PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 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	
ABROCITINIB Tablet 100 mg Tablet 200 mg Cibinqo® Pfizer Australia Pty Ltd Category 2 submission (New PBS listing)	Atopic dermatitis	To request a General Schedule Authority Required listing for the treatment of severe atopic dermatitis.	Not Applicable	To be considered at a future PBAC meeting
ACALABRUTINIB Capsule 100 mg Calquence® AstraZeneca Pty Ltd Standard Re-entry submission (Change to PBS listing)	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)	Resubmission to request a General Schedule Authority Required listing for previously untreated CLL or SLL patients who are considered unsuitable for treatment with fludarabine-based chemoimmunotherapy, and unsuitable for venetoclax in combination with obinutuzumab, or who develop intolerance to venetoclax with obinutuzumab necessitating permanent treatment withdrawal.	Not Recommended	The PBAC did not recommend the listing of acalabrutinib for the treatment of patients with previously untreated CLL or SLL, who are considered unsuitable for treatment with fludarabine-based chemoimmunotherapy and venetoclax + obinutuzumab, and for patients who permanently discontinue venetoclax + obinutuzumab due to intolerance. The previous submission considered in July 2020 was for a broader population of CLL/SLL patients unsuitable for fludarabine-based chemotherapy. <u>Comparator: chlorambucil + obinutuzumab</u> The PBAC agreed that this was the main comparator for the proposed population. However, the key clinical criteria for venetoclax + obinutuzumab unsuitability were subjective, and the PBAC recognised the issue that some patients/prescribers may prefer acalabrutinib as an oral therapy despite not being truly unsuitable for venetoclax + obinutuzumab. Based on the proposed PBS restriction, the PBAC considered venetoclax + obinutuzumab to be a relevant comparator.

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				Clinical claim: superior effectiveness and safety compared with chlorambucil + obinutuzumab The clinical claim was based on the ELEVATE-TN trial, previously considered by the PBAC in July 2020. The PBAC considered that a claim of superior comparative effectiveness was reasonable in relation to progression-free survival, noting the more mature data from the ELEVATE-TN trial in the resubmission with follow-up over approximately four years showed consistency of effect. At the same time, it remained of the view that overall survival data remained immature and there may not be a difference in overall survival over the longer term given subsequent lines of effective therapy are available. The PBAC considered that a superior safety claim was reasonable. Economic claim: cost-utility versus chlorambucil + obinutuzumab The economic analysis was highly uncertain, and the incremental cost-effectiveness ratio was likely underestimated. A revised model, with a price reduction and reduced time horizon, would be required for PBAC decision making. Additionally, the sponsor would be required to provide further evidence that a proposed expenditure cap could be realised in practice, as this was critical to the resubmission's cost-effectiveness estimates and financial impact.
				Sponsor's comment: The sponsor had no comment.

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ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe Hulio® Alphapharm Pty Ltd Category 3 submission (New PBS listing)	Severe Crohn disease; Moderate to severe ulcerative colitis; Severe active juvenile idiopathic arthritis; Complex refractory fistulising Crohn disease; Severe active rheumatoid arthritis; Severe psoriatic arthritis; Ankylosing spondylitis; Severe chronic plaque psoriasis; Moderate to severe hidradenitis suppurativa.	To request listing of adalimumab biosimilar under the same conditions as its reference biologic.	Recommended	The PBAC recommended the Authority Required listing of adalimumab (Hulio) in the form of 40 mg in 0.8 mL pre-filled syringe and pre-filled pen as a biosimilar brand of Humira®. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Hulio would be acceptable if it were cost-minimised to Humira for the same indications. The PBAC advised that, Abrilada®, Amgevita®, Hadlima®, Hulio, Humira, Hyrimoz® and Idacio® PFS should be treated as equivalent to each other; and Abrilada, Amgevita, Hadlima, Hulio, Humira, Hyrimoz and Idacio PFP should be treated as equivalent to each other for the purpose of substitution.
ADALIMUMAB Injection 80 mg in 0.8 mL pre-filled syringe Humira® AbbVie Pty Ltd Category 4 submission (Change to listing)	Severe Crohn disease; Moderate to severe ulcerative colitis.	To request General Schedule Authority Required listing of an additional strength of adalimumab as an induction dose for patients weighing less than 40 kg with Crohn disease or ulcerative colitis.	Recommended	The PBAC recommended Authority Required listings of adalimumab 80 mg/0.8 mL pre-filled syringe (PFS) (1 pack) as an induction dose for patients with moderate to severe ulcerative colitis or severe Crohn disease weighing less than 40 kg on the basis of cost neutrality with the existing listings of adalimumab 40 mg PFS (2 pack). The PBAC accepted that availability of adalimumab 80 mg/0.8 mL PFS on the PBS will provide an alternative treatment course for this patient population in which patients will require only one 80 mg injection instead of two 40 mg injections at induction of their treatment.

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AMIFAMPRIDINE Tablet 10 mg Ruzurgi® The Trustee For Orspec Pharma Unit Trust Category 1 submission (New PBS listing)	Lambert-Eaton myasthenic syndrome	To request a General Schedule Authority Required (Written) listing for the treatment of Lambert-Eaton myasthenic syndrome in adults and children aged six years and above.	Not Recommended	The PBAC did not recommend the listing of amifampridine for the treatment of Lambert-Eaton myasthenic syndrome in adults and children aged 6 years and above. The PBAC noted the high clinical need for effective treatments for these patients. The PBAC considered that the submission's claim of superior comparative effectiveness was reasonable, however the magnitude of the effect was uncertain due to the limitations of the available clinical evidence and the high risk of bias. The PBAC considered that amifampridine was inferior to placebo in terms of comparative safety. The PBAC considered the incremental cost effectiveness ratio was unacceptably high and uncertain at the proposed price. The PBAC nominated the Early Re-entry re-submission pathway for this item. Sponsor's comment: The sponsor had no comment.
APALUTAMIDE Tablet 60 mg Erlyand® Janssen-Cilag Pty Ltd Category 2 submission (New PBS listing)	Prostate cancer	To request a General Schedule Authority Required listing for the treatment of patients with metastatic hormone-sensitive prostate cancer who have low-volume disease, or who have high-volume disease and are too frail for chemotherapy.	Not Recommended	The PBAC did not recommend apalutamide for the treatment of metastatic hormone sensitive prostate cancer (mHSPC) in patients who have low volume (LV) disease, or high volume (HV) disease and who are unsuitable for chemotherapy. The PBAC noted that although apalutamide provides a moderate clinical benefit compared to androgen deprivation therapy alone for patients with mHSPC, it considered that there were issues with the listed contraindications and comorbidities for docetaxel unsuitability in the proposed restriction for the HV population and hence, the comparator proposed. The PBAC considered that the incremental cost effectiveness ratios presented in the submission were highly uncertain and likely underestimated. In addition, the PBAC considered that the financial impact estimates were high and likely overestimated.

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				Sponsor's comment: Janssen is disappointed that the PBAC did not recommend Erlyand and considers that the population requested for listing are the mHSPC patients with the highest clinical need for additional PBS therapies. Janssen does not agree with the PBAC's comment that apalutamide provides moderate clinical benefit versus ADT. The TITAN trial demonstrates that apalutamide is associated with a statistically significant and clinically important 39% reduction in the risk of death versus ADT after adjustment for treatment switching. Janssen recognise the challenges in defining the restriction for the requested population. However, inclusion of docetaxel as a comparator creates significant cost-effectiveness challenges for new agents to gain PBS reimbursement. We will review the details of the outcome to understand implications and consider next steps.
APALUTAMIDE Tablet 60 mg Erlyand® Janssen-Cilag Pty Ltd Standard Re-entry submission (New PBS listing)	Prostate cancer	Resubmission to request a General Schedule Authority Required listing for the treatment of castration-resistant prostate cancer with no distant metastases on conventional imaging.	Recommended	The PBAC recommended the listing of apalutamide for the treatment of patients with non-metastatic castration resistant prostate cancer. The PBAC was satisfied that apalutamide provides, for some patients, a moderate overall survival benefit compared to standard of care and was non-inferior in terms of efficacy and safety compared to darolutamide. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of apalutamide would be acceptable if it were cost-minimised to darolutamide. The PBAC recommended potential flow on changes to the PBS restrictions for darolutamide, abiraterone and enzalutamide to prevent the subsequent use of novel hormonal agents.

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AVALGLUCOSIDASE ALFA Powder for injection 100 mg in 10 mL Nexviazyme® Sanofi-Aventis Australia Pty Ltd Category 2 submission (New PBS listing)	Pompe disease	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of Pompe disease.	Not Recommended	The PBAC did not recommend the Section 100 (Highly Specialised Drugs Program) listing of avalglucosidase alfa (AVAL) for the treatment of infantile-onset Pompe disease (IOPD), juvenile-onset Pompe disease (JOPD) or adult-onset Pompe disease (AOPD). The primary comparator for AVAL was alglucosidase alfa (ALGLU), a medicine currently included on the life-saving drugs program for this population. The PBAC considered AVAL treatment for late onset Pompe disease (LOPD), including the AOPD and JOPD populations, was likely non-inferior to ALGLU. The PBAC considered the lack of evidence for the IOPD population made the clinical claim of non-inferiority for that population highly uncertain but that, overall, AVAL was likely to provide similar health outcomes to ALGLU. The PBAC considered AVAL was an effective treatment for IOPD and LOPD (compared to no treatment) but the extent of benefit was uncertain. The PBAC considered the incremental cost effectiveness ratio for AVAL compared to no treatment was very high and uncertain.
				Sponsor's comment: The sponsor had no comment.

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BEVACIZUMAB Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL Abevmy® Alphapharm Pty Ltd Category 3 submission (New PBS listing)	Relapsed or recurrent glioblastoma; Advanced (unresectable) Barcelona Clinic Liver Cancer; Stage B or Stage C hepatocellular carcinoma; Stage IV (metastatic) non-small cell lung cancer (NSCLC); Advanced carcinoma of cervix; Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer; Metastatic colorectal cancer.	To request listing of bevacizumab biosimilar under the same conditions as its reference biologic.	Recommended	The PBAC recommended the listing under Section 100 (Efficient Funding of Chemotherapy), of a new biosimilar brand of bevacizumab, Abevmy, for the same conditions as the currently listed biosimilar brand, Mvasi®. The PBAC's recommendation for listing was based on its assessment that the cost-effectiveness of Abevmy would be acceptable if it were cost-minimised to Mvasi.
BUDESONIDE Tablet (orally disintegrating) 0.5 mg Tablet (orally disintegrating) 1 mg Jorveza® Dr Falk Pharma Australia Pty Ltd Early Re-entry submission (New PBS listing)	Eosinophilic oesophagitis (EoE)	Resubmission to request an Authority Required listing for the treatment of EoE.	Recommended	The PBAC recommended the Authority Required (immediate assessment) listing of budesonide orally disintegrating tablets (BOT) for the treatment of EoE. The PBAC noted TGA approval for maintenance therapy of EoE and registration of BOT 0.5 mg for this indication. Although uncertainty remained regarding the cost-effectiveness, the PBAC considered BOT likely cost-effective at the proposed price. The PBAC considered the uptake used to inform the financial estimates and Risk Sharing Arrangement should be based on the March 2021 DUSC advice.

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BUPRENORPHINE Buvidal® Weekly: Injection (modified release) 8 mg in 0.16 mL pre-filled syringe Injection (modified release) 16 mg in 0.32 mL pre-filled syringe Injection (modified release) 24 mg in 0.48 mL pre-filled syringe Injection (modified release) 32 mg in 0.64 mL pre-filled syringe Buvidal® Monthly: Injection (modified release) 64 mg in 0.18 mL pre-filled syringe Injection (modified release) 96 mg in 0.27 mL pre-filled syringe Injection (modified release) 128 mg in 0.36 mL pre-filled syringe Injection (modified release) 160 mg in 0.45 mL pre-filled syringe (new strength) Buvidal® Weekly; Buvidal® Monthly Camurus Pty Ltd Category 2 submission (New PBS listing)	Opioid dependence	To request: a General Schedule listing in addition to the existing Section 100 (Opiate Dependence Treatment Program) listing under the same circumstances as the currently listed Buvidal®; listing an additional 160 mg strength of Buvidal Monthly under the same circumstances as the currently listed Buvidal Monthly; removing the requirement that a patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with Buvidal to align with recent regulatory updates by the TGA.	Recommended	The PBAC recommended the listing of the new form, 160 mg monthly prolonged release buprenorphine, for the treatment of opiate dependence on the basis that it should be available only under special arrangements under Section 100 for opiate dependence with restricted benefit. The PBAC also recommended changing the PBS restriction to remove the requirement for stabilisation on sublingual buprenorphine or sublingual buprenorphine/naloxone prior to commencing treatment with weekly prolonged release buprenorphine, consistent with the recent amendment to the TGA indication. The PBAC did not recommend the requested price increase and could not make a decision for the consideration of the Section 85 (Restricted Benefit) listing in addition to the current Section 100 (Opiate Dependence Treatment Program). The PBAC noted the current Post-market Review of Opiate Dependence Treatment Program medicines (ODTP PMR), which will consider barriers to access including affordability of ODTP medicines. The PBAC considered that the request for dual Section 85/100 listing should be informed by the ODTP PMR. The sponsor may wish to resubmit to the PBAC concerning these matters after the outcomes of the ODTP PMR become available.

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CABOTEGRAVIR Tablet containing cabotegravir 30 mg Vocabria® CABOTEGRAVIR AND RILPIVIRINE Pack containing 1 injection of cabotegravir 600 mg in 3 mL and 1 injection of rilpivirine 900 mg in 3 mL Cabenuva® ViiV Healthcare Pty Ltd Standard Re-entry submission (New PBS listing)	Human Immunodeficiency virus (HIV)	Resubmission to request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of HIV infection in adults who are virologically suppressed.	Recommended	The PBAC recommended the Section 100 (Highly Specialised Drugs Program – Community Access) listing of cabotegravir and rilpirivine long-acting injectable (CAB LA + RPV LA) for the management of HIV infection. In making this recommendation, the PBAC considered CAB LA + RPV LA to be of non-inferior comparative effectiveness to daily oral anti-retroviral therapy (ART) in terms of virologic suppression and recognised that some people living with HIV (PLHIV) in certain populations, such as Aboriginal and/or Torres Strait Islander people, those living in rural or remote settings, and individuals with complex living or social circumstances, had issues adhering to a daily oral regimen and would potentially have improved QoL from a long-acting injectable option administered in a clinical setting. The Committee welcomed the input from consumers and clinicians, which highlighted the potential benefits the listing of a long-acting injectable option may have for some PLHIV. The PBAC considered the magnitude of this benefit was difficult to quantify and differentiate from patient preference or convenience factors, which may also lead some patients to take up a long-acting injectable option. The PBAC considered that as CAB LA + RPV LA offers benefits in terms of quality of life and increased adherence for some PLHIV compared to daily oral ART, a premium over the least costly alternative daily oral ART option was reasonable.

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CEMIPLIMAB Solution for I.V. infusion 350 mg in 7 mL Libtayo® Sanofi-Aventis Australia Pty Ltd Category 2 submission (New PBS listing)	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with stage IV NSCLC expressing PD-L1 with a tumour proportion score ≥50%.	Recommended	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of cemiplimab for the treatment of previously untreated metastatic NSCLC, in patients with a programmed cell death ligand 1 (PD-L1) tumour proportion score (TPS) ≥50%. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of cemiplimab would be acceptable if it were cost-minimised against pembrolizumab. The PBAC advised that the equi-effective doses are cemiplimab 350 mg Q3W and pembrolizumab 200 mg Q3W. The PBAC advised flow on changes to the pembrolizumab NSCLC restriction criteria for consistency with the cemiplimab restriction criteria.
CEMIPLIMAB Solution for I.V. infusion 350 mg in 7 mL Libtayo® Sanofi-Aventis Australia Pty Ltd Standard Re-entry submission (New PBS listing)	Squamous cell carcinoma (SCC)	Resubmission to request Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of metastatic or locally advanced cutaneous SCC in patients who are not candidates for curative surgery or curative radiation.	Not Applicable	To be considered at a future PBAC meeting

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CLADRIBINE Tablet 10 mg Mavenclad® Merck Healthcare Pty Ltd Category 2 submission (Other business)	Multiple sclerosis	To request the PBAC consider the equi-effective doses of cladribine and other PBS-listed therapies for the treatment of relapsing-remitting multiple sclerosis.	Not Recommended	The PBAC did not recommend amending the existing equi-effective doses of cladribine and fingolimod (and other disease modifying therapies (DMTs)) for the treatment of relapsing-remitting multiple sclerosis (RRMS), on the basis that the evidence presented did not satisfactorily establish that 2 years of treatment with cladribine (plus 1 or 2 years of no treatment) is non-inferior to either 3 or 4 years of treatment with fingolimod. In making the decision not to recommend re-specifying the equi-effective doses, the PBAC considered the clinical comparison presented, primarily based on a naïve comparison of the extension phases of the CLARITY (cladribine) and FREEDOMS (fingolimod) studies was not reliable for decision-making due to a lack of comparability between the studies. Further, the PBAC considered that the real-world evidence presented was not reliable for the purposes of establishing non-inferiority as it did not include direct measures of the comparative effectiveness of cladribine and fingolimod in years 3 and 4. The PBAC considered that the existing equi-effective doses and therapeutic relativities for cladribine and fingolimod remained appropriate.
				Sponsor's comment: The sponsor had no comment.

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DAPAGLIFLOZIN Tablet 10 mg Forxiga® AstraZeneca Pty Ltd Matters Outstanding (Change to PBS listing)	Chronic kidney disease	To consider new information from the sponsor following deferral of both dapagliflozin submissions at the July 2021 PBAC meeting.	Not Recommended	The PBAC did not recommend extending the existing listing of dapagliflozin to include a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with chronic kidney disease. The PBAC reiterated that it was satisfied that dapagliflozin added to standard care provides, for some patients, a significant improvement in efficacy over standard care alone. The PBAC remained of the view that the listing would be cost-effective at the price proposed in the pre-PBAC response from July 2021. However, the revised financial estimates remained high and uncertain, and did not form a reliable basis for a Risk Sharing Arrangement with the Australian Government. The PBAC considered that the outstanding issues could be easily resolved in a simple resubmission for dapagliflozin using the early re-entry pathway. <u>Sponsor's comment</u>: The sponsor had no comment.
DARATUMUMAB Solution for subcutaneous injection 1,800 mg in 15 mL vial Darzalex® SC Janssen-Cilag Pty Ltd Category 1 submission (New PBS listing)	Amyloid light-chain (AL) amyloidosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing, for use in combination with cyclophosphamide, bortezomib and dexamethasone, for the treatment of patients with newly diagnosed AL amyloidosis.	Not Recommended	The PBAC did not recommend daratumumab SC, for use in combination with cyclophosphamide, bortezomib and dexamethasone (CyBorD) for the treatment of patients with newly diagnosed systemic AL amyloidosis. The PBAC recognised that there are no treatments on the PBS available specifically for this condition, and it considered that the addition of daratumumab SC plus CyBorD offered high added therapeutic value. However, the PBAC considered that there were uncertainties in the cost-effectiveness analysis and financial estimates, particularly due to the overlap between patients with AL amyloidosis and multiple myeloma. The PBAC considered that these uncertainties could be managed through a re-specified economic analysis that included more conservative assumptions, and a Risk Sharing Arrangement. The PBAC nominated the Early Resolution re-submission pathway for this item.

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				Sponsor's comment: Whilst Janssen is disappointed that the PBAC did not recommend daratumumab for systemic AL amyloidosis, we welcome the PBAC's nomination of the early resolution pathway having recognised that daratumumab offered high added therapeutic value for a population with high and urgent unmet medical need for PBS reimbursed treatment. Janssen remains committed to ensuring people with AL amyloidosis can access the best available treatments and will review the details of the outcome and the PBAC's requirements to move forward with the early resolution pathway.
ECULIZUMAB Solution concentrate for I.V. infusion 300 mg in 30 mL Soliris® Alexion Pharmaceuticals Australasia Pty Ltd Standard Re-entry submission (Change to PBS listing)	Neuromyelitis optica spectrum disorder (NMOSD)	Resubmission to request an Authority Required (Written) listing for the treatment of patients with relapsing NMOSD who are anti-aquaporin-4 (AQP4) antibody positive.	Not Recommended	The PBAC did not recommend the listing of eculizumab for the treatment of patients with NMOSD who are AQP4 antibody positive. Although the PBAC considered that eculizumab was more effective than best supportive care in reducing relapses, the magnitude of this effect on disability progression and quality of life remained highly uncertain. The PBAC noted that although the resubmission partly addressed some of the concerns with the economic model, the incremental cost effectiveness ratio (ICER) remained excessively high (> $1,055,000 per quality adjusted life year) and advised that a substantial price reduction would be required to achieve an acceptable ICER. The PBAC noted that although the number of eligible patients had been reduced compared to the November 2020 submission, as eculizumab was proposed as a lifelong prophylactic treatment, at the proposed price, the cost of listing remained high. Comparator: Best supportive care/placebo The PBAC accepted that best supportive care was an appropriate comparator but considered that rituximab is

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				also a relevant compactor and a formal comparison would be informative. <u>Clinical claim: Superior effectiveness and non-inferior safety compared with best supportive care/placebo</u> The PBAC considered that eculizumab was more effective than best supportive care/placebo in reducing relapses; however, the magnitude of this effect on disability progression and quality of life outcomes remained highly uncertain. The PBAC considered that the claim of non-inferior comparative safety was reasonable. <u>Economic claim: Cost-utility analysis compared with best supportive care/placebo.</u> The PBAC considered the ICER remained unacceptably high. The PBAC noted that the resubmission only partly addressed some of the issues raised in response to the original submission.
				<u>Sponsor's comment</u>: There are no TGA approved therapies reimbursed for neuromyelitis optica spectrum disorder (NMOSD) in Australia and given the severity and rare nature of this disease, Alexion is committed to continue to work with the Government to reach an agreement that ensures equitable access for people living with this devastating disease.

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EMPAGLIFLOZIN Tablet 10 mg Jardiance® Boehringer Ingelheim Pty Ltd Category 2 submission (Change to PBS listing)	Chronic heart failure	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with chronic heart failure with reduced ejection fraction.	Recommended	The PBAC recommended the listing of empagliflozin for the treatment of patients with chronic heart failure with reduced ejection fraction (HFrEF), New York Heart Association classification II-IV, left ventricular ejection fraction (LVEF) ≤40%, who are receiving standard care including a beta blocker, and an angiotensin-converting enzyme inhibitor (ACEi), or an angiotensin II receptor blocker (ARB), or an angiotensin receptor with neprilysin inhibitor (ARNi). Although the submission presented a modelled economic evaluation against standard of care, the PBAC's recommendation for listing was based on its assessment that the cost-effectiveness of empagliflozin would be acceptable if it were cost-minimised against dapagliflozin, which was recommended for listing of this indication at the PBAC's September 2021 Intracycle meeting. The PBAC considered that a claim of non-inferior comparative effectiveness was adequately supported by the clinical evidence and international clinical guidelines, and advised that empagliflozin for HFrEF should share the expenditure caps that the PBAC had recommended for a Risk-Sharing Arrangement for dapagliflozin. The PBAC considered that the equi-effective doses were empagliflozin 10 mg per day and dapagliflozin 10 mg per day.
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS Sachets containing oral powder 12.5 g, 30 EAA Supplement™ Vitaflo Australia Pty Limited Category 4 submission (Change to PBS listing)	Gyrate atrophy of the choroid and retina; Urea cycle disorders	To request EAA Supplement with new formulation and new pack size continue to be listed on the PBS; and to request a change of maximum quantity from four packs (200 sachets) to six packs (180 sachets).	Recommended	The PBAC recommended the listing of EAA Supplement with new formulation, pack size and maximum quantity to replace the current PBS listed EAA Supplement.

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ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4 Rymti® Alphapharm Pty Ltd Category 3 submission (New PBS listing)	Rheumatoid arthritis; Plaque psoriasis; Ankylosing spondylitis; Psoriatic arthritis; Juvenile idiopathic arthritis; Paediatric plaque psoriasis.	To request listing of etanercept biosimilar under the same conditions as its reference biologic, with exclusion of children and adolescents who weigh less than 62.5 kg.	Recommended	The PBAC recommended the Authority Required listing of Rymti in the form of 50 mg in 1 mL pre-filled syringe as a biosimilar brand of Enbrel®. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Rymti would be acceptable if it were cost-minimised to Enbrel. The PBAC advised that, the same form and strength of Brenzys®, Enbrel and Rymti should be treated as equivalent to each other for the purpose of substitution.

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FLUTICASONE FUROATE WITH UMECLIDINIUM AND VILANTEROL Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 doses Trelegy® Ellipta® 200/62.5/25 GlaxoSmithKline Australia Pty Ltd Category 2 submission (New PBS listing)	Severe asthma	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe asthma.	Recommended	The PBAC recommended the Authority Required (STREAMLINED) listing of fluticasone furoate (FF) with umeclidinium (UMEC) and vilanterol (VI) fixed dose combination (FDC) for maintenance therapy of severe asthma. The recommended listing is for one strength: FF/UMEC/VI 200/62.5/25 mcg. The PBAC considered the claim of non-inferior effectiveness and safety to the FDC of mometasone furoate (MF) 136 mcg, with indacaterol (IND) 114 mcg and glycopyrronium (GLY) 46 mcg was reasonable. The PBAC considered for purposes of satisfying Section 101(3B) of the *National Health Act 1953*, any high dose inhaled corticosteroid (ICS) with long-acting beta2-agonist (LABA) + tiotropium (TIO) combination are relevant alternative therapies. The PBAC's recommendation was therefore, among other matters, based on its assessment that the cost of FF/UMEC/VI should be no greater than the lowest price combination of the PBS listed components of triple therapy that are available for asthma at comparable doses. Flow-on restriction changes to the MF/IND/GLY FDC and tiotropium severe asthma listings were also recommended to make it consistent with FF/UMEC/VI, which includes amendment to an Authority Required (STREAMLINED) listing (MF/IND/GLY only; tiotropium would remain a Restricted Benefit).

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FOLLITROPIN ALFA 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 Gonal-f® Pen Merck Healthcare Pty Ltd Category 2 submission (Other business)	Assisted reproductive technology	To request the PBAC consider the therapeutic relativities of Gonal-f Pen and biosimilar therapies.	Not Recommended	The PBAC did not recommend an increase to the price of Gonal-f as it considered that the clinical claim of the superior comparative effectiveness of Gonal-f to all of the follitropin alfa biosimilars was not adequately supported by the data presented in the submission. The PBAC also reaffirmed its previous advice that Gonal-f and Ovaleap® should be treated as equivalent to each other for the purposes of substitution.
				Sponsor's comment: The sponsor had no comment.

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GEMTUZUMAB OZOGAMICIN Powder for Injection 5 mg Mylotarg® Pfizer Australia Pty Ltd Standard Re-entry submission (New PBS listing)	Acute myeloid leukaemia (AML)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing for use in combination with standard intensive chemotherapy, for patients with previously untreated de novo CD33-positive AML, except acute promyelocytic leukaemia, who do not have a unfavourable cytogenetic profile.	Recommended	The PBAC recommended the listing of gemtuzumab ozogamicin, in combination with standard intensive chemotherapy (an anthracycline and cytarabine), for the treatment of patients with previously untreated, de novo CD33-positve AML except acute promyelocytic leukaemia, who have favourable/intermediate/unknown cytogenetic risk (where the unknown risk is due to inconclusive test results). The PBAC recommended that gemtuzumab ozogamicin should be available only under special arrangements under Section 100 (Efficient Funding of Chemotherapy Program). The PBAC is satisfied that gemtuzumab ozogamicin provides, for some patients, a significant improvement in efficacy over standard of care. The PBAC remained of the view that the exact magnitude of the overall survival benefit was difficult to determine, and that the economic model was complex and difficult to assess. Nonetheless, although the resubmission had not addressed all areas of uncertainty, the PBAC considered that the cost-effectiveness of the listing would be acceptable, in the context of a reduced price offered and a high clinical need in a smaller, more defined population of patients most likely to see benefit, than that which had been assumed by the resubmission.

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GILTERITINIB Tablet 40 mg (as fumarate) Xospata® Astellas Pharma Australia Pty Ltd Category 2 submission (New PBS listing)	Acute myeloid leukaemia (AML)	To request a General Schedule Authority Required listing for the treatment of relapsed or refractory FLT3 mutation-positive AML.	Not Recommended	The PBAC did not recommend the listing of gilteritinib for the treatment of relapsed or refractory FLT3 mutation-positive AML. The PBAC considered that the clinical claim of superior effectiveness over salvage chemotherapy may be reasonable, but that long-term survival was uncertain based on the available evidence. The PBAC considered that revisions to the inputs for the economic model were required, including, among other matters, removing use as maintenance therapy post hematopoietic stem-cell transplantation (HSCT), reducing the time horizon, and adjusting the point at which patients can be considered cured. A price reduction would be required to achieve cost-effectiveness under this revised scenario, and a resubmission would need to make corresponding updates and other changes to the financial estimates. The PBAC nominated the Early Re-entry re-submission pathway for this item.
				Sponsor's comment: Astellas Pharma Australia welcomes the PBAC feedback and will work towards the early re-entry re-submission pathway to resolve the outstanding issues, so patients in Australia with refractory or relapsed FLT3 mutation AML can greatly benefit from gilteritinib being available through the PBS.

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IMATINIB Tablet 600 mg Imatab® Juno Pharmaceuticals Pty Ltd Committee Secretariat submission (New PBS listing)	Chronic myeloid leukaemia (CML); Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL); Myelodysplastic or myeloproliferative disorder (MDS/MPD); Aggressive systemic mastocytosis (ASM) with eosinophilia; Chronic eosinophilic leukaemia (CEL) or Hypereosinophilic syndrome (HES); Dermatofibrosarcoma protuberans (DFSP); Gastrointestinal stromal tumour (GIST); Malignant GIST.	To request listing of an additional strength under the same circumstances as the currently listed imatinib.	Recommended	The PBAC recommended the listing of imatinib (Imatab) 600 mg tablets on a cost-minimisation basis to the existing PBS listed imatinib 100 mg and 400 mg tablets, and under the same circumstances as the restrictions that allow for a daily dose of 600 mg with the exception of not allowing prescribers to request an increase to the maximum quantity.
INSULIN ASPART Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 Injections (human analogue), pre-filled pen, 100 units per mL, 3 mL, 5 Truvelog®; Truvelog® Solostar Sanofi-Aventis Australia Pty Ltd Category 3 submission (New PBS listing)	Diabetes mellitus	To request listing of insulin aspart biosimilars under the same conditions as their reference brands.	Recommended	The PBAC recommended the listing of a new biosimilar brand of insulin aspart in the form of 100 IU/mL cartridge (Truvelog) and 100 IU/mL pre-filled pen (Truvelog Solostar), under the same circumstances as the PBS-listed reference brands, NovoRapid Penfill and NovoRapid Flexpen. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Truvelog and Truvelog Solostar would be acceptable if they were cost-minimised to NovoRapid Penfill and NovoRapid Flexpen respectively.

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IXEKIZUMAB Injection 80 mg in 1 mL single dose pre-filled pen Taltz® Eli Lilly Australia Pty Ltd Category 2 submission (Change to PBS listing)	Non radiographic axial spondyloarthritis (nr-axSpA)	To request a General Schedule Authority Required (Written) listing for the treatment of nr-axSpA, under the same circumstances as currently PBS listed biological disease-modifying antirheumatic agents for this indication.	Recommended	The PBAC recommended the Authority Required listing of ixekizumab for the treatment of nr-axSpA. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of ixekizumab would be acceptable if it were cost-minimised to the least costly biologic disease-modifying anti-rheumatic drug (bDMARD) for this indication. The PBAC noted the flow-on restriction changes to other bDMARD listings for nr-axSpA to include ixekizumab in the administrative notes that lists eligible therapies for this indication.
LAROTRECTINIB Capsule 25 mg Capsule 100 mg Oral solution 20 mg per mL, 100 mL Vitrakvi® Bayer Australia Ltd Standard Re-entry submission (New PBS listing)	Solid tumours harbouring neurotrophic receptor tyrosine kinase (NTRK) gene fusions	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult and paediatric patients with locally advanced or metastatic solid tumours harbouring NTRK gene fusions.	Deferred	<u>Paediatric NTRK fusion population and adult high frequency NTRK fusion population</u> The PBAC deferred making its decision on whether to recommend the listing of larotrectinib for the treatment of patients with NTRK fusion tumours that are either unresectable locally advanced, metastatic, or locally advanced and would otherwise require disfiguring surgery or limb amputation to achieve a complete surgical resection. The PBAC was of a mind to recommend the listing for paediatric patients with NTRK fusion tumours and adult patients with high frequency NTRK fusion tumours on the basis that the ICER was acceptable at the proposed price, pending MSAC advice on the funding of the codependent NTRK testing. <u>Adult with low frequency NTRK fusion population</u> The PBAC did not recommend the listing of larotrectinib for the treatment of adult patients with low frequency NTRK fusion tumours that are either unresectable locally advanced, metastatic, or locally advanced and would otherwise require disfiguring surgery or limb amputation to achieve a complete surgical resection. The PBAC considered that the incremental cost-effectiveness ratio (ICER) for this population remained high and uncertain. Further, the PBAC considered there is less unmet clinical need within this

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				patient population given there are effective alternative treatments available for adult low frequency NTRK fusion tumours. The PBAC considered that an incremental benefit of larotrectinib compared to Standard of Care in the adult low frequency subgroup was not clearly supported by the additional larotrectinib single-arm data and noted that the data remained immature at the latest data cut. The PBAC advised that, given there would unlikely be sufficient data forthcoming to address the uncertainty around the effectiveness of larotrectinib, a further substantial price reduction would be required to achieve a cost-effective price. <u>Comparator: Standard of Care (SoC)</u> The PBAC considered that the comparators specified in the resubmission were more representative of current SoC in the last treatment line setting where larotrectinib is proposed to be used in the adult low frequency subgroup. <u>Clinical claim: Superior effectiveness and non-inferior safety compared with SoC</u> The PBAC maintained its previous consideration that the claim of superior effectiveness compared to SoC for the low frequency adult population was not sufficiently supported. The PBAC maintained that, overall, the available data indicated a manageable safety profile for larotrectinib, although there were insufficient data to assess the long-term safety of larotrectinib.

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				Economic claim: Cost-utility analysis compared with SoC The PBAC considered the ICER was uncertain and likely underestimated given there was insufficient evidence to support an incremental benefit compared to SoC. The PBAC noted that the analysis for the adult low frequency tumour subgroup was particularly sensitive to the time horizon, OS and PFS extrapolation and duration of lenvatinib SoC treatment duration.
				Sponsor's comment: Bayer welcomes the PBAC's minded recommendation for the paediatric patients with NTRK gene fusion tumours and adult patients with high frequency NTRK gene fusion tumours. Bayer will continue to work with the PBAC to enable earliest possible access to larotrectinib for these patients following MSAC's outcome. Bayer is disappointed the PBAC did not recommend larotrectinib for adult low frequency NTRK gene fusion population. Bayer maintains larotrectinib provides significant clinically relevant benefit for all patients with solid tumours harbouring a NTRK gene fusion. Bayer will continue to work with the PBAC and collaborate with all stakeholders to find a suitable path forward for the adult with low frequency NTRK gene fusion patient population.

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MECASERMIN Solution for injection 40 mg in 4 mL vial Increlex® Ipsen Pty Ltd Category 1 submission (New PBS listing)	Primary insulin-like growth factor 1 deficiency (Primary IGFD)	To request a Section 100 Authority Required (Written) listing for the treatment of children and adolescents with growth failure due to primary IGFD.	Not Recommended	The PBAC did not recommend mecasermin for the long-term treatment of growth failure in children and adolescents from 2 to 18 years with severe Primary IGFD. The PBAC noted that no other therapies are currently available for this condition. The PBAC considered that a claim of superior efficacy was reasonable based on improved height outcomes, however mecasermin has inferior safety when compared with no treatment. The PBAC considered the proposed PBS criteria inadequately defined the appropriate patient population. The PBAC considered that the incremental cost effectiveness ratio was high and uncertain at the proposed price, and that further validation of the estimated utilisation was required. The PBAC nominated the Early Re-entry re-submission pathway for this item.
				Sponsor's comment: Ipsen thanks the PBAC for their recognition of the unmet need in patients with severe Primary IGFD, and looks forward to further working with the committee in order to reach an outcome for children with this rare condition.

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MEPOLIZUMAB Injection 100 mg in 1 mL single dose pre-filled pen Nucala® GlaxoSmithKline Australia Pty Ltd Category 1 submission (Change to PBS listing)	Chronic rhinosinusitis with nasal polyps	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of chronic rhinosinusitis with nasal polyps.	Not Recommended	The PBAC did not recommend mepolizumab for treatment of chronic rhinosinusitis (CRS) with nasal polyps (NP; collectively CRSwNP) for patients who have received at least one previous surgery for the removal of NP. Overall, the PBAC considered the clinical claim of superior effectiveness compared SoC was reasonable in patients with CRSwNP. However, the PBAC considered the blood eosinophil count (BEC) threshold for access to mepolizumab should be increased from ≥150 cells/µL to ≥300 cells/µL. The PBAC considered that the submission had underestimated the incremental cost-effectiveness ratio (ICER) due to reliance on optimistic assumptions and inputs in the economic model. The PBAC considered the revised base case proposed by ESC was appropriate and that the resulting revised ICER high and uncertain at the proposed price. The PBAC considered the financial estimates were highly uncertain and advised that a Risk Sharing Arrangement would be required if patients unsuitable for surgery were to be included.
				Sponsor's comment: GSK looks forward to working with the PBAC to ensure timely access to mepolizumab (Nucala) for people with chronic rhinosinusitis with nasal polyps (CRSwNP), a chronic condition with limited treatment options currently available in Australia.

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NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® Bristol-Myers Squibb Australia Pty Ltd Category 2 submission (Change to PBS listing)	Non-human epidermal growth factor receptor 2 (HER-2) positive gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with advanced or metastatic non-HER-2-positive gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma.	Not Recommended	The PBAC did not recommend the listing of nivolumab in combination with chemotherapy for the treatment of treatment of advanced or metastatic non-HER-2 positive advanced or metastatic gastric cancer, gastro-oesophageal junction cancer, or oesophageal adenocarcinoma. The PBAC noted that the clinical need for effective treatments in this therapeutic area is high, given the poor prognosis for patients and the poor efficacy and high toxicity of current treatments. The PBAC considered the evidence presented demonstrated treatment with nivolumab resulted in a clinically meaningful improvement in progression free survival and overall survival. However, the PBAC considered the incremental cost-effectiveness ratio in this setting at the proposed price was high and moderately uncertain. The PBAC nominated the Early Resolution re-submission pathway for this item.
				Sponsor's comment: Bristol-Myers Squibb Australia looks forward to continuing to work with the PBAC and the Department of Health to provide access to nivolumab plus chemotherapy for the first-line treatment of patients with non-HER2-positive advanced or metastatic gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma.

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OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® AstraZeneca Pty Ltd Standard Re-entry (Change to PBS listing)	Prostate cancer	Resubmission to request a General Schedule Authority Required listing for the treatment of adult patients with metastatic castration-resistant prostate cancer and homologous recombination repair BRCA1/2 gene variants (somatic and/or germline) who have progressed following a prior novel hormonal agent.	Recommended	The PBAC recommended olaparib for the treatment of metastatic castration resistant prostate cancer in patients with BRCA1 and BRCA2 pathogenic gene variants. The PBAC was satisfied that olaparib provides, for some patients, a significant improvement in efficacy over standard care (SoC), based on the results of the PROfound study. The PBAC considered that the mixed comparator of best supportive care (BSC) and cabazitaxel sufficiently reflected SoC in current Australian clinical practice and the comparator arm from the PROfound study could reasonably be used as a proxy for SoC. The PBAC noted that the resubmission had addressed a number of its previous concerns with the economic model and considered that the incremental cost-effectiveness ratio was within a cost-effective range despite some remaining uncertainty regarding the extent of the overall survival gain and the BRCA testing component.
OMALIZUMAB Xolair® Novartis Pharmaceuticals Australia Pty Limited Category 4 submission (New PBS listing)	Uncontrolled severe asthma; Severe chronic spontaneous urticaria; Uncontrolled severe allergic asthma	To combine the existing listings of 75 mg and 150 mg strengths to allow patients requiring 225mg and 375mg, respectively, to pay a single co-payment.	Not Recommended	The PBAC did not recommend combining the existing listings of the 75 mg and 150 mg strengths of omalizumab (Xolair) pre-filled syringe (PFS) under the Section 100 (Highly Specialised Drugs Program). The PBAC noted that the consumer comments described the financial burden to some patients who are currently paying two monthly co-payments for the treatment of uncontrolled severe allergic asthma. The PBAC considered that a solution to allow affected patients to pay a single monthly co-payment instead of two monthly co-payments would be that: i) the sponsor seeks the ARTG registration of a co-pack or other form that provides for the required dose; and ii) seeks PBS listing of this product or products. The PBAC would welcome a submission for a co-pack of omalizumab 75 mg and 150 mg PFS.
				Sponsor's comment: Novartis is unable to supply a co-pack for Xolair PFS for reasons outlined in the submission, and is disappointed that the PBAC has not recommended the proposed alternative.

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PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd Standard Re-entry submission (Change to PBS listing)	Squamous cell carcinoma of the head and neck (SCCHN)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of recurrent or metastatic SCCHN.	Deferred	The PBAC deferred its decision regarding pembrolizumab (Keytruda®) for first line treatment of recurrent or metastatic SCCHN in patients with programmed death ligand 1 (PD-L1) combined positive score (CPS) >1. The PBAC considered that, based on the data provided, pembrolizumab plus chemotherapy was clinically superior to first-line chemotherapy alone in the CPS ≥1 population and also in the allcomers population (regardless of CPS). The PBAC considered that, based on the results of the Keynote 048 trial, it is not possible to determine whether patients with CPS <1 derive benefit from pembrolizumab + chemotherapy as the trial was not powered to show a difference between CPS ≥1 and CPS <1. A statistically significant survival benefit was observed in the allcomers population treated with pembrolizumab plus chemotherapy at the interim analysis and the final analysis. The PBAC advised that, on this basis, it was preferable that listing of pembrolizumab in combination with chemotherapy not exclude patients with CPS <1. The PBAC considered that the claim of superior comparative effectiveness for pembrolizumab monotherapy was adequately supported by the data for patients with CPS ≥20. The PBAC was of a mind to recommend listing of pembrolizumab as the committee considered that the incremental cost-effectiveness ratios could be brought into an acceptable range with a price reduction, noting that the areas of uncertainty in the economic model had been somewhat reduced in the resubmission. The PBAC noted that advice from the Medical Services Advisory Committee (MSAC) was required regarding the PD-L1 testing component of the codependent submission. Subject to this advice, the PBAC expressed a preference for recommending the CPS ≥20 threshold for pembrolizumab monotherapy and an allcomers population for

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				pembrolizumab plus chemotherapy, noting that a greater price reduction would be required for the latter broader population compared to restricting to a CPS ≥1 threshold.
				Sponsor's comment: MSD welcomes the opportunity to work with PBAC and MSAC to expedite availability of pembrolizumab for patients with recurrent or metastatic squamous cell carcinoma of the head and neck.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd Category 2 submission (Change to PBS listing)	Oesophageal carcinoma or human epidermal growth factor receptor 2 (HER2)-negative gastroesophageal adenocarcinoma	To request listing a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of locally advanced or metastatic oesophageal carcinoma or HER-2-negative gastroesophageal junction adenocarcinoma.	Not Recommended	The PBAC did not recommend the listing of pembrolizumab, in combination with platinum-based chemotherapy, for the treatment of locally advanced (Stage III) or metastatic (Stage IV) oesophageal adenocarcinoma or oesophageal squamous cell carcinoma, or HER2-negative adenocarcinoma of the gastro-oesophageal junction. The PBAC noted the high clinical need for effective treatments in this therapeutic area. The PBAC considered the evidence presented demonstrated there was a clinically meaningful improvement in progression free survival and overall survival with pembrolizumab. However, the PBAC considered the incremental cost-effectiveness ratio in this setting at the proposed price was high and moderately uncertain. The PBAC nominated the Early Resolution re-submission pathway for this item.
				Sponsor's comment: MSD is pleased that the PBAC has recognised the high added therapeutic value that Keytruda® offers patients with oesophageal/GOJ cancer. MSD is looking forward to working with the PBAC to provide access to Keytruda® for this patient group as early as possible through the early resolution pathway.

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PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 15 VALENT ADSORBED 0.5 mL in pre-filled syringe Trade name to be confirmed Merck Sharp & Dohme (Australia) Pty Ltd Category 2 submission (New listing)	Prevention of pneumococcal disease	To request National Immunisation Program listing for the prevention of pneumococcal disease.	Recommended	The PBAC recommended that a 15-valent pneumococcal conjugate vaccine be a designated vaccine for the purposes of the *National Health Act 1953*, for the prevention of pneumococcal disease in non-Indigenous adults aged ≥70 years, Indigenous adults aged ≥50 years, and individuals at increased risk of pneumococcal disease aged ≥18 years. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of the 15-valent pneumococcal conjugate vaccine would be acceptable if it were cost-minimised against the nominated comparator, Prevenar 13 (a 13-valent pneumococcal conjugate vaccine).
POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL Eye drops 4mg-3mg per mL, single dose units 0.8 mL, 30 Systane® Alcon Laboratories (Australia) Pty Ltd Category 4 submission (Change to PBS listing)	Severe dry eye syndrome	To request a change in pack size from a pack of 28 x 0.8 mL unit doses to 30 x 0.8 mL unit doses.	Recommended	The PBAC recommended listing a new pack size of Systane (polyethylene glycol 400 with propylene glycol) eye drops with 30 x 0.8 mL unit doses at the same price per unit as the currently listed 28 x 0.8 mL unit doses pack.

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PREGABALIN Tablet 82.5 mg Tablet 165 mg Tablet 330 mg Lyrica® CR Upjohn Australia Pty Ltd Category 2 submission (New PBS listing)	Neuropathic pain	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of neuropathic pain in adults, where this condition is refractory to treatment with other drugs.	Deferred	The PBAC deferred making a recommendation for the listing of a controlled-released formulation of pregabalin (pregabalin CR) for the treatment of neuropathic pain to allow for utilisation analysis of immediate release pregabalin (pregabalin IR) and to further consider the potential quality use of medicines (QUM) issues with the CR formulation. The PBAC expressed concern about reports of potential misuse and diversion of pregabalin (and gabapentinoids more broadly) in Australia. The Committee considered it was prudent to review the utilisation of pregabalin and to consider current evidence of misuse and diversion in Australia prior to forming a view as to whether additional forms of pregabalin should be recommended for listing on the PBS. Furthermore, the PBAC had additional QUM concerns specifically related to pregabalin CR which require further consideration, including the risk of prescribing errors, increased confusion amongst prescribers and patients and other factors unique to the controlled release formulation. The PBAC referred the matter of pregabalin use to the Drug Utilisation Sub-Committee (DUSC) for consideration at a future meeting.
				Sponsor's comment: The sponsor had no comment.

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PREGABALIN Oral solution 20 mg per mL, 473 mL Pregabalin-AFT® AFT Pharmaceuticals (Au) Pty Ltd Category 4 submission (New PBS listing)	Neuropathic pain	To request an Authority Required (STREAMLINED) listing of pregabalin solution under the same circumstances as the existing listings of pregabalin capsules.	Deferred	The PBAC deferred making a recommendation for the listing of pregabalin 20 mg per mL oral liquid (Pregabalin-AFT) for the treatment of neuropathic pain to allow for a review of the utilisation of the currently listed immediate release pregabalin capsules and to further consider potential quality use of medicines issues. The PBAC expressed concern about reports of potential misuse and diversion of pregabalin (and gabapentinoids more broadly) in Australia. The Committee considered it was prudent to review the utilisation of pregabalin and to consider current evidence of misuse and diversion in Australia prior to forming a view as to whether additional forms of pregabalin should be recommended for listing on the PBS. The PBAC referred the matter of pregabalin use to the Drug Utilisation Sub-Committee (DUSC) for consideration at a future meeting. Sponsor's comment: The sponsor had no comment.
PROGESTERONE Pessary 200 mg Oripro® Orion Laboratories Pty Ltd Category 4 submission (Change to PBS listing)	Prevention of preterm birth	To request an increase of maximum quantity from 2 packs (30 units) to 3 packs (45 units), and a decrease in number of repeats from 5 to 3.	Recommended	The PBAC recommended increasing the maximum quantity from 30 pessaries (2 packs) to 45 pessaries (3 packs) and reducing the number of repeats from 5 to 3 of the PBS listed progesterone 200 mg pessary (Oripro) for the prevention of preterm birth, to align the number of patient co-payments with another brand of progesterone (Utrogestan®).

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REGORAFENIB Tablet 40 mg (as monohydrate) Stivarga® Bayer Australia Ltd Standard Re-entry submission (New PBS listing)	Colorectal cancer	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for beyond second-line treatment of patients with metastatic colorectal cancer.	Not Recommended	The PBAC did not recommend the listing of regorafenib for the treatment of metastatic colorectal cancer (mCRC) after treatment with two or more prior therapies, on the basis that the evidence presented indicated regorafenib is toxic and would adversely impact patients' overall quality of life, whilst having a limited impact on prognosis. The PBAC considered while there was a clinical need for additional safe and effective later-line therapies in mCRC, the modest efficacy and poor safety profile of regorafenib meant it did not fulfil this need. <u>Comparator: Trifluridine/tipiracil</u> The PBAC considered this was reasonable. <u>Clinical claim: Regorafenib is of non-inferior comparative effectiveness and safety to trifluridine/tipiracil</u> Despite uncertainties with the indirect comparisons and variability with the sensitivity analyses, the PBAC considered the claim of non-inferior comparative effectiveness to trifluridine/tipiracil was likely to be reasonable. The PBAC noted the evidence presented indicated regorafenib is associated with significant risk of adverse events, including many of grade III or higher severity. The PBAC was particularly concerned about the high number of hand-foot skin reactions of this severity (16.6% in the CORRECT trial) and the impact on patients' ability for self-care. It was also noted more than 7% of patients experienced diarrhoea at this level of severity, which may require hospitalisation. The PBAC also noted the TGA black box warning for rare cases of fatal hepatotoxicity. The Committee considered regorafenib and trifluridine/tipiracil have distinct adverse event profiles, however it was noted the haematological adverse effects of

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				trifluridine/tipiracil are generally easier to manage than the severe dermatological reactions with regorafenib, and regorafenib was associated with statistically significantly higher rates of adverse events leading to treatment discontinuation. Based on the available evidence, the PBAC did not agree with the submission's claim of non-inferior comparative safety to trifluridine/tipiracil and considered reforafenib was likely inferior. <u>Economic claim: Cost minimisation approach versus trifluridine/tipiracil based on drug costs only.</u> The PBAC considered the cost minimisation approach inappropriately did not include costs for differing adverse event management costs between regorafenib and trifluridine/tipiracil.
				<u>Sponsor's comment</u>: Bayer is disappointed the PBAC did not recommend regorafenib for an additional later-line therapy for treatment of patients with mCRC.
RISANKIZUMAB Injection 150mg in 1 mL pre-filled pen Injection 150mg in 1 mL pre-filled syringe Skyrizi® AbbVie Pty Ltd Category 4 submission (New PBS listing)	Severe chronic plaque psoriasis	To request listing of new forms of risankizumab under the same circumstances as the currently listed risankizumab.	Recommended	The PBAC recommended the listing of risankizumab 150 mg/1 mL pre-filled pen (PFP) and 150 mg/1 mL PFS under the same circumstances as the currently listed risankizumab 75 mg/0.83 mL pre-filled syringe (PFS), on a cost-minimisation basis with the least costly biologic currently listed on the PBS for chronic plaque psoriasis.

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RITUXIMAB Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL Ruxience® Pfizer Australia Pty Ltd Category 3 submission (New PBS listing)	Non-Hodgkin's lymphoma (NHL); Chronic lymphocytic leukaemia (CLL); Rheumatoid arthritis (RA); Granulomatosis with polyangiitis (Wegener's granulomatosis) (GPA); Microscopic polyangiitis (MPA)	To request listing of rituximab biosimilar under the same conditions as the currently listed rituximab.	Recommended	The PBAC recommended the listing of a new biosimilar brand of rituximab (Ruxience) under the same conditions as the biosimilar brands currently listed on the PBS (Riximyo® and Truxima®). The PBAC's recommendation for listing was based on its assessment that the cost-effectiveness of Ruxience would be acceptable if it were cost-minimised to Riximyo and Truxima.
SACITUZUMAB GOVITECAN Powder for injection 180 mg Trodelvy® Gilead Sciences Pty Limited Category 1 submission (New PBS listing)	Breast cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of adult patients with unresectable, locally advanced or metastatic triple negative breast cancer, who have received two or more prior therapies, at least one of them in the locally advanced or metastatic setting.	Not Recommended	The PBAC did not recommend sacituzumab govitecan (SG) for the treatment of unresectable, locally advanced or metastatic triple negative breast cancer (TNBC). The PBAC considered that SG provides superior efficacy compared with the current standard of care, notably an improvement in overall survival and acknowledged the consumer comments that emphasised the impact of improved survival for this patient group. The PBAC also acknowledged the high clinical need for effective therapies for patients with this condition, who have poorer survival outcomes than patients with other breast cancer subtypes. However, the PBAC considered that specific inputs to the economic model should be revised and that the incremental cost-effectiveness ratio was unacceptably high at the proposed price. The PBAC considered that a price reduction would be required to achieve a cost-effective listing. The PBAC nominated the Early Resolution re-submission pathway for this item.

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				Sponsor's comment: Gilead shares the PBAC's view that sacituzumab govitecan addresses a high and urgent unmet clinical need in patients with unresectable, locally advanced or metastatic TNBC. The company is working collaboratively with the PBAC and the Department under the early resolution re-submission pathway towards listing in the shortest possible time.
SECUKINUMAB Injection 75 mg in 0.5 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen Injection 300 mg in 2 mL pre-filled pen Injection 300 mg in 2 mL pre-filled syringe Cosentyx® Novartis Pharmaceuticals Australia Pty Limited Category 2 submission (New PBS listing)	Paediatric psoriasis	To request a General Schedule Authority Required (Written) listing for the treatment of paediatric patients with psoriasis, including the addition of a new 75 mg pre-filled syringe, 300 mg pre-filled pen and 300 mg pre-filled syringe.	Recommended	The PBAC recommended the listing of secukinumab for the treatment of paediatric patients with severe chronic plaque psoriasis. Whilst there were limitations to the clinical comparison, the PBAC was satisfied that secukinumab is non-inferior to ustekinumab in this indication in the context of the available evidence. The PBAC considered that secukinumab would be cost-effective in paediatric patients at a price no greater than the price for ustekinumab in the same indication and population. The PBAC noted flow on changes to the restriction criteria for ustekinumab and etanercept would be required.

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SILTUXIMAB Powder for injection 100 mg Powder for injection 400 mg Sylvant® Eusa Pharma (UK) Ltd Early Re-entry submission (New PBS listing)	Idiopathic multicentric Castleman's disease (iMCD)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of iMCD.	Recommended	The PBAC recommended a Section 100 (Highly Specialised Drugs Program) listing of siltuximab for the treatment of iMCD. The PBAC considered that the revised economic model provided in the pre-PBAC response was reasonable and the resulting incremental cost-effectiveness ratio was within the acceptable range. The PBAC considered that its previous concerns about the financial estimates had been addressed with the prevalence-based approach provided in the resubmission. Overall, the PBAC considered that the concerns raised at the July 2021 meeting had been sufficiently addressed.
TEPOTINIB Tablet 225 mg (as hydrochloride monohydrate) Tepmetko® Merck Healthcare Pty Ltd Category 1 submission (New PBS listing)	Non-small cell lung cancer (NSCLC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with locally advanced or metastatic MET exon 14 skipping alterations-positive NSCLC.	Deferred	The PBAC deferred making a recommendation to list tepotinib for the treatment of locally advanced or metastatic IV NSCLC patients who have evidence of a MET proto-oncogene, receptor tyrosine kinase (*MET*) gene alteration that causes skipping of exon 14 (*MET*ex14sk). The PBAC was of a mind to recommend tepotinib pending MSAC advice on the funding of the codependent *MET*ex14sk testing. The PBAC considered that, despite the uncertainties associated with the indirect comparisons presented in the submission, on balance, it was likely tepotinib provided similar health outcomes to pembrolizumab in combination with chemotherapy in the proposed population. The PBAC considered that tepotinib would be acceptably cost effective if it were cost-minimised against pembrolizumab in combination with chemotherapy, taking into account the number of patients needed to be tested to identify one patient with a *MET*ex14sk alteration. The PBAC considered a Risk Sharing Arrangement would be appropriate to manage the uncertainty associated with a number of cost-minimisation analysis inputs and assumptions, including the treatment duration of tepotinib.
				Sponsor's comment: The sponsor had no comment.

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TRASTUZUMAB Powder for I.V. infusion 440 mg Herzuma® Celltrion Healthcare Australia Pty Ltd Committee Secretariat submission (New PBS listing)	Metastatic (Stage IV) HER2 positive breast cancer; Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastroesophageal junction; Early HER2 positive breast cancer	To request listing of an additional strength under the same circumstances as the currently listed strengths of Herzuma.	Recommended	The PBAC recommended the listing of a new vial size of 440 mg trastuzumab as Section 100 Efficient Funding of Chemotherapy program Authority Required (STREAMLINED) under the same conditions as the currently trastuzumab 60 mg, 150 mg and 420 mg listings
TRIENTINE Tablet 150 mg (as tetrahydrochloride) Cuprior® Orphalan Category 1 submission (New PBS listing)	Wilson disease	To seek a General Schedule Authority Required listing for the treatment of patients with Wilson disease who are intolerant to penicillamine.	Not Recommended	The PBAC did not recommend trientine tetrahydrochloride (4HCl) for the treatment of patients with Wilson Disease (WD) intolerant to penicillamine/D-penicillamine (DPA) therapy. Although the PBAC accepted that chelation therapy prevents the progression of WD, the PBAC considered that the proposed place in therapy for trientine 4HCl and the nomination of best supportive care (BSC) as the comparator were unacceptable as they were inconsistent with current clinical practice and the available treatment guidelines. The PBAC therefore considered that the economic evaluation that compared trientine 4HCl with BSC was uninformative. In addition, the PBAC considered that the financial estimates were high, particularly at the proposed price. The PBAC considered that a cost-minimisation approach versus DPA would be more appropriate. The PBAC nominated the Early Re-entry re-submission pathway for this item.

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				Sponsor's comment: Orphalan is disappointed with the PBAC's decision not to recommend a PBS listing for trientine 4HCl to treat WD. We are concerned that in this setting, there is now a lack of access to any effective chelating therapies to treat this life-threatening condition. We will continue to work with the PBAC process to help ensure equitable and sustainable access to trientine 4HCl for the patient population intolerant to DPA.
TRIENTINE Capsule 250 mg (as dihydrochloride) Waymade® Clinect Pty Ltd Category 1 submission (New PBS listing)	Wilson disease	To seek a General Schedule Authority Required listing for the treatment of patients with Wilson disease who are intolerant to penicillamine.	Not Recommended	The PBAC did not recommend trientine dihydrochloride (2HCl) for the treatment of patients with Wilson Disease (WD) intolerant to penicillamine/D-penicillamine (DPA) therapy. Although the PBAC accepted that chelation therapy prevents the progression of WD, the PBAC considered that the proposed place in therapy for trientine 2HCl and the nomination of no active treatment as the comparator were unacceptable as they were inconsistent with current clinical practice and the available treatment guidelines. The PBAC therefore considered that the economic evaluation that compared trientine 2HCl with no active treatment was uninformative. In addition, the PBAC considered that the financial estimates were high, particularly at the proposed price. The PBAC considered that a cost-minimisation approach versus DPA would be more appropriate. The PBAC nominated the Early Re-entry re-submission pathway for this item.
				Sponsor's comment: The sponsor had no comment.

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ADRENALINE I.M. injection 150 mcg in 0.3 mL single dose syringe auto-injector I.M. injection 300 mg in 0.3 mL single dose syringe auto-injector Adrenaline Auto Inject Sun-JV® AdrenaJect® Sun Pharma	Anaphylaxis	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC with support from the sponsor.
ALENDRONIC ACID Tablet, effervescent 70 mg Binosto® Pharmbio Pty Ltd	Osteoporosis	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC.
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE Sachets containing oral powder 12.5 g, 30 MSUD Explore 5 Vitaflo Australia Pty Limited	Maple syrup urine disease (MSUD)	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC, noting that alternative products were available.
ARIPIPRAZOLE Powder for injection 400 mg (as monohydrate) with diluent pre-filled dual chamber syringe Abilify Maintena® Lundbeck Australia Pty Ltd	Schizophrenia	Review of positive PBAC recommendations not accepted by applicants	Recommendation extended for 12 months.
BUDESONIDE Capsule (modified release) 3 mg Budenofalk® Dr Falk Pharma Australia Pty Ltd	Mild to moderate Crohn disease	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC with the support of the sponsor.

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CANAKINUMAB Solution for injection 150 mg in 1 mL Ilaris® Novartis Pharmaceuticals Australia	Cryopyrin associated periodic syndromes (CAPS)	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC.
CERTOLIZUMAB PEGOL Injection 200mg in 1 mL pre-syringe pen Solution for injection 200 mg in 1 mL pre-filled pen Cimzia® UCB Australia Pty Ltd	Severe chronic plaque psoriasis	Review of positive PBAC recommendations not accepted by applicants	Recommendation extended for 12 months.
CETUXIMAB Solution for IV infusion 100 mg in 20 mL, 500 mg in 100 mL Erbitux® Merck Australia Pty Ltd	Recurrent or metastatic squamous cell carcinoma of the head and neck	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC with the support from the sponsor.
DENOSUMAB Injection 120 mg in 1.7 mL Xgeva® Amgen Australia Pty Ltd	Bisphosphonate-refractory hypercalcaemia of malignancy (HCM)	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC with the support from the sponsor.
HIGH DOSE INACTIVATED TRIVALENT INFLUENZA VACCINE (SPLIT VIRION) Injection 0.5 mL Fluzone® High-Dose Sanofi-Aventis Australia Pty Ltd	National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over	Review of positive PBAC recommendations not accepted by applicants	Recommendation extended for 12 months.
IBRUTINIB Capsule 140 mg Imbruvica® Janssen-Cilag Pty Ltd	Chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma (SLL)	Review of positive PBAC recommendations not accepted by applicants	Recommendation extended for 12 months.

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PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND Powder for I.V. injection containing 250 mg paclitaxel Abraxane® Specialised Therapeutics Australia Pty Ltd	Adenocarcinoma of the pancreas and breast cancer	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC, noting that there was an alternative vial size available.
PARITAPREVIR with RITONAVIR with OMBITASVIR Tablet 75 mg-50 mg-12.5 mg Technivie® AbbVie Pty Ltd	Hepatitis C	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC with the support from the sponsor.
RADIUM (223Ra) Injection containing radium (233Ra) dichloride 6.6 MBq/6 mL Xofigo® Bayer Australia Ltd	Metastatic castrate resistant prostate cancer	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC.
SARILUMAB Injection 150 mg in 1.14 mL pre-filled syringe Injection 200 mg in 1.14 mL pre-filled syringe Kevzara® Sanofi-Aventis Australia Pty Ltd	Rheumatoid arthritis	Review of positive PBAC recommendations not accepted by applicants	Recommendation was rescinded by the PBAC with the support from the sponsor.

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IVERMECTIN Tablet 3 mg, 4 Stromectol® Merck Sharp & Dohme (Australia) Pty Ltd (Other business)	Scabies	To seek PBAC recommendation on whether it would be appropriate to amend the current PBS restriction for ivermectin (Stromectol) for treatment of human sarcoptic (typical) scabies to remove the requirement for prior failure of, or contraindication to, topical therapy for the Aboriginal and Torres Strait Islander population.	The PBAC recommended to extend the listing of ivermectin 3 mg tablets for the treatment of human sarcoptic (typical) scabies for patients who identify as Aboriginal and Torres Strait Islander, removing the requirement to have first failed, or be contraindicated to, topical therapy. In making its recommendation, the PBAC took into consideration, among other matters, the clinical need of the patient population and the compliance and tolerability issues experienced with the existing topical therapies.
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 did not recommend making amendments to PBS listings of antipsychotic medications per Recommendation 65 of the Royal Commission into Aged Care Quality and Safety Final Report. Following consultation with stakeholders, the PBAC considered Recommendation 65 is not implementable at present due to substantial risk of unintended consequences. The PBAC noted that changes already made to the PBS restrictions for risperidone, the only medicine registered in Australia for the treatment of behavioural and psychological symptoms of dementia, have reduced utilisation. The PBAC will continue to monitor the use of antipsychotics in aged care.

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Review of PBS Authority Required (Written) listings – Tranches 4 and 5	Medicines for the treatment of cardiovascular, blood and hormone conditions, neurological disorders, ocular and rare diseases	To request that the Pharmaceutical Benefit Advisory Committee (PBAC) consider the Authority Required (Written) restriction level for PBS-listed medicines (Tranches 4 & 5) and recommend any required amendments.	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 4 and 5 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 4 and 5 medicine(s). The PBAC applied the following key criteria to assist in determining the requirement to maintain a written Authority level of restriction: (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. Overall, the PBAC accepted the DUSC October 2021 advice on the need to amend or maintain the current written Authority level of each medicine and made the following recommendations:
1. Riociguat	1. Chronic thromboembolic pulmonary hypertension (CTEPH)		<u>1. Chronic thromboembolic pulmonary hypertension (CTEPH):</u> The PBAC noted that riociguat was the only specific PBS subsidised medicine for the CTEPH indication. The PBAC agreed with DUSC that PBS restrictions for riociguat for CTEPH are more burdensome than for medicines, including riociguat, to treat pulmonary arterial hypertension (PAH) i.e. PAH PBS restrictions are initial treatment Authority Required (Written), continuing treatment Authority Required (Telephone/Electronic). The PBAC recommended an amendment to the authority requirements for continuing treatment for riociguat for CTEPH from Authority Required (Written) to Authority Required (Telephone/Electronic) noting the stable market, the robustness of the initial written restriction criteria and for consistency with the level of authority of the PBS restrictions for medicines to treat PAH.

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2.Eltrombopag, romiplostim	2. Idiopathic thrombocytopenic purpura (ITP)		2. Idiopathic thrombocytopenic purpura (ITP): The PBAC agreed with DUSC that due to the growth in eltrombopag and romiplostim utilisation and an increasing incident and prevalent population, an amendment to the current initial treatment written authority level for eltrombopag and romiplostim for ITP was not supported at this time. The PBAC recommended that the authority requirements for first continuing treatment with eltrombopag and romiplostim for ITP be amended from Authority Required (Written) to Authority Required (Telephone/Electronic) to ease administrative burden for prescribers and improve patient access to timely treatment. The PBAC noted the PBS restriction treatment criterion requiring that the most recent platelet count be provided should remain when the authority level is amended.
3.Pasireotide, pegvisomant	3. Acromegaly		3. Acromegaly: The PBAC noted the high cost of treatment per patient and that both medicines had special pricing arrangements in place. The PBS/RPBS expenditure for both medicines had increased year on year over the Review period, with total PBS/RPBS expenditure in 2020 at $3.7 million (based on published prices). In 2020, pegvisomant accounted for 55% of total expenditure. The PBAC did not recommend an amendment to the authority requirements for pasireotide or pegvisomant for acromegaly at this time, noting the market immaturity and instability, increasing costs associated with pegvisomant use, the risk of leakage to first line therapy and the risk of leakage for pasireotide to non- PBS subsidised indications and to off label use.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
4. Donepezil, galantamine, memantine, rivastigmine	4. Alzheimer disease		4. Alzheimer disease: The PBAC agreed with DUSC that amendment of the current initial treatment restriction authority requirements and any resultant change in utilisation would be unlikely to create financial risk to government due to the availability of generics for donepezil, galantamine and memantine and the current low unit cost per prescription. The PBAC acknowledged the administrative burden for prescribers and Services Australia associated with the written authority application for the initial (2) treatment restriction. The PBAC recalled the role of written authority PBS restrictions for medicines to treat Alzheimer disease in promoting Quality Use of Medicines (QUM) and in reducing the risk of use outside the PBS restrictions to treat other memory loss and behavioural conditions. The PBAC recommended that the initial (1) treatment (Telephone/Electronic) and initial (2) treatment (Written) authority restrictions for all four medicines for Alzheimer disease be amended to a single initial treatment Authority Required (Telephone/Electronic) restriction to ease administrative burden for specialist prescribers. The PBAC agreed that QUM will be maintained through the current restriction requirement for the condition to be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist) and that prior to continuing treatment, a comprehensive assessment must be undertaken and agreement reached between the patient, patient's family or carer and the treating physician that treatment is continuing to produce worthwhile benefit.
5. Modafinil, armodafinil	5. Narcolepsy		5. Narcolepsy: The PBAC considered that there is a high risk of leakage within and outside of the PBS indication for modafinil and armodafinil due to the number of non-PBS subsidised indications and off-label uses. The PBAC also considered there may be some non-PBS prescribing for students and for lifestyle reasons. The PBAC did not recommend an amendment to the authority requirements for modafinil or armodafinil for narcolepsy at this time, given the continued market instability and demonstrated growth and the high risk of leakage within and outside of the indication.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
6. Aflibercept, dexamethasone, ranibizumab	6. Diabetic macular oedema (DMO)		6. Diabetic macular oedema (DMO): The PBAC acknowledged the administrative burden associated with the objective assessment initial treatment criteria and completing the written authority application. The PBAC noted that prescribing of these medicines on the PBS is limited to ophthalmologists or accredited ophthalmology registrars in consultation with an ophthalmologist. The PBAC also noted sponsor comments that clinicians report the detailed requirements of written authority applications result in less time to consult with patients or delegation of the responsibility for completion. However, the PBAC agreed with DUSC that the initial therapy written authority application is necessary to assist in limiting use to the population where use is cost-effective. The PBAC recommended an amendment to the authority requirements for the continuing treatment restriction for DMO for ranibizumab, aflibercept and dexamethasone from Authority Required (Telephone/Electronic) to Authority Required (STREAMLINED). The PBAC considered this amendment would not substantially increase the financial risk to the government and would assist in reducing the administrative burden for specialist clinicians and improve timely access to treatment for patients.
7. Aflibercept, dexamethasone, ranibizumab	7. Retinal vein occlusion (RVO)		7. Retinal vein occlusion (RVO): The PBAC acknowledged the administrative burden associated with the objective assessment initial treatment criteria and the written authority application. The PBAC noted that prescribing of these medicines on the PBS is limited to ophthalmologists or accredited ophthalmology registrars in consultation with an ophthalmologist. The PBAC noted sponsor comments that clinicians report the detailed requirements of written authorities results in less time to consult with patients or delegation of the responsibility for completion. The PBAC agreed with DUSC that the written authority application is necessary to mitigate the risk of leakage within the indication to treatment of early disease and outside of the indication to treat proliferative diabetic retinopathy. The PBAC recommended an amendment to the authority requirements for the continuing treatment restriction for RVO for ranibizumab, aflibercept and dexamethasone from Authority Required (Telephone/Electronic) to Authority Required (STREAMLINED). The PBAC considered this amendment would not substantially increase the financial risk to the government and would assist in reducing the administrative burden for specialist clinicians and improve timely access to treatment for patients.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
8. Aflibercept, ranibizumab	8. Subfoveal choroidal neovascularisation (CNV)		8. <u>Subfoveal choroidal neovascularisation (CNV):</u> The PBAC acknowledged the administrative burden associated with the objective assessment initial treatment criteria and the written authority application. The PBAC noted that prescribing of these medicines on the PBS is limited to ophthalmologists or accredited ophthalmology registrars in consultation with an ophthalmologist. The PBAC noted sponsor comments that clinicians report the detailed requirements of the written authority application results in less time to consult with patients or delegation of the responsibility for completion. The PBAC agreed with DUSC that the written authority application is necessary to mitigate the risk of leakage outside of the PBS subsidised indication to proliferative diabetic retinopathy, the progressively growing market for CNV due to AMD, the immaturity of the CNV due to PM and rare diseases markets and the associated financial risk to government. The PBAC agreed with DUSC advice that the authority requirements across DMO, RVO and CNV PBS indications should be consistent. The PBAC recommended an amendment to the authority requirements for the continuing treatment restriction for CNV for ranibizumab and aflibercept from Authority Required (Telephone/Electronic) to Authority Required (STREAMLINED). The PBAC considered this amendment would not substantially increase the financial risk to the government and would assist in reducing the administrative burden for specialist clinicians and improve timely access to treatment for patients.
9. Eculizumab	9. Atypical haemolytic uraemic syndrome (aHUS)		<u>9. Atypical haemolytic uraemic syndrome (aHUS):</u> The PBAC considered the market for eculizumab is not yet stable, with continuous growth in incident and prevalent patients. The PBAC acknowledged the high administrative burden for prescribers associated with the current initial and continuing written authority applications for eculizumab. The PBAC considered written authority applications necessary to assist in maintaining cost-effectiveness by minimising the risk of leakage within the indication and to treat related conditions. The PBAC did not recommend an amendment to the authority requirements for eculizumab for aHUS, noting the financial risk to the government through any fluctuation in patient numbers and the risk of leakage to use in similar indications without other treatment options.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
NOVEMBER 2021 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
Continued Dispensing Arrangements	Various	To request the PBAC to consider the stakeholder feedback and provide advice on proposed changes to the guiding principles for Continued Dispensing arrangements recommended in May 2020	The PBAC considered recent stakeholder feedback from a range of groups including consumer, medical and pharmacy organisations on the ongoing arrangements for Continued Dispensing. The PBAC noted that the Government had extended the Continued Dispensing Emergency Measures until 30 June 2022. The PBAC did not suggest any changes to the list of medications endorsed in May 2020 that it considered appropriate to be made available under ongoing Continued Dispensing arrangements after the expiry of the emergency measures. Based on the feedback received, the PBAC suggested some minor updates to the guiding principles for continued dispensing, most notably that the medication should have been supplied to the patient within the preceding three months, rather than six months, to qualify for continued dispensing.

Submission category types

Category 1	A request for PBS or NIP listing of one or more of the following: • 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: • Listing of a new pharmaceutical item of a listed medicine. • Consideration as an exempt item (Exempt item as per subsection 84AH of the *National Health Act 1953*). • 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	Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following: • 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.

Version 2
Amendment
1. Continued Dispensing Arrangements

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: • 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.
Early resolution pathway	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: • 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. 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.
Facilitated resolution pathway	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.