

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
JULY 2021 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>ACALABRUTINIB</p> <p>Capsule 100 mg</p> <p>Calquence®</p> <p>Astrazeneca Pty Ltd</p> <p>Category 1 submission (Change to listing)</p>	<p>Relapsed and/or refractory mantle cell lymphoma (R/R MCL)</p>	<p>To request a General Schedule, Authority Required (online/telephone) listing for the treatment of patients with R/R MCL who have received at least one prior therapy or who have developed an intolerance to another Bruton's tyrosine kinase (BTK).</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of acalabrutinib for the treatment of patients with R/R MCL who have received at least one prior therapy and have a WHO performance status of 0 or 1. The PBAC considered that acalabrutinib should be available to BTK inhibitor-naïve patients or patients who have developed an intolerance to another BTK inhibitor necessitating permanent treatment withdrawal.</p> <p>The PBAC noted that the comparison between acalabrutinib and ibrutinib using single arm data was uncertain but was satisfied the efficacy and safety analyses were consistent with non-inferiority. The PBAC considered the cost effectiveness of acalabrutinib would be acceptable if it was cost minimised against ibrutinib.</p>
<p>ADALIMUMAB</p> <p>Injection 20 mg in 0.4 mL pre-filled syringe</p> <p>Injection 40 mg in 0.8 mL pre-filled syringe</p> <p>Injection 40 mg in 0.8 mL pre-filled pen</p> <p>Abrilada®</p> <p>Pfizer Australia Pty Ltd</p> <p>Category 3 submission (Change to listing)</p>	<p>Crohn disease; Ulcerative colitis; Juvenile idiopathic arthritis; Rheumatoid arthritis; Psoriatic arthritis; Ankylosing spondylitis; Plaque psoriasis; Hidradenitis suppurativa</p>	<p>To request both General Schedule and Section 100 (Highly Specialised Drug Program) listing of adalimumab biosimilar under the same conditions as its reference biologic.</p>	<p>Recommended</p>	<p>The PBAC recommended the Authority Required listing of adalimumab (Abrilada) in the form of 20 mg in 0.4 mL pre-filled syringe (PFS), 40 mg in 0.8 mL PFS and 40 mg in 0.8 mL pre-filled pen (PFP), for the same indications as the reference brand Humira, on the basis of cost-minimisation to Humira for the requested indications. The PBAC advised that, under Section 101(4AACD) of the National Health Act 1953, in the Schedule of Pharmaceutical Benefits, Abrilada, Amgevita, Hadlima, Hyrimoz, Humira and Idacio PFS should be treated as equivalent to each other; and Abrilada, Amgevita, Hadlima, Hyrimoz, Humira and Idacio PFP should be treated as equivalent to each other for the purpose of substitution, for respective PBS-listed indications (i.e. 'a' flagged in Schedule with a NOTE stating PBS of one form and PBS of another form are equivalent for the purpose of substitution).</p> <p>The PBAC advised that the biosimilar uptake drivers should be applied to Abrilada, consistent with previous recommendations regarding the application of the drivers to other biosimilar brands of adalimumab</p>

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<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE</p> <p>Sachets containing oral powder 25 g, 30</p> <p>HCU express 15®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Committee Secretariat submission (Change to listing)</p>	<p>Pyridoxine non-responsive homocystinuria</p>	<p>To request HCU Express 15 with new formulation continue to be listed on the PBS under existing conditions.</p>	<p>Recommended</p>	<p>The PBAC recommended continuing the Restricted Benefits listings of HCU Express 15 with new formulation. The PBAC considered the new formulation was safe and would continue to meet the Australian adequate intake levels and recommended dietary intake values of patients eligible for PBS subsidised use.</p>
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE</p> <p>Sachets containing oral powder 34 g, 30</p> <p>PKU express 20®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Committee Secretariat submission (Change to listing)</p>	<p>Phenylketonuria</p>	<p>To request PKU Express 20 with new formulation continue to be listed on the PBS under existing conditions.</p>	<p>Recommended</p>	<p>The PBAC recommended continuing the Restricted Benefits listings of PKU Express 20 with new formulation. The PBAC considered the new formulation was safe and would continue to meet the Australian adequate intake levels and recommended dietary intake values of patients eligible for PBS subsidised use.</p>

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<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE</p> <p>Sachets containing oral powder 25 g, 30</p> <p>PKU express 15®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Committee Secretariat submission (Change to listing)</p>	<p>Phenylketonuria</p>	<p>To request PKU Express 15 with new formulation continue to be listed on the PBS under existing conditions.</p>	<p>Recommended</p>	<p>The PBAC recommended continuing the Restricted Benefits listings of PKU Express 15 with new formulation. The PBAC considered the new formulation was safe and would continue to meet the Australian adequate intake levels and recommended dietary intake values of patients eligible for PBS subsidised use.</p>
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE</p> <p>Sachets containing oral powder 25 g, 30</p> <p>TYR express 15®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Committee Secretariat submission (Change to listing)</p>	<p>Tyrosinaemia</p>	<p>To request TYR Express 15 with new formulation continue to be listed on the PBS under existing conditions.</p>	<p>Recommended</p>	<p>The PBAC recommended continuing the Restricted Benefits listings of PKU Express 15 with new formulation. The PBAC considered the new formulation was safe and would continue to meet the Australian adequate intake levels and recommended dietary intake values of patients eligible for PBS subsidised use.</p>

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<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE</p> <p>Sachets containing oral powder 25 g, 30</p> <p>MSUD Express 15®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Committee Secretariat submission (Change to listing)</p>	<p>Maple syrup urine disease</p>	<p>To request MSUD Express 15 with new formulation continue to be listed on the PBS under existing conditions.</p>	<p>Recommended</p>	<p>The PBAC recommended continuing the Restricted Benefits listings of TYR Express 15 with new formulation. The PBAC considered the new formulation was safe and would continue to meet the Australian adequate intake levels and recommended dietary intake values of patients eligible for PBS subsidised use.</p>
<p>BARICITINIB</p> <p>Tablet 2 mg Tablet 4 mg</p> <p>Olumiant®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>Category 2 submission (Change to listing)</p>	<p>Severe atopic dermatitis (AD)</p>	<p>To request a General Schedule, Authority Required (written) listing for the treatment of patients with severe AD.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of baricitinib for the treatment of adults with severe AD. Whilst the PBAC accepted that the claim of inferior efficacy of baricitinib compared to dupilumab was reasonable, the magnitude of difference in response was uncertain. The PBAC also considered that the safety profile for baricitinib is inferior to dupilumab and noted concerns remain regarding the long-term safety of baricitinib. As such the PBAC considered that the clinical place of baricitinib was unclear. Given the uncertainty in the clinical data and because the cost comparison presented in the submission did not capture the full cost and consequences of listing baricitinib on the PBS, the PBAC considered that the economic analysis was not reliable for decision-making.</p> <p><u>Sponsor's Comment:</u> Lilly is disappointed Olumiant was not recommended for patients with severe atopic dermatitis. We will work to address unresolved differences in the interpretation of the data for this medicine which is already used widely and with consistent, long-term safety in Australia and many jurisdictions across the world, including in atopic dermatitis.</p>

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<p>BORTEZOMIB</p> <p>Powder for injection 2.5 mg</p> <p>Bortezomib Juno®</p> <p>Juno Pharmaceuticals Pty Ltd</p> <p>Committee Secretariat submission (Change to listing)</p>	<p>Multiple Myeloma</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) listing of a new bortezomib brand with an additional strength under the same conditions as the currently listed brand.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of a new vial size of 2.5 mg of bortezomib as a Section 100 Efficient Funding of Chemotherapy program benefit under the existing circumstances of use applying to bortezomib powder for injection 1 mg, 3 mg and 3.5 mg.</p>
<p>BORTEZOMIB</p> <p>Powder for injection 1 mg</p> <p>Powder for injection 2.5 mg</p> <p>Powder for injection 3 mg</p> <p>Powder for injection 3.5 mg</p> <p>DBL Bortezomib®</p> <p>Pfizer Australia Pty Ltd</p> <p>Committee Secretariat submission (Change to listing)</p>	<p>Multiple Myeloma</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) listing of a new bortezomib brand with an additional strength under the same conditions as the currently listed brand.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of a new vial size of bortezomib 2.5 mg (DBL Bortezomib) under Section 100 (Efficient Funding of Chemotherapy) for the treatment of patients with multiple myeloma under the same circumstances as currently listed forms of bortezomib.</p>

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<p>BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL</p> <p>Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 7.2 micrograms (as bromide) and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses</p> <p>Breztri Aerosphere®</p> <p>Astrazeneca Pty Ltd</p> <p>Category 2 submission (New listing)</p>	<p>Moderate to severe chronic obstructive pulmonary disease (COPD)</p>	<p>To request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of moderate to severe COPD.</p>	<p>Recommended</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of the fixed dose combination (FDC) of budesonide (BUD) with glycopyrronium (GLY) and formoterol (FOR), for maintenance treatment of moderate to severe COPD that is not adequately treated by a combination of an inhaled corticosteroid (ICS) with long-acting beta2-agonist (LABA) or LABA with a long-acting muscarinic antagonist (LAMA).</p> <p>The PBAC considered that the claim of non-inferior effectiveness and safety to the FDC of fluticasone furoate (FF), umeclidinium (UMEC) and vilanterol (VIL), was reasonable. However, the PBAC considered for the purposes of satisfying Section 101(3B) of the <i>National Health Act 1953</i>, FF/UMEC/VIL, BEC/GLY/FOR as well as any triple combination therapy via concomitant use of a LAMA, LABA and ICS are relevant alternative therapies. The PBAC's recommendation was therefore, among other matters, based on its assessment that the cost of BUD/GLY/FOR should be no greater than the lowest price combination of the PBS listed components of the triple therapy that are available for COPD.</p> <p>The PBAC accepted the following equi-effective doses as the basis for the cost-minimisation analysis: BUD/GLY/FOR (160/7.2/4.8 mcg) two inhalations twice daily = FF/UMEC/VI (100/62.5/25 mcg) one inhalation once daily = BEC/GLY/FOR 100mcg/6mcg/10mcg two inhalations twice daily.</p>

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<p>DAPAGLIFLOZIN Tablet 10 mg Forxiga® AstraZeneca Pty Ltd Category 1 submission (Change to listing)</p>	<p>Chronic kidney disease (CKD)</p>	<p>To request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of CKD.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation for dapagliflozin for the treatment of patients with CKD. The PBAC is satisfied that dapagliflozin added to standard care provides, for some patients, a significant improvement in efficacy over standard care alone. The PBAC considered that the listing would be cost effective at the price proposed in the pre-PBAC response and it was therefore of a mind to recommend a General Schedule Authority Required (STREAMLINED) listing. However, the PBAC remained concerned about the uncertainty of the estimated financial impact, particularly in the context of a high R/PBS impact.</p> <p>The PBAC noted that the proposed population was broader than the DAPA-CKD trial population, and considered that the PBS listing would need to be restricted to those in whom clinical effectiveness had been established and for whom there was no alternative therapy available. The PBAC also noted that although the resubmission had presented additional information to estimate the overall net impact of listing for both CKD and heart failure with reduced ejection fraction (HFrEF) (see agenda item 7.01, July 2021 PBAC meeting), it had not provided estimates for total dapagliflozin PBS utilisation including type 2 diabetes mellitus. The PBAC considered that these estimates were necessary to inform its advice to the Australian Government about an appropriate risk sharing arrangement to ensure that the subsidy of dapagliflozin is restricted to the populations in whom PBAC has considered it cost effective. The PBAC therefore requested that the Department obtain these estimates from the sponsor before it reconsiders this submission for CKD (and the resubmission for HFrEF).</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

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<p>DAPAGLIFLOZIN</p> <p>Tablet 10 mg</p> <p>Forxiga®</p> <p>AstraZeneca Pty Ltd</p> <p>Standard Re-entry resubmission (Change to listing)</p>	<p>Heart failure</p>	<p>Resubmission to request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of heart failure with reduced ejection fraction.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation for dapagliflozin for the treatment of patients with chronic heart failure with reduced ejection fraction (HFrEF). The PBAC is satisfied that dapagliflozin added to standard care provides, for some patients, a significant improvement in efficacy over standard care alone. The PBAC considered that the listing would be cost effective at the price proposed in the pre-PBAC response, and it was therefore of a mind to recommend a General Schedule Authority Required (Streamlined) listing. However, the PBAC remained concerned about the risk of use outside the proposed PBS restriction (and noted similar concerns for the chronic kidney disease (CKD) listing, which it was also inclined to recommend) (see agenda item 6.03, July 2021 PBAC meeting).</p> <p>The PBAC noted that although the resubmission had presented additional information to estimate the overall net impact of listing for both HFrEF and CKD, it had not provided estimates for total dapagliflozin PBS utilisation including type 2 diabetes mellitus. The PBAC considered that these estimates were necessary to inform its advice to the Australian Government about an appropriate risk sharing arrangement to ensure that the subsidy of dapagliflozin is restricted to the populations in whom PBAC has considered it cost effective. The PBAC therefore requested that the Department obtain these estimates from the sponsor before it reconsiders this resubmission for HFrEF (and the submission for CKD).</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p>DARATUMUMAB</p> <p>Solution for subcutaneous injection 1,800 mg in 15 mL vial</p> <p>Darzalex®</p> <p>Janssen-Cilag Pty Ltd</p> <p>Category 2 submission (Change to listing)</p>	<p>Relapsed and/or refractory multiple myeloma (RRMM)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program), Authority Required (online/telephone) listing of a new 1,800 mg subcutaneous flat dosing regimen in addition to the current 16 mg/kg intravenous weight-based dosing regimen for the treatment of RRMM.</p>	<p>Recommended</p>	<p>The PBAC recommended the dual General Schedule and Section 100 (Efficient Funding of Chemotherapy – Related Benefits), Authority Required listings of a flat 1,800 mg subcutaneously (SC) delivered form of daratumumab for all indications for which the intravenous (IV) form of daratumumab is currently listed. The PBAC advised the listing of the SC form should be on a cost minimisation basis with the IV formulation of daratumumab.</p>

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<p>DAROLUTAMIDE</p> <p>Tablet 300 mg</p> <p>Nubeqa®</p> <p>Bayer Australia Limited</p> <p>Early Re-entry resubmission (New listing)</p>	<p>Castration resistant carcinoma of the prostate</p>	<p>Resubmission to request an Authority Required (telephone) listing for the treatment of castration resistant carcinoma of the prostate.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of darolutamide for the treatment of patients with non-metastatic castration resistant prostate cancer (m0CRPC). The PBAC was satisfied that darolutamide provides, for some patients, a moderate overall survival benefit compared to standard of care (SOC). The PBAC considered that at the updated proposed price, the revised economic model resulted in an incremental cost effectiveness ratio of darolutamide versus SOC in the m0CRPC setting which was cost-effective. The PBAC also considered that the revised estimated utilisation and financial impact estimates for the m0CRPC population were reasonable.</p>
<p>DECITABINE WITH CEDAZURIDINE</p> <p>Tablet containing decitabine 35 mg + cedazuridine 100 mg</p> <p>Inqovi®</p> <p>Otsuka Australia Pharmaceutical Pty. Ltd</p> <p>Early Re-entry resubmission (New listing)</p>	<p>High risk myelodysplastic syndromes (MDS) and chronic myelomonocytic leukaemia (CMML)</p>	<p>Resubmission to request an Authority Required (non-immediate/delayed) - In Writing only/Electronic listing for the treatment of high-risk MDS and CMML.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of decitabine+cedazuridine for the treatment of patients with MDS classified as intermediate-2 or high-risk according to the International Prognostic Scoring System (IPSS) and patients with CMML. The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of decitabine+cedazuridine would be acceptable if it were cost-minimised against azacitidine. The PBAC considered that the more conservative cost-minimisation analysis presented in the resubmission largely addressed the uncertainty around the claim of non-inferiority versus azacitidine. Further, the PBAC considered that the risk sharing arrangement proposed by the sponsor would address its previous concerns around use in a broader patient population compared with azacitidine.</p>

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<p>ELEXACAFITOR/ TEZACAFITOR/ IVACAFITOR AND IVACAFITOR</p> <p>Pack containing 56 tablets of elexacaftor 100 mg with tezacaftor 50 mg and ivacaftor 75 mg and 28 tablets of ivacaftor 150 mg</p> <p>Trikafta®</p> <p>Vertex Pharmaceuticals (Australia) Pty Ltd</p> <p>Other Business (New listing)</p>	<p>Cystic fibrosis (CF)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of CF in patients aged 12 years or older who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) for the treatment of CF patients aged 12 years and older who have one F508del mutation and one minimal function mutation in the CFTR gene (F/MF population). In making its recommendation, the PBAC noted that the sponsor had not provided a formal proposal for the PBAC's reconsideration following its May 2021 advice, and it therefore could not make a recommendation at this time for listing for the broader population of CF patients aged 12 years and older who have at least one F508del mutation in the CFTR gene, while the parameters it had previously outlined had not been addressed by the sponsor. The PBAC nominated the Early Re-entry resubmission pathway* for this item.</p> <p>However, in order to facilitate access to ELX/TEZ/IVA for a patient population that does not currently have access to treatment, the PBAC decided to recommend listing in the F/MF population, where the PBAC advice to date in relation to the cost-effectiveness and patient estimates was most closely aligned with that request.</p>
<p>ELOTUZUMAB</p> <p>Powder for I.V. infusion 300 mg Powder for I.V. infusion 400 mg</p> <p>Empliciti®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>Category 3 submission (New listing)</p>	<p>Relapsed and/or refractory multiple myeloma (RRMM)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (online/telephone) listing, in combination with lenalidomide and dexamethasone, for the treatment of RRMM.</p>	<p>Recommended</p>	<p>The PBAC recommended elotuzumab as a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for multiple myeloma that has progressed after at least one prior therapy, when administered in combination with lenalidomide and dexamethasone (ELd). Listing of ELd was recommended on a cost minimisation basis against carfilzomib plus dexamethasone (Cd). Although no new clinical evidence was presented in the resubmission, the PBAC considered that a claim of non-inferior efficacy may be reasonable, noting the uncertainty with the indirect treatment comparison reflected in the available clinical evidence and that a statistically significant gain in overall survival was demonstrated for ELd over lenalidomide plus dexamethasone (Ld), the magnitude of which was similar to that observed for Cd over bortezomib plus dexamethasone (Bd). The PBAC considered the revisions to the cost minimisation analysis, including the revised equi-effective doses, to be reasonable.</p>

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<p>ENZALUTAMIDE</p> <p>Capsule 40 mg</p> <p>Xtandi®</p> <p>Astellas Pharma Australia Pty Ltd</p> <p>ABIRATERONE</p> <p>Tablet 250 mg Tablet 500 mg</p> <p>Zytiga®</p> <p>Janssen-Cilag Pty Ltd</p> <p>Other Business (Change to listing)</p>	<p>Castration resistant carcinoma of the prostate</p>	<p>Request by the PBAC to consider changing the PBS indication for these items from metastatic castration resistant carcinoma of the prostate to castration resistant carcinoma of the prostate.</p>	<p>Not recommended</p>	<p>The PBAC did not recommend amending the existing abiraterone and enzalutamide restrictions for castration resistant prostate cancer to remove the criteria that the disease be metastatic. The PBAC noted the concerns raised by the sponsor of abiraterone regarding the potential for use earlier in the treatment algorithm than intended, and that neither sponsor provided an estimate of the financial implications for revising the listings.</p> <hr/> <p><u>Sponsor's Comment:</u></p> <p>Janssen-Cilag Pty Ltd: Janssen is supportive of this outcome as it is consistent with the clinical evidence available for abiraterone and will continue to ensure its appropriate use.</p> <p>Astellas Pharma Australia Pty Ltd: The sponsor had no comment.</p>
<p>ESKETAMINE</p> <p>Nasal spray solution 28 mg</p> <p>Spravato®</p> <p>Janssen-Cilag Pty Ltd</p> <p>Category 1 submission (New listing)</p>	<p>Treatment resistant depression</p>	<p>To request a Section 100 (Highly Specialised Drugs Program), Authority Required (telephone) listing for the treatment of treatment resistant depression, in combination with a newly initiated oral antidepressant.</p>		<p>Not Recommended</p>

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				<p><u>Sponsor's Comment:</u> Janssen is pleased the PBAC agree that there is an unmet clinical need for Australians living with depression. Esketamine nasal spray is a novel therapy providing patients with clinically meaningful improvement in symptoms in a disease where there has been little innovation for a long period of time. Janssen is committed to working collaboratively with the PBAC, Department of Health and clinical and patient communities to ensure this novel therapy is made available to patients on the PBS as soon as possible.</p>
<p>ETANERCEPT</p> <p>Injection 50 mg in 1 mL single use dose-dispenser cartridge, 4</p> <p>Enbrel®</p> <p>Pfizer Australia Pty Ltd</p> <p>Category 4 submission (Change to listing)</p>	<p>Rheumatoid arthritis; Plaque psoriasis; Ankylosing spondylitis; Psoriatic arthritis; Juvenile idiopathic arthritis; Paediatric plaque psoriasis</p>	<p>To request both General Schedule and Section 100 (Highly Specialised Drugs Program) listings of etanercept in dose dispenser cartridges under the same conditions as the currently listed pre-filled syringes.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of etanercept injection 50 mg in 1 mL single use dose-dispenser cartridges, 4 (etanercept DDC) on the basis that it should be made available for the same indications under both General Schedule and Section 100 (Highly Specialised Drugs Program) as the currently listed etanercept injection 50 mg in 1 mL single use pre-filled syringes, 4 (etanercept PFS). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of etanercept DDC would be acceptable if it were cost-minimised to etanercept PFS.</p> <p>The PBAC advised the equi-effective doses of etanercept DDC and etanercept PFS are: 50 milligrams of etanercept DDC = 50 milligrams of etanercept PFS.</p> <p>The PBAC advised that under Section 101(4AACD) of the <i>National Health Act 1953</i>, in the Schedule of Pharmaceutical Benefits, the same strengths of etanercept DDC, etanercept PFS and etanercept auto-injector should be considered equivalent at the pharmacy level (i.e. 'a'-flagged in the Schedule) for the purpose of substitution. The PBAC was satisfied that the differences in administration techniques of the DDC, PFS and auto-injector would be appropriately managed in clinical practice.</p>

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<p>FOLLITROPIN ALFA</p> <p>Injection 300 I.U. in 0.5 mL multi-dose cartridge Injection 450 I.U. in 0.75 mL multi-dose cartridge Injection 900 I.U. in 1.5 mL multi-dose cartridge</p> <p>Ovaleap®</p> <p>Theramex Australia Pty Ltd</p> <p>Category 3 submission (Change to listing)</p>	<p>Assisted Reproductive Technology; Anovulatory infertility; Infertility</p>	<p>To request both General Schedule and Section 100 (IVF Program) listings of a biosimilar under the same conditions as its reference biologic.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of follitropin alfa (Ovaleap) as a biosimilar brand of Gonal-f, on a cost-minimisation basis to Gonal-f, where the equi-effective doses are 1.0 I.U. follitropin alfa (Ovaleap) and 1.0 I.U. follitropin alfa (Gonal-f). The PBAC advised under Section 101(4AACD) of the <i>National Health Act 1953</i>, that Gonal-f and Ovaleap brands of follitropin alfa should be treated as equivalent in the Schedule of Pharmaceutical Benefits ('a' flagged) for the purposes of substitution.</p>
<p>HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE</p> <p>Oral liquid 250 mL, 30</p> <p>KetoVie® Peptide 4:1</p> <p>Cortex Health Pty Ltd</p> <p>Category 3 submission (Change to listing)</p>	<p>Ketogenic diet</p>	<p>To present additional data to progress the November 2020 recommended listing for KetoVie Peptide 4:1.</p>	<p>Recommended</p>	<p>The PBAC recommended the General Schedule, Authority Required (online/telephone) listing of high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (KetoVie Peptide 4:1) for ketogenic diet.</p>

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<p>HYDROCORTISONE</p> <p>Capsule containing granules 0.5 mg Capsule containing granules 1 mg Capsule containing granules 2 mg Capsule containing granules 5 mg</p> <p>Alkindi®</p> <p>Chiesi Australia Pty Ltd</p> <p>Category 3 submission (Change to listing)</p>	<p>Adrenal Insufficiency</p>	<p>To request an Authority Required (STREAMLINED) listing for replacement therapy of adrenal insufficiency for patients aged six or younger.</p>	<p>Recommended</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of Alkindi for replacement therapy of adrenal insufficiency in patients aged 6 years of age or under. The PBAC considered that Alkindi would facilitate accurate dosing in paediatric patients and may be easier to administer to paediatric patients than hydrocortisone tablets, which need to be crushed prior to administration. The PBAC considered that the magnitude of the price requested by the sponsor was not adequately justified however, considered that Alkindi would be adequately cost-effective if listed with a modest price advantage compared to the existing 4 mg tablets.</p>
<p>HYPROMELLOSE</p> <p>Eye drops 3 mg per mL, 10 mL</p> <p>Revive Tears®</p> <p>Petrus Pharmaceuticals Pty Ltd</p> <p>Committee Secretariat submission (Change to listing)</p>	<p>Severe dry eye syndrome, including Sjogren's syndrome</p>	<p>To request a Restricted benefit listing of a new brand under the same conditions as the currently listed hypromellose eye drops; and to seek advice on therapeutic bioequivalence.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of a new generic brand of hypromellose 3 mg per mL eye drops (Revive Tears), under the same circumstances as the existing PBS-listed brands, Genteal and In a Wink Moisturising, for the treatment of severe dry eye syndrome (including Sjogren's syndrome). The PBAC advised, under Section 101 (4AACD) of the <i>National Health Act 1953</i>, that Revive Tears should be treated as equivalent to Genteal and In a Wink Moisturising for the purposes of substitution (i.e. 'a' flagged).</p>
<p>INCLISIRAN</p> <p>Injection 284 mg in 1.5 mL pre-filled syringe</p> <p>Leqvio®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Category 2 submission (New listing)</p>	<p>Hypercholesterolaemia</p>	<p>To request a General Schedule, Authority Required (online/telephone) listing for the treatment of heterozygous familial hypercholesterolaemia, and non-familial hypercholesterolaemia with atherosclerotic cardiovascular disease.</p>	<p>Withdrawn</p>	

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<p>LANADELUMAB</p> <p>Solution for subcutaneous injection 300 mg in 2 mL</p> <p>Takhzyro®</p> <p>Takeda Pharmaceuticals Australia Pty Ltd</p> <p>Category 2 submission (New listing)</p>	<p>Hereditary angioedema (HAE)</p>	<p>Resubmission to request an Authority Required (online/telephone) listing for the prevention of recurrent attacks of hereditary angioedema (C1-esterase inhibitor deficiency or dysfunction) in patients aged 12 years and older.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of lanadelumab for the prophylaxis of recurrent attacks of HAE. The PBAC, noting that danazol was no longer available in Australia and that there was currently no intervention available for patients with an attack frequency of 8 per month or fewer, considered that there was a moderate clinical need for effective and tolerable prophylactic therapies for these HAE patients. The PBAC considered that for some patients, lanadelumab provided a moderate clinical benefit in terms of a reduction in HAE attack frequency versus standard of care. The PBAC noted that although the updated economic model resulted in an incremental cost effectiveness ratio which remained uncertain, the associated financial risk was managed by the proposed risk sharing arrangement in this small and definable patient population.</p>
<p>LORLATINIB</p> <p>Tablet 25 mg Tablet 100 mg</p> <p>Lorviqua®</p> <p>Pfizer Australia Pty Ltd</p> <p>Category 2 submission (Change to listing)</p>	<p>Locally advanced (stage IIIB) or metastatic (stage IV) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)</p>	<p>To request a General Schedule, Authority Required (online/telephone) listing for the treatment of locally advanced (Stage IIIB) or metastatic (Stage IV) ALK-positive NSCLC in patients who have not received prior treatment with an ALK inhibitor.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation for the line-agnostic listing of lorlatinib for the treatment of patients with Stage IIIB or Stage IV non-squamous or not otherwise specified type NSCLC with evidence of an ALK gene rearrangement in tumour material as the TGA Delegate's Overview was not available at the time of consideration. However, the PBAC was of a mind to recommend the Authority Required line-agnostic listing of lorlatinib based on, among other matters, its assessment that the cost-effectiveness of lorlatinib would be acceptable if it were cost-minimised against the least costly alternative therapies (alectinib, brigatinib, ceritinib).</p> <p><u>Sponsor's Comment:</u> Pfizer Australia is committed to working with the PBAC and the Department of Health to make lorlatinib available for the first-line treatment of locally advanced or metastatic ALK-positive non-small cell lung cancer at the earliest opportunity.</p>

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<p>LUMACAFTOR + IVACAFTOR</p> <p>Tablet containing lumacaftor 100 mg with ivacaftor 125 mg</p> <p>Orkambi®</p> <p>Vertex Pharmaceuticals (Australia) Pty. Ltd.</p> <p>Category 2 submission (Other matters)</p>	<p>Cystic fibrosis</p>	<p>To provide additional data as specified in the Deed of Supply.</p>	<p>Advice provided</p>	<p>This item was submitted to the PBAC by the sponsor to consider additional analyses related to the requirements of the Deed of Agreement (the Deed) currently in place between the sponsor and the Commonwealth for the PBS listing of lumacaftor/ivacaftor (Orkambi) and tezacaftor/ivacaftor (Symdeko). The PBAC advised the data provided did not adequately meet the requirements of the Deed in that the magnitude of the long-term benefits of lumacaftor/ivacaftor or tezacaftor/ivacaftor, in terms of the reduction in the decline in lung function and the reduction in the number of pulmonary exacerbations, remained uncertain. The PBAC considered that the sponsor should submit additional data to meet the requirements of the Deed, and that this item would be reconsidered by the PBAC in December 2021.</p>
<p>MELATONIN</p> <p>Tablet 1 mg Tablet 5 mg</p> <p>Slenyto®</p> <p>Aspen Pharmacare Australia Pty Ltd</p> <p>Early Re-entry resubmission (New listing)</p>	<p>Insomnia</p>	<p>Resubmission to request an Authority Required (Telephone) listing for the treatment of insomnia in patients between the ages of 2 to 18 with Smith-Magenis syndrome.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation for the listing of melatonin for the treatment of insomnia in patients with Smith Magenis Syndrome to allow further discussions with the sponsor regarding a cost-effective price.</p> <p><u>Sponsor's Comment:</u> Aspen is pleased that the PBAC has accepted there is a clinical need for Slenyto PRM in the SMS population. Aspen is looking forward to working with the PBAC/PBS pricing section to finalise the price for melatonin (Slenyto PRM) tablets. Aspen is also keen to continue working with the PBAC to potentially expand the listing to include ASD patients in the future.</p>
<p>METHOXSALEN</p> <p>Solution for blood fraction 20 microgram per mL, 10 mL</p> <p>Uvadex®</p> <p>Terumo Bct Australia Pty Ltd</p> <p>Category 3 submission (Change to listing)</p>	<p>Steroid dependent or steroid intolerant or steroid refractory chronic graft versus host disease (cGVHD)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing for the treatment of patients with steroid dependent or steroid intolerant or steroid refractory cGVHD, as part of treatment with integrated, closed system, extracorporeal photopheresis.</p>	<p>Deferred</p>	<p>The PBAC deferred its consideration of methoxsalen for the treatment of patients with steroid dependent, steroid intolerant or steroid refractory cGVHD, to await the outcome of the Medical Services Advisory Committee (MSAC) consideration on the funding of the co-dependent extracorporeal photopheresis (ECP), before making a final decision on PBS funding.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

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<p>NIRAPARIB</p> <p>Capsule 100 mg</p> <p>Zejula®</p> <p>Glaxosmithkline Australia Pty Ltd</p> <p>Category 2 submission (New listing)</p>	<p>High grade epithelial ovarian, fallopian tube, or primary peritoneal cancer (HGEOC)</p>	<p>To request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of newly diagnosed, advanced, HGEOC that is responsive (complete/partial) to platinum-based chemotherapy.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend niraparib for the treatment of newly diagnosed advanced, HGEOC, who are in response to platinum-based chemotherapy. The PBAC was unable to assess the incremental clinical and economic effectiveness based on the submission provided, which did not include the relevant comparator for patients with BRCA1/2 pathogenic gene variants who would be treated with olaparib or for patients who would otherwise be treated with bevacizumab. The PBAC noted that the progression free survival benefit from treatment with niraparib varied depending on the presence of BRCA1/2 pathogenic gene variants and homologous repair deficiency (HRD) status. The PBAC considered there may be differences in benefits and harms in the different patient subgroups, if niraparib is used in place of olaparib, bevacizumab or standard medical management, and that these potential differences were not adequately presented in the submission.</p>
				<p>Sponsor's Comment: GSK is disappointed by the PBAC's decision not to recommend niraparib (Zejula), for newly diagnosed advanced, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer (HGEOC), who are in response to platinum-based chemotherapy. However, we remain committed to working with the PBAC to ensure Australian women with ovarian cancer have timely access to Zejula.</p>
<p>NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p>Opdivo®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>Category 1 submission (Change to listing)</p>	<p>Second-line squamous cell oesophageal carcinoma (2L OSCC)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for 2L OSCC that have failed treatment with a fluoropyrimidine and platinum containing treatment regimen.</p>	<p>Recommended</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy – Public and Private Hospital) Authority Required (Streamlined) listing of nivolumab for the treatment of patients with advanced or metastatic OSCC who have disease progression following treatment with a fluoropyrimidine and platinum-based chemotherapy regimen. The PBAC considered there is a moderate clinical need in this patient population, given the availability of subsidised alternatives (but noted the toxicity and limited benefit of the alternative treatments). The PBAC acknowledged the moderate added benefit (small survival benefit, some improvement in quality of life, moderate reduction in adverse events) provided by nivolumab. The PBAC considered that the incremental cost effectiveness ratio was high at the proposed price and a price reduction would be required to ensure nivolumab is cost-effective in this population.</p>

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<p>NUSINERSEN</p> <p>Solution for injection 12.6 mg in 5 mL</p> <p>Spinraza®</p> <p>Biogen Australia Pty Ltd</p> <p>Standard Re-entry resubmission (Change to listing)</p>	<p>Spinal muscular atrophy (SMA)</p>	<p>Resubmission to extend the current Section 100 (Highly Specialised Drugs Program), Authority Required (written) listing to include adults with SMA.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend extending the listing of nusinersen to include the treatment of SMA in patients with symptom onset prior to 19 years of age, and removal of the age limit of 18 years for initiation of treatment.</p> <p>The PBAC recognised the clinical need for effective treatments for adult SMA. However, the PBAC considered that the adult population most likely to benefit from treatment with nusinersen remained inadequately defined in the resubmission. The PBAC noted that the magnitude and durability of treatment benefit remained uncertain and considered that the incremental cost-effectiveness ratio (ICER) was exceptionally high at the price proposed.</p> <p>The PBAC advised that a substantial price reduction commensurate with the benefit of treatment in adult SMA patients, a risk sharing arrangement (RSA), and a Managed Access Program (MAP) which accounts for the number of patients treated and the number of patients who respond to treatment, would be required to achieve a cost-effective listing for adult patients.</p> <p><u>Comparator: Placebo/standard of care (SOC)</u> The PBAC accepted that SOC was an appropriate comparator</p> <p><u>Clinical claim: Superior effectiveness and non-inferior safety compared with SOC</u> The PBAC considered that, while the claim of superior comparative effectiveness was reasonable, the magnitude and durability of benefit remained uncertain.</p> <p>The PBAC considered that the claim of non-inferior comparative safety was not adequately supported by the data, and reiterated that there may be long term implications from repeated lumbar puncture administrations.</p> <p><u>Economic claim: Cost-utility analysis compared with SOC</u> The PBAC considered the ICER was unacceptably high and likely underestimated. The PBAC considered that the model's assumption that patients on nusinersen do not progress and the estimated duration of benefit of nusinersen was not adequately substantiated by the available evidence. The PBAC also considered that utility gains associated with nusinersen treatment may have been overestimated.</p>

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				<p><u>Type IIIb paediatric patients</u> The PBAC recommended extending the existing listing of nusinersen to include the treatment of all paediatric patients with Type III SMA who experienced symptom onset prior to 18 years of age, noting this would provide equity of access across paediatric patients. The PBAC made this recommendation on the basis of the reduced nusinersen price and inclusion in the existing caps as proposed by the sponsor.</p> <p><u>Sponsor's Comment:</u> Biogen welcomes the PBAC's decision to recommend nusinersen for paediatric patients with Type IIIb SMA who have experienced symptom onset between 3 and 18 years of age. Biogen will be working with the Department of Health towards a PBS listing in this patient population at the earliest opportunity.</p> <p>Biogen is disappointed the PBAC did not recommend nusinersen for adults with SMA aged over 18 years at treatment initiation who have experienced signs and symptoms of SMA prior to 19 years of age.</p> <p>Biogen believes that there is alignment with the PBAC that nusinersen is a novel medicine that provides a clinically relevant benefit for adult patients with SMA and that there are no current PBS subsidised therapies available for these patients.</p> <p>Biogen will assess the options available and collaborate with all stakeholders to find a suitable path forward. Biogen would like to take this opportunity to thank the SMA community and healthcare professionals who supported the submission.</p>
<p>OPICAPONE Capsule 50 mg Ongentys® Maxx Pharma Pty Ltd Category 2 submission (New listing)</p>	<p>Parkinson Disease (PD)</p>	<p>To request a General Schedule, Restricted benefit listing for the treatment of PD, as adjunctive therapy to levodopa-decarboxylase inhibitor combinations in patients motor function fluctuations due to end-of-dose effects.</p>	<p>Recommended</p>	<p>The PBAC recommended listing opicapone as a General Schedule Restricted Benefit for PD under the same conditions as and on a cost minimisation basis with entacapone.</p>

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<p>PALBOCICLIB</p> <p>Tablet 75 mg Tablet 100 mg Tablet 125 mg</p> <p>Ibrance®</p> <p>Pfizer Australia Pty Ltd</p> <p>Category 4 submission (Change to listing)</p>	<p>Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer</p>	<p>To request an Authority Required listing of palbociclib tablets under the same conditions as the already listed capsules.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of Ibrance® (palbociclib) tablets on the PBS under the same conditions as the existing listings for palbociclib capsules.</p>
<p>RAVULIZUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 3 mL Solution concentrate for I.V. infusion 1,100 mg in 11 mL</p> <p>Ultomiris®</p> <p>Alexion Pharmaceuticals Australasia Pty Ltd</p> <p>Standard Re-entry resubmission (New listing)</p>	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program), Authority Required (Written) listing for the treatment of adults with PNH.</p>	<p>Recommended</p>	<p>The PBAC recommended the Authority Required (non-immediate assessment) listing of ravulizumab for the treatment of PNH, on the basis that it should be available only under special arrangements under the Section 100 – Highly Specialised Drugs Program. The PBAC considered the clinical evidence presented demonstrated that ravulizumab was likely to be non-inferior in safety and effectiveness compared to eculizumab. The PBAC noted that eculizumab is currently funded on the Life Saving Drugs Program. The PBAC considered the submission for ravulizumab provided an opportunity to reassess the cost-effectiveness of eculizumab for listing on the PBS. The PBAC considered the clinical data presented supported a survival advantage for eculizumab over best supportive care. Although the magnitude of the survival benefit in PNH remained uncertain and the cost-effectiveness was very high, the PBAC considered eculizumab would be appropriate for inclusion on the PBS at a reduced price. The PBAC advised ravulizumab be listed on the basis of a cost-minimisation to eculizumab.</p>

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<p>RIPRETINIB</p> <p>Tablet 50 mg</p> <p>Qinlock®</p> <p>Specialised Therapeutics PM Pty Ltd</p> <p>Early Re-entry resubmission (New listing)</p>	<p>Gastrointestinal stromal tumour (GIST)</p>	<p>Resubmission to request an Authority Required (Written) listing for the treatment of metastatic or unresectable malignant GIST.</p>	<p>Recommended</p>	<p>The PBAC recommended the Authority Required (immediate/real-time assessment) listing of ripretinib for treatment of advanced GIST. The resubmission provided a revised price and financial estimates in response to previous concerns raised by the PBAC. In addition, the resubmission included updated survival data from the key clinical trial. The PBAC considered the revised incremental cost-effectiveness ratio (ICER) was high but likely overestimated due to the survival benefit being underestimated as a result of using the less favourable earlier data cut and the control group crossing over to receive treatment with ripretinib. The PBAC considered the ICER was acceptable in the context of advanced GIST being a rare cancer with an unmet need for effective third line treatment. In addition, the PBAC considered the revised financial estimates addressed previous concerns.</p>
<p>SECUKINUMAB</p> <p>Injection 150 mg in 1 mL pre-filled pen</p> <p>Cosentyx®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Category 4 submission (Change to listing)</p>	<p>Ankylosing spondylitis</p>	<p>To request an increase in the maximum quantity to 2 and a reduction in the number of repeats from 5 to 2.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend increasing the maximum quantity from 1 to 2 or reducing the number of repeats from 5 to 2 of the PBS listed secukinumab 150 mg injection for the continuing treatment phase of the following PBS indications:</p> <ul style="list-style-type: none"> • Ankylosing spondylitis • Severe chronic plaque psoriasis • Severe psoriatic arthritis • Non-radiographic axSpA. <p>The PBAC noted that it is usual practice for drugs listed on the General Schedule to have a maximum quantity per prescription that provides supply for one months' treatment as per PBAC Guidelines and that the current maximum quantity and number of repeats for secukinumab are consistent with the PBAC Guidelines.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

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<p>SELINEXOR</p> <p>Tablet 20 mg</p> <p>Xpovio®</p> <p>Antengene (Aus) Pty. Ltd.</p> <p>Category 1 submission (New listing)</p>	<p>Relapsed and/or refractory multiple myeloma (RRMM)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing, in combination with bortezomib and dexamethasone, for the treatment of RRMM.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend selinexor, in combination with bortezomib and dexamethasone (SBd), for the treatment of RRMM. The PBAC noted that SBd provided, for some patients, an improvement in progression free survival compared to the primary comparator bortezomib plus dexamethasone (Bd) but noted that the data for overall survival were immature and difficult to interpret. The PBAC considered that the economic model overestimated the benefits of SBd treatment compared to Bd, resulting in an incremental cost effectiveness ratio that was underestimated. The PBAC considered that the indirect treatment comparisons presented between SBd and the secondary comparator carfilzomib plus dexamethasone (Cd), did not adequately support non-inferiority and hence, the cost minimisation analysis between SBd and Cd was not informative. The PBAC considered that the utilisation estimates for SBd were overestimated, particularly given the toxicity associated with SBd treatment, and that the financial impact estimates were underestimated due to the application of unlikely substitution assumptions.</p>
				<p><u>Sponsor's Comment:</u> Antengene is committed to working with the PBAC to secure equitable access to selinexor in a triplet regimen for both patients and physicians in relapsed/refractory multiple myeloma. We wish to thank and acknowledge the contribution of clinicians, patients, and advocacy groups in supporting this submission.</p>
<p>SELINEXOR</p> <p>Tablet 20 mg</p> <p>Xpovio®</p> <p>Antengene (Aus) Pty. Ltd.</p> <p>Category 1 submission (New listing)</p>	<p>Triple class refractory/penta-refractory multiple myeloma (TCR/PR MM)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing, in combination with dexamethasone, for the treatment of TCR/PR MM in patients who have received at least four prior therapies.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend selinexor, for use in combination with dexamethasone (Sd), for the treatment of TCR/PR MM. The PBAC, noting the lack of comparative data between Sd and the nominated comparator, salvage chemotherapy consisting of dexamethasone, cyclophosphamide, etoposide and cisplatin, considered that the clinical claims of superior efficacy and safety was not supported. The PBAC considered that the economic model was unreliable for decision making and that the financial impact estimates were likely overestimated.</p>
				<p><u>Sponsor's Comment:</u> Antengene is committed to working with the PBAC to secure equitable access to selinexor for patients and physicians in penta-refractory multiple myeloma. Patients at this late stage have very limited options and it is important for them to have access to novel agents with a new mechanism of action. We wish to thank and acknowledge the contribution of clinicians, patients, and advocacy groups in supporting this submission</p>

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<p>SELINEXOR</p> <p>Tablet 20 mg</p> <p>Xpovio®</p> <p>Antengene (Aus) Pty. Ltd.</p> <p>Category 1 submission (New listing)</p>	<p>Relapsed and/or refractory diffuse large B-cell lymphoma (RR DLBCL)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing for the treatment of RR DLBCL in patients who have received at least two lines of systemic therapy.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend selinexor for the treatment of adult patients with RR DLBCL after at least two lines of systemic therapy. The PBAC, noting the lack of comparative data between selinexor and the nominated comparator, rituximab in combination with gemcitabine and oxaliplatin (RGenOx), considered that the clinical claims of superior efficacy and safety were not supported. The PBAC considered that the economic model was unreliable for decision making and that the financial estimates were highly uncertain.</p>
				<p><u>Sponsor's Comment:</u> Antengene is committed to working with the PBAC to secure equitable access to selinexor for patients and physicians in relapsed/refractory diffuse large B-Cell lymphoma. Patients at this late stage have very limited options and it is important for them to have access to novel agents with a new mechanism of action. We wish to thank and acknowledge the contribution of clinicians, patients, and advocacy groups in supporting this submission.</p>
<p>SILTUXIMAB</p> <p>Powder for injection 100 mg Powder for injection 400 mg</p> <p>Sylvant®</p> <p>Eusa Pharma (UK) Ltd</p> <p>Category 1 submission (New listing)</p>	<p>Idiopathic multicentric Castleman's disease (iMCD)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program), Authority Required (online/telephone) listing for the treatment of iMCD.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend siltuximab for the treatment of iMCD. The PBAC considered the claim of superior efficacy compared to placebo was reasonable based on improvements in durable tumour and symptomatic response. The PBAC considered that siltuximab was inferior to placebo in terms of safety profile. The PBAC considered that despite uncertainties in the clinical data, including those associated with a small sample size in the pivotal clinical trial, the benefits of treatment were clinically meaningful in the context of iMCD being a rare condition with unmet clinical need. However, the PBAC considered the incremental cost-effectiveness ratio was high and uncertain at the proposed price. Furthermore, the PBAC considered the approach used to estimate the number of patients to be treated with siltuximab was unreliable.</p> <p>The PBAC nominated the Early Re-entry re-submission pathway* for this item.</p>
				<p><u>Sponsor's Comment:</u> The Sponsor will work with the PBAC to ensure this treatment, in a high clinical need disease, continues to be made available to patients.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p>TRABECTEDIN</p> <p>Powder for I.V. infusion 0.25 mg Powder for I.V. infusion 1 mg</p> <p>Yondelis®</p> <p>Specialised Therapeutics Pharma Pty Ltd</p> <p>Category 2 submission (New listing)</p>	<p>Advanced (unresectable and/or metastatic) leiomyosarcoma (LMS)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for the treatment of unresectable or metastatic LMS following a prior anthracycline-containing regimen.</p>	<p>Recommended</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing of trabectedin for the treatment of LMS. Noting the evidence presented for trabectedin included a population with liposarcoma (LPS) and that the treatment effect was similar across both sarcomas, together with the high clinical need for additional treatment options for LPS that is a rare and aggressive cancer, the PBAC also recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of trabectedin for LPS.</p> <p>The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of trabectedin would be acceptable if it were cost-minimised against pazopanib. The PBAC advised the equi-effective doses were:</p> <ul style="list-style-type: none"> • Trabectedin 2.93 mg as a 24-hour infusion Day 1 of each 21-day treatment cycle for 21.80 weeks; and • Pazopanib 700.35 mg orally once daily for 21.80 weeks. <p>The PBAC's recommendation for listing in LPS was based on, among other matters, its assessment, that the cost-effectiveness of trabectedin would be acceptable if it were priced the same as for the LMS population.</p>
<p>TRIPTORELIN</p> <p>Powder for I.M. injection (prolonged release) 22.5 mg (as embonate), with solvent</p> <p>Diphereline®</p> <p>Ipsen Pty Ltd</p> <p>Category 2 submission (Change to listing)</p>	<p>Central precocious puberty (CPP)</p>	<p>To request a General Schedule, Restricted Benefit listing for the treatment of CPP.</p>	<p>Recommended</p>	<p>The PBAC recommended the General Schedule, Restricted Benefit listing of triptorelin for the treatment of CPP at the same price for which it is currently listed for the treatment of locally advanced/metastatic prostate cancer. In making this recommendation, the PBAC considered the evidence presented supported a conclusion that triptorelin is of non-inferior comparative efficacy and safety to leuporelin for the management of CPP.</p>

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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p>UPADACITINIB</p> <p>Tablet 15 mg Tablet 30 mg</p> <p>Rinvoq®</p> <p>Abbvie Pty Ltd</p> <p>Category 2 submission (Change to listing)</p>	<p>Severe atopic dermatitis (AD)</p>	<p>To request a General Schedule, Authority Required (Telephone) listing for the treatment of severe atopic dermatitis.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation to list upadacitinib for severe AD as a TGA Delegate's Overview was not available at the time of PBAC consideration. The PBAC was of a mind to recommend 15 mg and 30 mg upadacitinib on a cost minimisation basis compared to dupilumab, pending receipt of a positive TGA Delegate's Overview. The PBAC acknowledged the clinical need for additional systemic treatments for severe AD and considered that upadacitinib provides an overall clinical benefit similar to the comparator, dupilumab. The PBAC did not accept the submission's claim that upadacitinib 30 mg is superior to dupilumab in terms of response, based on the direct head to head evidence presented, although acknowledged that the response to treatment may be faster with upadacitinib. The PBAC considered that safety for upadacitinib 30 mg may be inferior to dupilumab.</p> <p><u>Sponsor's Comment:</u> AbbVie welcomes the PBAC's minded recommendation for 15mg and 30mg upadacitinib for severe AD patients. AbbVie maintains that upadacitinib 30 mg is superior to dupilumab, based on the results of the head-to-head trial demonstrating superiority of upadacitinib on the primary endpoint at Week 16. AbbVie will continue to work with the PBAC to enable earliest possible access to upadacitinib for patients living with severe AD following receipt of the Delegate's Overview.</p>
<p>VENETOCLAX</p> <p>Tablet 50 mg Tablet 100 mg</p> <p>Venclexta®</p> <p>AbbVie Pty Ltd</p> <p>Early Re-entry resubmission (Change to listing)</p>	<p>Acute myeloid leukaemia</p>	<p>Resubmission to request a General Schedule - Authority Required (online/telephone) listing for the treatment of patients with newly diagnosed acute myeloid leukaemia, who are ineligible for standard intensive remission induction chemotherapy.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of venetoclax in combination with azacitidine, for the treatment of patients with newly diagnosed acute myeloid leukaemia, who are ineligible for standard intensive remission induction chemotherapy. The PBAC was satisfied that venetoclax in combination with azacitidine provides, for some patients, a significant improvement in efficacy over low-intensity azacitidine or low-dose cytarabine. The early re-entry resubmission had addressed most issues previously identified by the PBAC (in terms of the economic model, financial estimates and risk sharing arrangement proposal), although there were some additional changes made, which the PBAC did not accept. The PBAC also noted that azacitidine sponsors would be consulted on the azacitidine listing prior to implementation.</p>

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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p>ZANUBRUTINIB</p> <p>Capsule 80 mg</p> <p>Brukinsa®</p> <p>BeiGene Aus Pty Ltd</p> <p>Category 2 submission (New listing)</p>	<p>Waldenstrom macroglobulinemia (WM)</p>	<p>To request a General Schedule, Authority Required (Telephone) listing for the treatment of adult patients with Waldenstrom macroglobulinemia.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of zanubrutinib for the treatment of adult patients with WM (for the requested populations of: (i) patients who are treatment-naïve and unsuitable for chemo-immunotherapy; or (ii) patients with relapsed/refractory disease who have received at least one prior therapy). The PBAC acknowledged the meaningful consumer support and engagement with regards to this submission, including a consumer hearing with patient group representatives held prior to the PBAC meeting. The PBAC recognised that there are no treatments on the PBS specifically for WM and considered that zanubrutinib offered, for some patients, high added therapeutic value in terms of tolerability, response outcomes and quality of life. However, the PBAC did not have a reliable basis to determine a cost-effective price for zanubrutinib as the economic model did not reflect the expected treatment outcomes of improved quality of life and reduced need for subsequent therapies, including chemotherapy, but instead was based on projected large gains in overall survival, which were not supported by the clinical data and were considered clinically implausible. The PBAC considered the estimated use and financial impact to be underestimated.</p> <p>The PBAC nominated the Facilitated Resolution pathway* for this item.</p>
<p>ZANUBRUTINIB</p> <p>Capsule 80 mg</p> <p>Brukinsa®</p> <p>BeiGene Aus Pty Ltd</p> <p>Category 1 submission (New listing)</p>	<p>Relapsed and/or refractory mantle cell lymphoma (R/R MCL)</p>	<p>To request a General Schedule, Authority Required (telephone) listing for the treatment of R/R MCL.</p>		<p>Recommended</p>

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DRUG NAME, FORM(S), STRENGTH(S) AND SPONSOR	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p align="center">ADALIMUMAB Injection 40 mg in 0.8 mL vial Humira® AbbVie Pty Ltd</p>	<p align="center">Same as currently PBS subsidised indications for adalimumab</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation was rescinded by the PBAC with support from the sponsor.</p>
<p align="center">BUDESONIDE Capsule 3 mg Entocort® Chiesi Australia Pty Ltd</p>	<p align="center">Mild to Moderate Crohn Disease</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation extended for 6 months</p>
<p align="center">ENOXAPARIN Injection 120 mg in 0.8 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled syringe Clexane Forte®; Enoxaparin Winthrop®; Clexane Forte Safety-Lock® Sanofi-Aventis Australia Pty Ltd</p>	<p align="center">Unrestricted benefit</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">To be reviewed at November 2022 PBAC meeting.</p>
<p align="center">FLUTICASONE FUROATE fluticasone furoate 50 microgram/actuation powder for inhalation, 30 actuations Arnuity Ellipta® GlaxoSmithKline Australia Pty Ltd</p>	<p align="center">Asthma</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation was rescinded by the PBAC, noting that there were two alternate strengths of fluticasone furoate (July 2019) listed on the PBS.</p>
<p align="center">GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE Sachets containing oral powder 33.3 g, 16 PKU GMP® Nutricia Australia Pty Limited</p>	<p align="center">Phenylketonuria</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation extended for 6 months</p>

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DRUG NAME, FORM(S), STRENGTH(S) AND SPONSOR	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p align="center">LIRAGLUTIDE</p> <p>Solution for injection, 6 mg per mL, 2 x 3 mL pre-filled pen</p> <p align="center">Victoza®</p> <p align="center">Novo Nordisk Pharmaceuticals Pty Ltd</p>	<p align="center">Diabetes</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation was rescinded by the PBAC with support from the sponsor.</p>
<p align="center">RAMUCIRUMAB</p> <p>100 mg in 10 mL vial 500 mg in 50 mL vial</p> <p align="center">Cyramza®</p> <p align="center">Eli Lilly Australia Pty Ltd</p>	<p align="center">Advanced gastric or gastro-oesophageal junction adenocarcinoma</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation extended for 6 months</p>
<p align="center">RANOLAZINE</p> <p>Tablet (modified release) 375 mg, 500 mg, 750 mg</p> <p align="center">Ranexa®</p> <p align="center">A. Menarini Australia Pty Limited</p>	<p align="center">Symptomatic treatment of stable angina pectoris</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation was rescinded by the PBAC with support from the sponsor.</p>
<p align="center">SECUKINUMAB</p> <p>150 mg /mL powder for injection 150 mg/mL pre-filled syringe</p> <p align="center">Cosentyx®</p> <p align="center">Novartis Pharmaceuticals Australia Pty Ltd</p>	<p align="center">Severe chronic plaque psoriasis</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation extended for 6 months</p>
<p align="center">SEVELAMER</p> <p>Powder for oral liquid, 2.4 g</p> <p align="center">Renvela®</p> <p align="center">Sanofi-Aventis Australia Pty Ltd</p>	<p align="center">Chronic kidney disease</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation extended for 6 months</p>

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DRUG NAME, FORM(S), STRENGTH(S) AND SPONSOR	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p align="center">SOMATROPIN</p> <p>Multiple forms and strengths</p> <p>Multiple brands</p> <p>Endocrine Society of Australia and Australian Paediatric Endocrine Group</p>	<p align="center">Severe growth hormone deficiency (GHD)</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation was rescinded by the PBAC with support from the organisations.</p>
<p align="center">TENOFIVIR ALAFENAMIDE</p> <p>Tablet 25 mg</p> <p>Vemlidy®</p> <p>Gilead Sciences</p>	<p align="center">Chronic hepatitis B</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation extended for 6 months</p>
<p align="center">TRIGLYCERIDES MEDIUM CHAIN FORMULA</p> <p>Oral liquid 500 mL, 12</p> <p>Nutrini Peptisorb®</p> <p>Nutricia Australia Pty Ltd</p>	<p align="center">Change to pack size/quantities</p>	<p align="center">Review of positive PBAC recommendations not accepted by applicants</p>	<p align="center">Recommendation extended for 12 months</p>

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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Recommendation 65 of the Royal Commission into Aged Care Quality and Safety Final Report	Antipsychotic medications	To seek PBAC recommendation on whether amendments to PBS listings of antipsychotic medications are appropriate in light of Recommendation 65 of the Royal Commission into Aged Care Quality and Safety's Final Report.	The PBAC deferred making a recommendation on whether amendments to Pharmaceutical Benefits Scheme (PBS) listings of antipsychotic medications are appropriate in light of Recommendation 65 of the Royal Commission into Aged Care Quality and Safety (Royal Commission) Final Report, pending targeted consultation with clinical and professional groups in relation to practical implementation and a utilisation review of risperidone following changes to listing recommended in August 2019. The PBAC acknowledged the findings of the Royal Commission, expressed concern about the prescribing rates of antipsychotics in aged care and recognised that action is required. The PBAC considered further consultation was required to ascertain the practicality and potential unintended consequences of amending PBS listings of antipsychotics. The PBAC will consider this matter further once the requested consultation and utilisation analyses are available.
Review of PBS Authority Required (Written) listings – Tranche 3 1. Omalizumab	Medicines for the treatment of allergic, respiratory, and gastrointestinal conditions 1. Severe chronic spontaneous urticaria (CSU)	To request that the PBAC consider the Authority Required (Written) restriction level for PBS-listed medicines (Tranche 3) and recommend any required amendments.	<p>The PBAC noted the key Review findings from the PBS Authority Required (Written) listings report, which included an analysis of PBS utilisation data for Tranche 3 medicines. The PBAC also noted the input provided by sponsors through submission of pre-subcommittee responses (PSCRs) on the written authority level of their Tranche 3 medicine(s).</p> <p>The PBAC applied the following key criteria to assist in determining the requirement to maintain a written Authority level of restriction:</p> <p>(1) Potential for use in a population in which the medicine is not cost-effective or where the PBAC has not determined the comparative effectiveness and cost; and (2) Potential for high cost per patient or high total cost to the health system and the government's budget. The PBAC also considered the following factors: quality use of medicines (QUM), safety, and administrative burden.</p> <p>Overall, the PBAC accepted the DUSC June 2021 advice on the need to amend or maintain the current written Authority level of each medicine and made the following recommendations:</p> <p><u>1. Severe chronic spontaneous urticaria (CSU):</u></p> <p>The PBAC noted the high number of incident patients over the four calendar years since first PBS listing in September 2017 have contributed to increases in the treated annual prevalent population.</p> <p>The PBAC did not recommend an amendment to the authority requirements for omalizumab for CSU, noting the annual increase in omalizumab prevalent patient numbers demonstrated market instability and associated financial implications for government.</p>

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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
2.Omalizumab	2. Severe allergic asthma (SAA)		<p><u>2. Severe allergic asthma (SAA):</u></p> <p>The PBAC agreed with DUSC advice and did not recommend an amendment to the authority requirements for initial treatment with omalizumab for SAA, noting the consistent increase in incident and prevalent patient numbers demonstrated the market was not yet stable.</p> <p>The PBAC recommended that the authority requirements for continuing treatment with omalizumab for SAA be amended from Authority Required (Written) to Authority Required (Telephone/Electronic) to ease administrative burden for prescribers and for consistency with the continuing authority requirements for omalizumab for CSU.</p>
3.Benralizumab, mepolizumab	3. Severe eosinophilic asthma (SEA)		<p><u>3. Severe eosinophilic asthma (SEA):</u></p> <p>The PBAC considered the SEA market relatively immature, noting steady growth in numbers of treated prevalent patients for both medicines. The PBAC noted that benralizumab dominated the market in 2020, accounting for 55% of expenditure and 52% of written authority approvals. The PBAC also noted that PBS expenditure on these SEA medicines has grown year on year annually to \$65 million in 2020 (at published prices).</p> <p>The PBAC did not recommend an amendment to the authority requirements for benralizumab or mepolizumab for SEA at this time, given that the market is not yet stable.</p>
4. Ivacaftor, lumacaftor+ivacaftor	4. Cystic fibrosis (CF)		<p><u>4. Cystic fibrosis (CF):</u></p> <p>The PBAC acknowledged the large financial risk associated with CF medicines and that high individual patient cost would be of substantial concern if not managed by a Deed of Agreement.</p> <p>The PBAC agreed with DUSC that the utilisation of these medicines is reliant on potential market changes as new products enter the CF market</p> <p>The PBAC recommended no amendment to current authority requirements for ivacaftor and lumacaftor+ ivacaftor given the comparatively high cost of these medicines, the associated financial implications to government and the potential for market instability with the introduction of new medicines.</p>

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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
5. Infliximab, ustekinumab, vedolizumab, adalimumab	5. Severe Crohn disease (adult)		<p><u>5. Severe Crohn disease (adult):</u></p> <p>The PBAC noted the impact of biosimilars on utilisation and expenditure remains uncertain, though infliximab and adalimumab will likely reduce in cost due to statutory price reductions.</p> <p>The PBAC did not recommend an amendment to the authority requirements for infliximab, ustekinumab, vedolizumab and adalimumab and noted a restriction change across PBS indications could be considered once biosimilars are well established and utilisation has stabilised.</p>
6. Infliximab, adalimumab	6. Crohn disease: moderate to severe and severe (paediatric)		<p><u>6. Crohn disease: moderate to severe and severe (paediatric):</u></p> <p>The PBAC noted the progressive decreases in expenditure are likely due to the introduction of biosimilars for infliximab and expect the decreases in expenditure to continue with the introduction of adalimumab biosimilars to the PBS on 1 April 2021.</p> <p>The PBAC did not recommend an amendment to the authority requirements for infliximab and adalimumab and noted a restriction change across PBS indications could be considered once biosimilars are well established and utilisation has stabilised.</p>
7. Infliximab, adalimumab	7. Fistulising Crohn disease		<p><u>7. Fistulising Crohn disease:</u></p> <p>The PBAC noted the number of prevalent patients for fistulising Crohn disease has increased year on year to 2020 indicating the market is not yet stable.</p> <p>The PBAC noted in 2020 the cost to the government based on published prices was just under \$30 million. The PBAC also noted there are no Deeds of Agreement in place for these medicines.</p> <p>The PBAC did not recommend an amendment to the authority requirements for infliximab and adalimumab and noted a restriction change across PBS indications could be considered once the market has stabilised, biosimilars are well established and utilisation has stabilised.</p>

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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
8. Adalimumab, infliximab, golimumab, vedolizumab	8. Ulcerative colitis (UC)		<p><u>8. Ulcerative colitis (UC):</u></p> <p>The PBAC noted in 2020, 57% of PBS expenditure across all medicines was for vedolizumab. The PBAC also noted there was a special pricing arrangement in place for vedolizumab, but no Deeds of Agreement in place for other medicines for UC. Overall, PBS expenditure increased by 12% from 2019 to 2020.</p> <p>The PBAC noted DUSC concerns that existing telephone/electronic authority approvals for continuing therapy may undermine the effectiveness of uptake drivers where adalimumab biosimilars are not yet well established.</p> <p>The PBAC did not recommend an amendment to the authority requirements for infliximab, adalimumab, vedolizumab and golimumab and considered a restriction change across PBS indications could be considered once biosimilars are well established and utilisation has stabilised.</p>
9. Nintedanib, pirfenidone	9. Idiopathic pulmonary fibrosis (IPF)		<p><u>9. Idiopathic pulmonary fibrosis (IPF):</u></p> <p>The PBAC agreed with DUSC advice that the market for IPF was not yet mature and still evolving, and that the number of TGA registered indications for nintedanib could be associated with a high risk of leakage although the Initial Authority restriction was considered rigorous.</p> <p>The PBAC did not recommend an amendment to the authority requirements for nintedanib or pirfenidone, given the immaturity of the market, the risk of leakage, the high cost of these medicines and the financial implications to the government.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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Submission category types

Category 1	A request for PBS or NIP listing of one or more of the following: <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	A request for PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication and do not meet the criteria for a Category 1 submission.
Category 3	Requests to change existing listings that do not change the population or cost-effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission.
Category 4:	A request for one or more of the following: <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.

Resubmission pathways

*There are four different resubmission pathways available to applicants following a 'not recommended' PBAC outcome. Resubmission pathways are not available for submissions that receive a positive recommendation from the PBAC. The resubmission pathways are classified into the following categories:	
Standard re-entry	The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where: <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	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.

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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>

Version 2

Amendment

1. ETANERCEPT (Enbrel®) – clarified ‘a’-flagging advice