: center;">Sachet, 8.4 g powder for oral liquid Sachet, 16.8 g powder for oral liquid</p> <p style="text-align: center;">Veltassa®</p> <p style="text-align: center;">Vifor Pharma Pty Limited</p> <p style="text-align: center;">Early re-entry submission (New PBS listing)</p>	<p style="text-align: center;">Hyperkalaemia</p>	<p style="text-align: center;">Resubmission to request a General Schedule Authority Required listing for the treatment of chronic hyperkalaemia in patients with stage 3 or stage 4 chronic kidney disease (CKD).</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of patiromer for the treatment of adult patients with CKD Stage 3-4, with chronic hyperkalaemia (at least two episodes of serum potassium ≥ 6.0 mmol/L in the previous 12 months), who are receiving at least one renin angiotensin aldosterone system inhibitor (RAASi) or are indicated for a RAASi but are unable to tolerate it due to prior occurrence of hyperkalaemia. The PBAC considered that the cost minimisation approach presented was appropriate and the financial impact estimates were reasonable.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL vial</p> <p align="center">Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">Category 1 submission (Change to PBS listing)</p>	<p align="center">Breast cancer</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally recurrent unresectable or metastatic triple negative breast cancer.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of pembrolizumab for the treatment of patients with locally recurrent unresectable or metastatic triple negative breast cancer whose tumours express PD-L1 (CPS ≥ 10). The PBAC noted there is a high clinical need for effective treatment in this patient population, who are typically young and have a poor prognosis. The PBAC is satisfied that pembrolizumab in combination with chemotherapy provides a meaningful improvement in overall survival, compared with standard chemotherapy alone. The PBAC considered that pembrolizumab would be cost-effective at the price proposed in the pre-PBAC response.</p>
<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">Matters outstanding (Change to PBS listing)</p>	<p align="center">Endometrial cancer</p>	<p align="center">To seek the PBAC's advice regarding whether the cost per patient based on the current price offers for pembrolizumab and lenvatinib for the treatment of endometrial cancer is acceptably cost-effective.</p>	<p align="center">Advice Provided</p>	<p>At its March 2022 meeting, the PBAC recommended the listing of pembrolizumab in combination with lenvatinib for the treatment of patients with advanced endometrial cancer who have disease progression following prior systemic therapy regardless of biomarker status.</p> <p>The PBAC noted the sponsors' price offers for pembrolizumab and lenvatinib resulted in an incremental cost-effectiveness ratio (ICER) higher than the basis of its March 2022 recommendation. The PBAC considered that, on balance, the resulting ICER was acceptably cost-effective, noting the high clinical need in this patient population.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL vial</p> <p style="text-align: center;">Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p style="text-align: center;">Category 1 submission (Change to PBS listing)</p>	<p style="text-align: center;">Breast cancer</p>	<p style="text-align: center;">To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of early stage triple negative breast cancer in patients who have not received prior systemic therapy.</p>	<p style="text-align: center;">Not Recommended</p>	<p>The PBAC did not recommend the listing of pembrolizumab, for the treatment of early stage triple negative breast cancer. The PBAC noted there is a high clinical need for effective treatment in this patient population, who are typically young and have a poor prognosis. The PBAC considered that pembrolizumab in combination with chemotherapy provides a meaningful improvement in event free survival, compared with standard chemotherapy alone, however overall survival data were immature. The PBAC advised that inputs to the economic model should be revised to reflect the uncertainty in overall survival, and a price reduction would be required for pembrolizumab to be considered cost effective in the early stage treatment setting.</p> <p>The PBAC nominated the early re-entry resubmission pathway for pembrolizumab.</p> <p><u>Sponsor's Comment:</u> MSD welcomes that the PBAC has acknowledged that there is a high clinical need for effective treatment in this patient population. Treatments for early stage, aggressive cancers such as triple negative breast cancer will have challenges regarding timing and maturity of survival outcomes. MSD is committed to working with the PBAC to expedite availability of pembrolizumab, so patients can get access to treatment without needing to await final overall survival data.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">PEMETREXED</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL vial</p> <p>Solution concentrate for I.V. infusion 500 mg in 20 mL vial</p> <p>Solution concentrate for I.V. infusion 1000 mg in 40 mL vial</p> <p align="center">Pemetrexed EVER Pharma</p> <p align="center">Interpharma Pty Ltd</p> <p align="center">Committee secretariat submission (New PBS listing)</p>	<p align="center">Mesothelioma Locally advanced or metastatic non-small cell lung cancer</p>	<p align="center">To request listing a new form of pemetrexed under the existing conditions as the currently listed pemetrexed powder for I.V. infusion.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy Program) listing of three new forms of pemetrexed (Pemetrexed EVER Pharma) 100 mg/4 mL, 500 mg/20 mL and 1000 mg/40 mL solutions for injection as unrestricted benefits under the same circumstances as the currently listed brands of pemetrexed powder for I.V. infusion.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>PNEUMOCOCCAL CONJUGATE VACCINE, 15 VALENT ADSORBED</p> <p>0.5 mL pre-filled syringe</p> <p>Vaxneuvance®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Category 2 submission (New PBS listing)</p>	<p>Prevention of pneumococcal disease</p>	<p>To request a National Immunisation Program listing for the prevention of pneumococcal disease in paediatrics.</p>	<p>Recommended</p>	<p>The PBAC recommended that 15-valent pneumococcal conjugate vaccine (15vPCV, Vaxneuvance®) 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"> • Non-indigenous infants and Aboriginal and Torres Strait Islander infants living in ACT, NSW, VIC and TAS: 3 doses at ages 2, 4 and 12 months (2+1 doses); • Infants with specified medical risk conditions and Aboriginal and Torres Strait Islander infants living in WA, NT, SA and QLD: 4 doses at ages 2, 4, 6 and 12 months (3+1 doses); • Children and adolescents between 12 months and 18 years newly diagnosed with a specified medical risk condition (1 dose); • Haematopoietic stem cell transplant recipients aged 12 months to <18 years: 3 doses at 6, 8, and 12 months after haematopoietic stem cell transplant (3 doses). <p>The PBAC's recommendation for listing for the existing paediatric populations was based on, among other matters, its assessment that the cost-effectiveness of 15vPCV would be acceptable if it were cost-minimised against the nominated comparator, 13-valent pneumococcal conjugate vaccine.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">RAVULIZUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 3 mL vial Solution concentrate for I.V. infusion 1.1 g in 11 mL vial</p> <p style="text-align: center;">Ultomiris®</p> <p>Alexion Pharmaceuticals Australasia Pty Ltd</p> <p style="text-align: center;">Category 2 submission (Change to PBS listing)</p>	<p style="text-align: center;">Atypical haemolytic uraemic syndrome (aHUS)</p>	<p style="text-align: center;">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of aHUS.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation regarding the PBS listing of ravulizumab for the treatment of aHUS pending resolution of substantial restriction issues, and amendments to the cost-minimisation approach (CMA) and financial estimates. The PBAC noted that the submission's request for PBS funding of ravulizumab for public hospital inpatients was inconsistent with PBS policy. The PBAC also considered that the submission's CMA had several uncertainties which would need to be resolved to ensure the cost of ravulizumab would be no greater than that of eculizumab. The PBAC also considered the estimated linear growth in utilisation over the forward estimates was not justified and that a risk sharing arrangement to cover the overall PBS cost of aHUS therapy with a C5 inhibitor would be required.</p> <p>The PBAC recommended a change to the circumstances under which meningococcal ACWY (MenACWY) and meningococcal B (MenB) vaccines be made available as designated vaccines for the purposes of Section 9B of the <i>National Health Act 1953</i>. The PBAC recommended that certain vaccines should be made available as designated vaccines for patients treated with ravulizumab as well as eculizumab, and noted that this aligned with the Australian Technical Advisory Group on Immunisation's advice.</p> <p><u>Sponsor's Comment:</u> Alexion is committed to working with the PBAC and Department of Health and Aged Care to enable PBS reimbursement of ravulizumab for people with aHUS; an ultra-rare, life-threatening condition.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">RELATLIMAB AND NIVOLUMAB</p> <p>Solution concentrate for I.V. infusion containing 80 mg relatlimab and 240 mg nivolumab in 20 mL vial</p> <p align="center">Opdualag®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p align="center">Standard re-entry submission (New PBS listing)</p>	<p align="center">Melanoma</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable Stage III or Stage IV malignant melanoma.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of relatlimab and nivolumab (RELA+NIVO), a fixed-dose combination treatment, for the treatment of patients with unresectable Stage III or IV malignant melanoma, on the basis that it should be available only under special arrangements under Section 100 (Efficient Funding of Chemotherapy). The PBAC was satisfied the RELA+NIVO was non-inferior in terms of efficacy and safety compared to nivolumab plus ipilimumab (NIVO+IPI) and therefore, recommended RELA+NIVO on a cost-minimisation basis to NIVO+IPI. The PBAC considered that the financial uncertainty relating to the substitution rates of RELA+NIVO for NIVO+IPI and programmed cell death protein (PD-1) inhibitor monotherapies may be mitigated by including RELA+NIVO in the existing PD-1 inhibitor risk sharing arrangement for melanoma.</p>
<p align="center">RIOCIGUAT</p> <p>500 microgram tablet, 84 1 mg tablet, 84 1.5 mg tablet, 84 2 mg tablet, 84 2.5 mg tablet, 84</p> <p align="center">Adempas®</p> <p align="center">Bayer Australia Ltd</p> <p>Category 4 submission (Change to PBS listing)</p> <p align="center">WITHDRAWN</p>	<p align="center">Pulmonary arterial hypertension Chronic thromboembolic pulmonary hypertension</p>	<p align="center">To request a change in pack size from a pack of 84 tablets to a pack of 42 tablets and an increase of maximum quantity and number of repeats for the existing listings of 0.5 mg, 1 mg, 1.5 mg, and 2 mg. The submission also requests an increase to the maximum number of repeats for the existing listings of 2.5 mg (84 pack size).</p>	<p align="center">Not Applicable</p>	<p align="center">This item was withdrawn.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">RISDIPLAM</p> <p>Powder for oral solution 0.75 mg per 1 mL, 80 mL</p> <p style="text-align: center;">Evrysdj®</p> <p style="text-align: center;">Roche Products Pty Ltd</p> <p>Standard re-entry submission (Change to PBS listing)</p>	<p style="text-align: center;">Spinal muscular atrophy (SMA)</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of:</p> <ul style="list-style-type: none"> (i) adults diagnosed with 5q SMA with symptom onset prior to 19 years of age, (ii) patients with confirmed genetic diagnosis of SMA (SMA1 deletion or mutation) who have a Survival Motor Neuron 2 (<i>SMN2</i>) gene copy number of 1 or 2, and (iii) patients with confirmed genetic diagnosis of SMA (SMA1 deletion or mutation) who have a <i>SMN2</i> gene copy number of 3. 	<p>Recommended</p>	<p>The PBAC recommended the listing of risdiplam for adults diagnosed with 5q SMA with symptom onset prior to 19 years of age and no initiation of disease-modifying treatment during childhood (population 1) and patients aged < 36 months with a confirmed genetic diagnosis of SMA (SMA1 deletion or mutation) who have an <i>SMN2</i> gene copy number of 1 or 2 and are pre-symptomatic (population 2) on the basis that it should be available only under special arrangements under Section 100. The PBAC's recommendation for listing in these populations was based on, among other matters, its assessment that the cost-effectiveness of risdiplam would be acceptable if it were cost minimised against nusinersen. The PBAC noted that the sponsor withdrew the request for listing of risdiplam for patients aged < 36 months with a confirmed genetic diagnosis of SMA (SMA1 deletion or mutation) who have a <i>SMN2</i> gene copy number of 3 and are pre-symptomatic.</p>
<p style="text-align: center;">RISEDRONIC ACID</p> <p>Tablet (enteric coated) containing risedronate sodium 35 mg</p> <p style="text-align: center;">Actonel® EC</p> <p style="text-align: center;">THERAMEX AUSTRALIA PTY LTD</p> <p>Matters outstanding (Change to PBS listing)</p>	<p style="text-align: center;">Osteoporosis</p>	<p>To request an expansion of the current risedronate listing to include patients with osteoporosis aged below 70 years of age.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend an amendment to the current age restriction on the PBS listing of risedronic acid (risedronate) for the primary prevention of fracture in patients with a bone mineral density (BMD) T-score of -2.5 or less, on the basis that the Medical Services Advisory Committee (MSAC) Executive advised that resubmission as a codependent application would be required to assess the cost-effectiveness and financial implications of expanded BMD testing on the Medicare Benefits Schedule to support such a listing.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">RISPERIDONE</p> <p>Powder for I.M. injection 75 mg (modified release) with 0.383 mL diluent in pre-filled syringe Powder for I.M. injection 100 mg (modified release) with 0.49 mL diluent in pre-filled syringe</p> <p align="center">Okedi®</p> <p align="center">Maxx Pharma Pty Ltd</p> <p align="center">Category 2 submission (New PBS listing)</p> <p align="center">To be considered at a future PBAC meeting</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">Not Applicable</p>	<p align="center">This item is to be considered at a future PBAC meeting.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">ROMOSUZUMAB</p> <p>Injection 105 mg in 1.17 mL single use pre-filled syringe</p> <p align="center">Evenity®</p> <p align="center">Amgen Australia Pty Limited</p> <p>Standard re-entry submission (Change to PBS listing)</p>	<p align="center">Osteoporosis</p>	<p align="center">Resubmission to request a General Schedule Authority Required (Telephone/electronic) listing for the treatment of severe established osteoporosis.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Authority Required (Telephone/electronic) listing of romosozumab for the treatment of severe osteoporosis in the first-line setting. The PBAC considered the clinical and cost-effectiveness evidence for romosozumab was adequate to support listing in the first-line setting but not an expansion to the current second-line listing. On this basis, the PBAC considered that romosozumab in the first-line setting provides, for some patients a significant improvement in efficacy over alendronate. The PBAC noted that the resubmission had addressed a number of its previous concerns with the economic model, but had not provided an economic analysis for romosozumab in the expanded second-line setting. The PBAC's recommendation for listing was based on, among other matters, its assessment that romosozumab would be cost-effective in the first-line setting if its price was reduced such that the incremental cost-effectiveness ratio was no higher than the revised base case in the July 2022 submission (\$35,000 to < \$45,000 per quality adjusted life year gained) and with a risk sharing arrangement to address the uncertainty associated with the size of the eligible first-line population and also with any residual concerns regarding the cost-effectiveness of romosozumab use in the first-line setting.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">TEBENTAFUSP</p> <p>Solution concentrate for I.V. infusion 100 mcg in 0.5 mL vial</p> <p style="text-align: center;">Kimmtrak®</p> <p style="text-align: center;">Synevi Pty Limited</p> <p>Category 1 submission (New PBS listing)</p>	<p style="text-align: center;">Advanced (unresectable or metastatic) human leukocyte antigen (HLA)-A*02:01-positive uveal melanoma</p>	<p style="text-align: center;">To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (telephone/online) listing for the treatment of HLA-A*02:01-positive adult patients with advanced (unresectable or metastatic) uveal melanoma.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend tebentafusp for the treatment of HLA-A*02:01-positive adult patients with advanced (unresectable or metastatic) uveal melanoma. The PBAC noted the unmet clinical need for new treatments in this setting and considered that tebentafusp was superior in terms of efficacy compared to pembrolizumab, but likely inferior in term of safety. The PBAC noted that there were uncertainties associated with the economic model and considered that these could be mitigated by reducing the time horizon applied and adjusting the utility values. The PBAC considered that a price reduction would be required for tebentafusp to be cost effective. The PBAC considered that the utilisation estimates for tebentafusp were reasonable.</p> <p>The PBAC nominated the early resolution resubmission pathway for tebentafusp.</p> <p><u>Sponsor's Comment:</u> SYNEVi on behalf of Immunocore and Medison is disappointed with the outcome but will continue working with the PBAC so that patients with advanced uveal melanoma will be able to access tebentafusp on the PBS.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">TICAGRELOR</p> <p style="text-align: center;">Tablet, 90 mg</p> <p style="text-align: center;">Brilinta®</p> <p style="text-align: center;">AstraZeneca Pty Ltd</p> <p style="text-align: center;">Category 3 submission (Change to PBS listing)</p>	<p style="text-align: center;">Acute coronary syndrome (ACS)</p>	<p style="text-align: center;">To request a change to the restriction level of the existing listing from Authority Required (STREAMLINED) to an unrestricted benefit.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend a change to the restriction level of ticagrelor for the treatment of ACS from Authority Required (STREAMLINED) to Unrestricted Benefit or Restricted Benefit to align with the recent change in restriction level of clopidogrel for the treatment of ACS. The PBAC considered that the submission's claim of nil financial impact to the Commonwealth was unreasonable given that ticagrelor may substitute for the less costly clopidogrel. The PBAC considered that the submission's nominated comparator, ticagrelor, was inappropriate, and that clopidogrel was the only relevant comparator.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">TILDRAKIZUMAB</p> <p>Injection 100 mg in 1 mL single dose pre-filled syringe</p> <p style="text-align: center;">Ilumya®</p> <p style="text-align: center;">Sun Pharma ANZ Pty Ltd</p> <p>Category 3 submission (Change to PBS listing)</p>	<p style="text-align: center;">Severe chronic plaque psoriasis (CPP)</p>	<p style="text-align: center;">To request adding a grandfathering restriction to allow eligible patients enrolled in two tildrakizumab clinical trials to transition to PBS-subsidised tildrakizumab after completing the clinical trials.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend adding a new grandfathering restriction to the existing PBS listing for tildrakizumab injection 100 mg in 1 mL single dose pre-filled syringe (Ilumya®) for the treatment of severe CPP for patients enrolled in two new clinical trials. The PBAC noted that an inclusion criterion for the two new clinical trials was a Psoriasis Area and Severity Index (PASI) score >12. While this was consistent with inclusion criteria for the clinical trials presented in the original submission for tildrakizumab considered by the PBAC in July 2018, it differed from the current PBS clinical criteria for initial treatment with tildrakizumab, which states that the condition must have a PASI score >15. The PBAC therefore considered that it was uncertain whether the patients in the clinical trials would have been eligible for treatment with tildrakizumab through the PBS prior to starting the trials.</p> <p>The PBAC noted that the intent of a grandfathering restriction is to allow access to subsidised treatment for eligible patients who start therapy before the requested PBS-listing is implemented. The PBAC considered that patients who start therapy as part of clinical trials that commence after the medicine has been PBS listed are not 'grandfathered' patients.</p> <p><u>Sponsor's Comment:</u> Sun Pharma is disappointed with the PBAC outcome.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">TOFACITINIB</p> <p style="text-align: center;">Tablet 5 mg</p> <p style="text-align: center;">Xeljanz®</p> <p style="text-align: center;">Pfizer Australia Pty Ltd</p> <p style="text-align: center;">Category 2 submission (Change to PBS listing)</p>	<p style="text-align: center;">Ankylosing spondylitis</p>	<p style="text-align: center;">To request a General Schedule Authority Required (Written) listing for the treatment of ankylosing spondylitis (AS).</p>	<p>Recommended</p>	<p>The PBAC recommended the General Schedule listing of tofacitinib (TOF) for the treatment of AS. The PBAC's recommendation was based on, among other matters, its assessment the cost-effectiveness of TOF would be acceptable if it were cost minimised to the least costly alternative therapy of adalimumab, etanercept, infliximab, golimumab, certolizumab pegol, ixekizumab, secukinumab and upadacitinib.</p> <p>The PBAC recommended flow-on changes to other AS listings to include TOF in the list of eligible therapies.</p>
<p style="text-align: center;">TOFACITINIB</p> <p style="text-align: center;">Tablet 5 mg Oral liquid 1 mg per mL, 240 mL</p> <p style="text-align: center;">Xeljanz®</p> <p style="text-align: center;">Pfizer Australia Pty Ltd</p> <p style="text-align: center;">Category 2 submission (New PBS listing)</p>	<p style="text-align: center;">Juvenile idiopathic arthritis</p>	<p style="text-align: center;">To request a General Schedule Authority Required (Written) listing for the treatment of severe active juvenile idiopathic arthritis (JIA).</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of tofacitinib (TOF) for the treatment of severe active JIA. The PBAC's recommendation was based on, among other matters, its assessment the cost-effectiveness of TOF would be acceptable if it were cost minimised to the least costly alternative therapy of adalimumab, etanercept and tocilizumab.</p> <p>The PBAC considered there was an unmet need for non-injectable treatment options for JIA and that an oral therapy would be likely to reduce the stress and anxiety associated with JIA treatment for patients and families with an aversion to injections.</p> <p>The PBAC recommended flow-on changes to other JIA listings to include TOF in the list of eligible therapies.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">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">Matters outstanding (New PBS listing)</p>	<p align="center">Breast Cancer</p>	<p>A resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Written) listing for the treatment of human epidermal growth factor receptor 2 positive (HER2) metastatic breast cancer in patients whose disease has progressed following treatment with at least one prior HER2-directed regimen in the metastatic setting or whose disease has progressed during or within 6 months following HER2-directed adjuvant treatment.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the listing of trastuzumab deruxtecan (T-DXd) for the treatment of HER2 positive breast cancer for patients who have progressed following up to two prior lines of HER2 directed therapy for metastatic disease, or relapsed during or within 6 months of receiving HER2 directed adjuvant therapy. The PBAC noted that the that Authority Required (telephone/online) listing should be available under the Section 100 (Efficient Funding of Chemotherapy) schedule. The PBAC was satisfied that T-DXd provides, for some patients, a substantial clinical benefit over trastuzumab emtansine that is likely to translate into clinically meaningful gains in overall survival, and that T-DXd offers high added therapeutic value compared to the treatment options currently available. The PBAC’s recommendation for listing was based on, among other matters, its assessment that the cost effectiveness of T-DXd would be acceptable using the economic model and price proposal in the March 2023 resubmission, with an adjustment to incorporate the cost-effective price of trastuzumab emtansine as managed through a risk sharing arrangement (RSA). The PBAC considered that a RSA would be necessary for T-DXd to address uncertainty associated with the proposed PBS population including the potential for use in a broader patient population where the use may not be cost-effective.</p> <p>In the context of T-DXd effectiveness, cost effectiveness and patient numbers being highly uncertain for those who have received more than two prior lines of HER2 directed therapy, the PBAC deferred its decision regarding the inclusion of these patients in its recommendation to seek further information on the likely size of this population and corresponding appropriate RSA parameters.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">UPADACITINIB</p> <p align="center">Tablet 15 mg</p> <p align="center">Rinvoq®</p> <p align="center">ABBVIE PTY LTD</p> <p align="center">Matters outstanding (Change to 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 General Schedule, Authority Required listing of upadacitinib (UPA) for the treatment of nr-axSpA on a cost minimisation basis with the least costly alternative biologic or targeted synthetic disease modifying anti-rheumatic drug (bDMARD/tsDMARD). The PBAC considered the claim of non-inferior comparative effectiveness and safety to the alternative treatments, including ixekizumab, golimumab, secukinumab and certolizumab pegol was adequately supported. The PBAC's recommendation was therefore, among other matters, based on its assessment that the cost of UPA should be no greater than the cost of the alternative therapies over two years.</p> <p>The PBAC recommended flow-on changes to other bDMARD/tsDMARD listings in nr-axSpA to include UPA in the list of eligible treatments in a treatment cycle.</p>
<p align="center">UPADACITINIB</p> <p align="center">Tablet 15 mg Tablet 30 mg Tablet 45 mg</p> <p align="center">Rinvoq®</p> <p align="center">Abbvie Pty Ltd</p> <p align="center">Category 2 submission (Change to PBS listing)</p> <p align="center">To be considered at a future PBAC meeting</p>	<p align="center">Crohn disease</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of severe Crohn disease.</p>	<p align="center">Not Applicable</p>	<p align="center">This item is to be considered at a future PBAC meeting.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">URSODEOXYCHOLIC ACID</p> <p align="center">Capsule 250 mg Tablet 500 mg</p> <p align="center">Ursofalk®</p> <p align="center">Dr Falk Pharma Australia Pty Ltd</p> <p align="center">Category 4 submission (Change to PBS listing)</p>	<p align="center">Primary biliary cholangitis</p>	<p align="center">To request an increase to the number of repeats for the treatment of primary biliary cholangitis.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended an increase to the maximum number of repeats for the PBS listings of ursodeoxycholic acid 250 mg capsule and 500 mg tablet forms from 2 repeats to 4 repeats. The PBAC noted this would provide, for most patients, up to at least 6 months' supply per prescription. This is expected to assist in improving patient access and reducing administrative burden for patients and prescribers.</p> <p>The PBAC recommended flow-on changes to all brands of ursodeoxycholic acid currently listed on the PBS.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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;">VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE</p> <p>Injection [1 vial] & adjuvant substance diluent [0.5 mL vial]</p> <p style="text-align: center;">Shingrix®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p style="text-align: center;">Standard re-entry submission (New PBS listing)</p>	<p style="text-align: center;">Prevention of herpes zoster and post-herpetic neuralgia</p>	<p>Resubmission to request a National Immunisation Program listing for the prevention of herpes zoster (HZ) and post-herpetic neuralgia in:</p> <ul style="list-style-type: none"> • adults 65 years of age with ongoing catch-up for adults over 65 years of age. • Aboriginal and Torres Strait Islander adults 50 years of age with ongoing catch-up for adults over 50 years of age. 	<p>Recommended</p>	<p>The PBAC recommended that varicella virus recombinant vaccine (RZV, Shingrix®) be a designated vaccine for the purposes of the <i>National Health Act 1953</i>, for the prevention of HZ and post-herpetic neuralgia. The PBAC considered the range of incremental cost effectiveness ratios presented in the resubmission were acceptable at the price requested in the resubmission for non-Indigenous individuals aged 70 years, Aboriginal and Torres Strait Islander individuals aged ≥ 50 years and immunocompromised individuals aged ≥ 18 years with conditions at ‘high risk’ of HZ infection [as advised by Australian Technical Advisory Group on Immunisation (ATAGI)]. These conditions include haemopoietic stem cell transplant, solid organ transplant, haematological malignancy and advanced or untreated HIV.</p> <p>The PBAC deferred a decision for the broader population of immunocompromised individuals aged ≥ 18 years at increased risk of HZ infection to seek further ATAGI advice on the appropriate definition of this population. The PBAC considered there was likely to be a broader population of immunocompromised individuals aged ≥ 18 years at increased risk of HZ for whom RVZ was cost effective, but this population had not yet been clearly defined.</p> <p>The PBAC did not recommend RZV for non-Indigenous individuals aged 65 to 69 years and individuals aged ≥ 71 years. The PBAC noted that these populations were of lower clinical priority and represented a high volume of doses. In the context of the total cost, the PBAC considered the extent of uncertainty regarding the cost-effectiveness of RZV in these populations to be too high.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">ZANUBRUTINIB</p> <p align="center">Capsule 80 mg</p> <p align="center">Brukinsa®</p> <p align="center">Beigene Aus Pty Ltd</p> <p align="center">Category 2 submission (Change to PBS listing)</p>	<p align="center">Chronic lymphocytic leukaemia (CLL)/Small lymphocytic leukaemia (SLL)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Streamlined) listing for the treatment of treatment naive CLL/SLL.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended extending the listing of zanubrutinib to include treatment naive CLL or SLL. The PBAC considered that the clinical claims of non-inferior effectiveness and safety to venetoclax plus obinutuzumab were reasonably supported, but with some uncertainty given the indirect treatment comparisons presented, and the immaturity of the clinical data. The PBAC’s recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of zanubrutinib would be acceptable if it were cost-minimised to venetoclax plus obinutuzumab.</p> <p>The PBAC recommended flow-on changes to the restriction criteria for other therapies for CLL/SLL would be required to incorporate the International Workshop on CLL guidance in relation to when to prescribe drug treatment.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>ZANUBRUTINIB</p> <p>Capsule 80 mg</p> <p>Brukinsa®</p> <p>Beigene Aus Pty Ltd</p> <p>Category 2 submission (Change to PBS listing)</p>	<p>Chronic lymphocytic leukaemia (CLL)/Small lymphocytic leukaemia (SLL)</p>	<p>To request a General Schedule Authority Required (Telephone/Streamlined) listing for the treatment of relapsed or refractory CLL/SLL considered unsuitable for treatment or retreatment with a purine analogue.</p>	<p>Recommended</p>	<p>The PBAC recommended an Authority Required (Telephone/Online) listing for zanubrutinib for relapsed or refractory CLL or SLL. The PBAC considered that the clinical claims of non-inferior efficacy and safety to ibrutinib were reasonably supported. The PBAC considered that the clinical claims of non-inferior efficacy and safety to acalabrutinib were also reasonably supported, but with some uncertainty given the indirect treatment comparisons presented. The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of zanubrutinib would be acceptable if it were cost-minimised to the least costly alternative of ibrutinib and acalabrutinib. The PBAC noted that in order for the cost per patient for zanubrutinib in relapsed/refractory disease to be equivalent to that for the alternative therapies it would be appropriate for zanubrutinib to join the current risk sharing arrangement in place for relapsed/refractory CLL/SLL.</p> <p>The PBAC recommended flow-on changes to the restriction criteria for other therapies for CLL/SLL would be required to incorporate the International Workshop on CLL guidance in relation to when to prescribe drug treatment.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">ARIPIPIRAZOLE</p> <p>Powder for injection 400 mg (as monohydrate) with diluent pre-filled dual chamber syringe</p> <p align="center">Abilify Maintena®</p> <p align="center">Lundbeck Australia Pty Ltd</p>	<p align="center">Schizophrenia</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC advised that the July 2018 recommendation could be revoked, noting that another form of the product was available on the PBS.</p>
<p align="center">AVELUMAB</p> <p>Solution concentrate for I.V. infusion 200 mg in 10 mL</p> <p align="center">Bavencio®</p> <p align="center">Merck Healthcare Pty Ltd</p>	<p align="center">Stage IV clear cell variant renal cell carcinoma</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC advised that the March 2021 recommendation be extended for 12 months (if listing process has not commenced by the end of February 2024 the sponsor will be asked to justify the recommendation again).</p>
<p align="center">IBRUTINIB</p> <p align="center">Capsule 140 mg</p> <p align="center">Imbruvica®</p> <p align="center">Janssen-Cilag Pty Ltd</p>	<p align="center">Chronic lymphocytic leukaemia (CLL)/ Small lymphocytic leukaemia (SLL)</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC advised that the March 2021 recommendation be extended for 12 months (if listing process has not commenced by the end of February 2024 the sponsor will be asked to justify the recommendation again).</p>
<p align="center">MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE</p> <p align="center">Injection 0.5 mL</p> <p align="center">MenQuadfi®</p> <p align="center">Sanofi-Aventis Australia Pty Ltd</p>	<p align="center">Prevention of meningococcal disease</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC advised that the March 2021 recommendation be extended for 12 months (if listing process has not commenced by the end of February 2024 the sponsor will be asked to justify the recommendation again).</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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">PANCREATIC EXTRACT</p> <p align="center">Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity</p> <p align="center">Creon®</p> <p align="center">Mylan Health Pty Ltd</p>	<p align="center">Cystic fibrosis and unrestricted benefit</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">The PBAC advised that the March 2021 recommendation be extended for 12 months (if listing process has not commenced by the end of February 2024 the sponsor will be asked to justify the recommendation again).</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>PBS Restrictions for Type 2 diabetes mellitus medicines</p> <p>PIOGLITAZONE DULAGLUTIDE SEMAGLUTIDE ERTUGLIFLOZIN EMPAGLIFLOZIN DAPAGLIFLOZIN SITAGLIPFLOZIN ALOGLIPTIN SAXAGLIPTIN SITAGLIPTIN LINAGLIPTIN VILDAGLIPTIN</p>	<p>Type 2 diabetes mellitus (T2DM) medicines</p>	<p>To review the PBS restrictions for T2DM medicines following the DUSC analysis considered by the PBAC in November 2022.</p>	<p>The PBAC recommended changes to the restrictions for dipeptidyl peptidase 4 (DPP4) inhibitors and sodium-glucose cotransporter 2 (SGLT2) inhibitors to reduce complexity. For DPP4 inhibitors, SGLT2 inhibitors and glucagon-like peptide-1 receptor agonists (GLP-1 RAs), the PBAC recommended removal of the requirement for contraindication or intolerance to metformin for patients to use these medicines in dual therapy with insulin.</p> <p>Regarding the November 2022 recommendation for a 15% price reduction to DPP4 and SGLT2 inhibitors, the PBAC recommended that the 15% price reduction should not apply to sitagliptin brands, as these brands had recently taken a 25% price reduction and were now subject to price disclosure. The PBAC recommended that if the 15% price reduction to SGLT2 inhibitors was implemented, then the outstanding March 2022 PBAC recommendation to expand the restrictions of dapagliflozin and empagliflozin to include dual therapy with metformin in patients with high cardiovascular risk without a glycaemic requirement, could be implemented without further price reductions or a financial cap.</p> <p>The PBAC recommended that the authority type for GLP-1 RAs, for therapy initiation for all indications, be changed from Authority Required (STREAMLINED) to Authority Required (telephone/electronic), but that continuing access should be via a streamlined authority. In making this recommendation, the PBAC considered the high use of GLP-1 RAs outside of the PBS restrictions, their high cost versus comparator treatments, and the administrative burden on prescribers associated with telephone/electronic authorities. The PBAC further recommended that the use of GLP-1 RAs in all T2DM indications should be restricted to patients who are contraindicated, intolerant or inadequately responsive to SGLT2 inhibitors. The PBAC noted that both SGLT2 inhibitors and GLP-1 RAs were PBS-listed based on a series of non-inferiority comparisons originating from insulin. The PBAC considered that the price reduction to SGLT2 inhibitors in 2015 meant that SGLT2 inhibitors were now more cost-effective than GLP-1 RAs.</p> <p>The PBAC recommended that relevant clinical groups be consulted on the proposed T2DM medicines restriction wording prior to implementation to ensure the restrictions are simple and clear and that the Department pursue quality use of medicines educational activities on the restrictions in concert with implementation. The PBAC recommended that the effectiveness of the restriction changes and compliance with the restrictions be investigated as part of future DUSC utilisation reviews.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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>Correspondence from Medical Services Advisory Committee (MSAC):</p> <p>Request for review of PBS restrictions regarding measurable residual disease testing in patients with acute lymphoblastic leukaemia</p> <p>BLINATUMOMAB</p>	<p>Drugs for the treatment of acute lymphoblastic leukaemia (ALL)</p>	<p>Residual disease testing in patients with ALL</p>	<p>The PBAC recommended amending the current PBS restrictions for blinatumomab in relation to the detection of measurable residual disease (MRD) in patients with ALL to align with the MRD testing methods supported for public funding by the Medical Services Advisory Committee (MSAC). The PBAC considered that it would be appropriate to make the following changes to the blinatumomab PBS listings: (i) remove the MRD threshold ($\geq 10^{-4}$ blasts) to allow use of testing methods with a higher sensitivity for MRD detection, (ii) include a wider range of MRD testing methodologies by replacing the term 'polymerase chain reaction' with 'molecular methods, and (iii) replace 'minimal residual disease' with the currently accepted term 'measurable residual disease'.</p>

Version 3

Amendment

1. VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE (Shingrix®)– Web outcome updated

Previous amendments

- 1.DOSTARLIMAB (Jemperli®) – Outcome added
- 2.PEMBROLIZUMAB (Keytruda®) – Outcome added

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MARCH 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
MARCH 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 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 High Added Therapeutic Value (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>