PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
March 2025 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	
AMIVANTAMAB Solution concentrate for I.V. infusion 350 mg in 7 mL Rybrevant® LAZERTINIB Tablet 80 mg (as mesylate monohydrate) Tablet 240 mg (as mesylate monohydrate) Lazcluze® JANSSEN-CILAG PTY LTD Category 2 (New PBS listing)	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for amivantamab and a General Schedule Authority Required (Telephone/Online) listing for lazertinib for the first line treatment of patients with epidermal growth factor receptor mutated locally advanced or metastatic (Stage IIIB-IV) NSCLC.	Not Recommended	The PBAC did not recommend amivantamab plus lazertinib (A+L) for treatment of patients with epidermal growth factor receptor mutated (*EGFR*m) locally advanced or metastatic (Stage IIIB-IV) non-small cell lung cancer, in patients either diagnosed *de novo* or following prior osimertinib therapy in the adjuvant setting. The PBAC acknowledged the moderate improvement in progression free survival and small improvement in overall survival of A+L over osimertinib. However, it considered that the magnitude of the clinical benefit was uncertain due to the immaturity of the OS data, the violation of the proportional hazards assumption, and quality of life favouring treatment with osimertinib. The PBAC considered the claim of inferior but manageable safety was not supported, observing that A+L is associated with substantial toxicity. The PBAC advised that the economic model would require revision to the inputs and considered that A+L was not cost-effective at the proposed price. The PBAC considered the submission's uptake rate of A+L to be to be substantially overestimated given the safety profile of the treatment. <u>Sponsor's Comment:</u> Janssen is disappointed that the PBAC did not recommend A+L for the first-line treatment of patients with *EGFR*m locally advanced/metastatic non-small cell lung cancer. Janssen considers that A+L provides a substantial improvement in PFS and OS over osimertinib and will work with the PBAC to make this treatment available for patients on the PBS.

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BULEVIRTIDE Powder for injection 2 mg Hepcludex® GILEAD SCIENCES PTY LTD Standard re-entry (New PBS listing)	Chronic hepatitis D	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis D.	Deferred	The PBAC deferred making a recommendation for the listing of bulevirtide for treatment of chronic hepatitis delta virus (hepatitis D). While the PBAC was of a mind to recommend bulevirtide, the PBAC noted that an integrated codependent submission for the MBS listing of ribonucleic acid polymerase chain reaction testing for chronic hepatitis D would be considered at the April 2025 MSAC meeting. The PBAC acknowledged that hepatitis D virus (HDV) is relatively rare in Australia, but there is a need for effective treatments. The PBAC reaffirmed its view that whilst the evidence indicates that bulevirtide is effective for some patients in terms of achieving a significant reduction in viral load and/or improvement in liver enzymes, the longer-term and patient-relevant benefits were highly uncertain. The PBAC noted that the resubmission included a small reduction in the proposed price for bulevirtide and revised some inputs in the economic analysis as requested, but a number of optimistic assumptions that were likely to have underestimated the incremental cost-effectiveness ratio remained. Overall, the PBAC considered that bulevirtide would be cost-effective with a further substantial price reduction, to address the remaining uncertainties in the economic model and bring the ICER into an acceptable range. The PBAC also considered the proposed utilisation of bulevirtide was uncertain but the estimates presented in the submission appeared to be reasonable. <u>Sponsor's Comment:</u> The sponsor had no comment.

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CAPIVASERTIB Tablet 160 mg Tablet 200 mg Truqap® ASTRAZENECA PTY LTD Matters arising from the minutes (New PBS listing)	Hormone receptor-positive (HR+) human epidermal growth factor receptor 2-negative (HER2-) locally advanced (unresectable) or metastatic breast cancer	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HR+/HER2- locally advanced unresectable or metastatic breast cancer with evidence of a serine/threonine protein kinase (AKT) pathway alteration, following recurrence or progression on or after endocrine therapy.	Recommended	The PBAC recommended capivasertib for treatment of HR+ HER2- locally advanced unresectable or metastatic breast cancer with evidence of a AKT pathway alteration, following recurrence or progression on or after endocrine therapy. The PBAC revised its previous decision to not recommend capivasertib following consideration of additional trial follow - up data and proposal of a substantial reduction in the price for capivasertib which it considered would result in acceptable cost-effectiveness. The PBAC noted that capivasertib was submitted as an integrated codependent submission, and the MSAC did not recommend the proposed MBS item for AKT pathway testing at its November 2024 MSAC meeting. The PBAC supported the conclusions of MSAC, specifically that the claim of co-dependence had not been established. On that basis, the PBAC considered that AKT pathway testing was likely to be useful, but was not mandatory in identifying patients likely to benefit from capivasertib. The PBAC considered that the PBS restriction should recommend but not mandate AKT pathway testing, as patients may have access to AKT testing privately, or through clinical trials.

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CIPAGLUCOSIDASE ALFA Powder for I.V. infusion 105 mg Pombiliti® MIGLUSTAT Capsule 65 mg Opfolda® AMICUS THERAPEUTICS PTY LTD Category 2 (New PBS listing)	Late onset Pompe disease	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of late onset Pompe disease.	Not Recommended	The PBAC did not recommend the listing of cipaglucosidase and miglustat (CIPAMIG) for the treatment of adults with late-onset Pompe disease (LOPD). The PBAC considered the available evidence supported that CIPAMIG was at least as effective and safe compared to existing enzyme replacement therapies for Pompe disease, avalglucosidase alfa (AVAL) and alglucosidase alfa (ALGLU). The PBAC considered CIPAMIG was not adequately cost-effective to list on the PBS based on the submission's cost-minimisation approach versus AVAL as the PBAC had previously considered it not adequately cost-effective for listing on the PBS. However, the PBAC acknowledged that the sponsor had taken this approach intentionally as the sponsor's intention was to list CIPAMIG on the Life Saving Drugs Program (LSDP) and a drug must first be considered by the PBAC as clinically effective but rejected for PBS listing because it fails to meet the required cost-effectiveness criteria, before it can be considered for LSDP listing. <u>Sponsor's Comment:</u> Amicus acknowledges the PBAC minutes and welcomes the opportunity to work with the LSDP to broaden the treatment options in Pompe disease.

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DABRAFENIB Capsule 50 mg (as mesilate) Capsule 75 mg (as mesilate) Tafinlar® TRAMETINIB Tablet 500 micrograms Tablet 2 mg Mekinist® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD Category 2 (Change to existing listing)	Non-small cell lung cancer (NSCLC)	To request a General Schedule Authority Required (STREAMLINED) listing of dabrafenib in combination with trametinib for the treatment of adult patients with BRAF V600E mutation positive advanced or metastatic NSCLC.	Recommended	The PBAC recommended the listing of dabrafenib in combination with trametinib (D+T) for the treatment of adult patients with BRAF V600E mutation positive metastatic (Stage IV) NSCLC. The PBAC considered that, despite the uncertainties associated with the indirect comparisons presented in the submission, on balance, it was likely D+T provided similar health outcomes to pembrolizumab in combination with chemotherapy in the proposed population. The PBAC considered that D+T would be acceptably cost effective if it were cost-minimised against pembrolizumab in combination with chemotherapy. The PBAC noted flow-on changes would be required to immunotherapy listings to allow them to be used after D+T, by amending one of the criteria to: Patient must not have previously been treated for this condition in the metastatic setting OR The condition must have progressed after treatment with only one of (i) tepotinib, (ii) selpercatinib, (iii) dabrafenib in combination with trametinib.
DAPSONE Tablet 50 mg Dapsomed® MEDSURGE HEALTHCARE PTY LTD Committee secretariat (New PBS listing)	Dermatitis herpetiformis Leprosy Actinomycotic mycetoma	To request a General Schedule Unrestricted Benefit listing of a new strength under the same conditions as the currently listed strengths of dapsone.	Recommended	The PBAC recommended listing of a new 50 mg strength of dapsone (Dapsomed®) under the same conditions as the currently listed strengths of dapsone and same dispensed price as the 25 mg tablet. The PBAC noted that the TGA considered Dapsomed to be bioequivalent to Dapsone. The PBAC advised the equi-effective doses to be 1 tablet of Dapsomed 50 mg = 2 tablets of Dapsone 25 g.

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DARATUMUMAB Solution for I.V. infusion 100 mg in 5 mL vial Solution for I.V. infusion 400 mg in 20 mL vial Solution for S.C. injection 1,800 mg in 15 mL vial Darzalex® JANSSEN-CILAG PTY LTD Standard re-entry (Change to existing listing)	Multiple myeloma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the I.V. and S.C. formulations and a General Schedule Authority Required (Telephone/Online) listing for the S.C. formulation for use in combination with lenalidomide and dexamethasone for the treatment of transplant ineligible, newly diagnosed multiple myeloma.	Recommended	The PBAC recommended daratumumab for use in combination with lenalidomide and dexamethasone (DLd) for the treatment of transplant ineligible, newly diagnosed multiple myeloma (TI NDMM). The PBAC welcomed input from individuals and organisations who described the benefits of first line treatment with DLd and highlighted the ongoing need for new and effective therapies for the treatment of multiple myeloma. The PBAC considered that the input from individuals, health care professionals and organisations provided valuable insights about the experience of individuals diagnosed with multiple myeloma, and the desire for improved treatment outcomes. The clinical evidence presented in the submission indicated that DLd improved progression free survival in patients when compared to lenalidomide plus dexamethasone (Ld) and bortezomib plus lenalidomide and dexamethasone (BLd). The PBAC was satisfied that for some patients DLd would be more effective than Ld and BLd. However, the clinical evidence presented in the submission did not allow confidence about the extent to which this benefit would be realised against BLd. The submission did not include comparison of overall survival between patients who had received DLd versus those who had received BLd. While the submission included evidence from clinical studies that DLd improved overall survival when compared to Ld, the PBAC did not consider the claim that BLd and Ld delivered similar outcomes was supported by the evidence presented. Because of these uncertainties, the PBAC considered that the benefits estimated in the economic model in support of the proposed price were overly optimistic. Further the PBAC considered that the economic model underestimated certain costs. The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of DLd would be acceptable with a price reduction. The PBAC considered that the revised estimated financial impact of listing DLd was overestimated and considered that a risk sharing arrangement (RSA) that included the use of daratumumab both in the first line (newly diagnosed) and second line settings would be required.

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				The PBAC noted that the RSA should account for the expected reduced use of second line daratumumab as a result of the first line listing. The PBAC also recommended flow-ons to daratumumab 2nd line listings for relapsed and/or refractory multiple myeloma to ensure that patients only receive daratumumab once per lifetime. The PBAC noted the large number of treatments listed on the PBS for the treatment of multiple myeloma. The PBAC recommended that the Department undertake a utilisation analysis to understand the treatment pathways and duration of treatment for PBS-listed therapies for multiple myeloma.
DENOSUMAB Injection 120 mg in 1 mL single use pre-filled syringe (PFS) Xgeva® AMGEN AUSTRALIA PTY LIMITED Category 4 (New PBS listing)	Giant cell tumour of bone Bone metastases	To request General Schedule Authority Required (STREAMLINED) listings of a new form for the treatment of giant cell tumour of bone and bone metastases.	Recommended	The PBAC recommended listing of a new pre-filled syringe form of denosumab (120 mg/1.0 mL injection, 1 mL PFS) for the treatment of giant cell tumour of bone and bone metastases under the same circumstances as the currently listed vial form of denosumab (120 mg/1.7 mL injection, 1.7 mL vial). The PBAC considered the equi-effective doses to be denosumab 120 mg PFS = denosumab 120 mg vial.

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DUPILUMAB Injection 200 mg in 1.14 mL single dose pre-filled pen (PFP) Injection 300 mg in 2 mL single dose PFP Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD Category 4 (New PBS listing)	Severe atopic dermatitis Uncontrolled severe asthma	To request the extension of two new forms to a General Schedule Authority Required listing for the treatment of severe atopic dermatitis in patients aged less than 12 years and a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years.	Recommended	The PBAC recommended listing of two new forms of dupilumab, 200 mg in 1.14 mL and 300 mg in 2 mL single dose PFP for the treatment of severe atopic dermatitis in patients aged less than 12 years on a cost minimisation basis to dupilumab pre-filled syringe (PFS). The PBAC further recommended the listing of dupilumab PFP for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years. The PBAC's recommendation for listing was based on, among other matters, its assessment that dupilumab PFP would be cost-effective if it were cost-minimised to the lowest cost alternative treatment for uncontrolled severe asthma.

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EFGARTIGIMOD ALFA Solution concentrate of I.V. infusion 400 mg in 20 mL Vyvgart® ARGENX AUSTRALIA PTY LTD Category 1 (New PBS listing)	Generalised myasthenia gravis (gMG)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.	Recommended	The PBAC recommended the listing of efgartigimod for the treatment of gMG. The PBAC appreciated the input provided by patients, carers and clinicians and found the comments very informative for understanding the high and unmet clinical need for new effective treatments and the potential use of the new therapies in practice. The comments outlined the significant impact that gMG can have on quality of life, including the impact on patient's families. The comments also described the limitations of currently available treatment options including adverse events and lengthy administration times. The clinical evidence presented in the submission had several limitations that created uncertainty as to whether efgartigimod would improve patient outcomes compared with intravenous immunoglobulin or plasma exchange. Overall, the PBAC considered there was insufficient evidence to suggest efgartigimod would be more effective or safer than these treatments. Further, the PBAC considered that there was insufficient evidence to suggest that efgartigimod was superior in terms of efficacy or safety compared with the other three therapies for gMG that were considered at the March 2025 meeting (zilucoplan, ravulizumab and rozanolixizumab). Overall, the PBAC advised that the four therapies should be considered to have similar efficacy and safety compared with each other and with intravenous immunoglobulin. The recommendation to list efgartigimod on the PBS was made on the basis of a cost-comparison versus intravenous immunoglobulin, supported by a cost-per-responder analysis versus placebo. The PBAC considered that the new gMG therapies should substitute for intravenous immunoglobulin and plasma exchange rather than be added on to or used in combination with these modalities. The PBAC advised that the prescribing criteria for intravenous immunoglobulin should be revised to ensure use remains appropriate in the context of the availability of the new therapies.

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EFLORNITHINE Tablet 192 mg (as hydrochloride) Ifinwil® NORGINE PTY LTD Category 1 (New PBS listing)	Neuroblastoma	To request a General Schedule Authority Required (Written) listing for the treatment of high-risk neuroblastoma (HRNB).	Recommended	The PBAC recommended the Section 100 (Highly Specialised Drugs Program) listing of eflornithine for post-maintenance treatment to prevent relapse in patients with HRNB who are in remission after receiving multiagent, multimodality therapy. The PBAC welcomed the input from individuals and organisations and noted they strongly supported the listing. The PBAC acknowledged the high clinical need for a post-maintenance treatment to prevent relapse of this condition. The PBAC considered that eflornithine provides a clinical benefit for patients compared to standard of care, and while the magnitude of benefit was uncertain, the PBAC acknowledged the difficulty of obtaining high quality clinical evidence in this patient group. The PBAC considered that the incremental cost-effectiveness ratio (ICER) was high and uncertain, partly because the sponsor's assumptions about the duration of benefit (extrapolation and time horizon) were optimistic. The PBAC considered that a more conservative time horizon would be required along with a price reduction to achieve an acceptable ICER. The PBAC considered the estimated number of incident neuroblastoma patients was overestimated and should be reduced to < 500 patients per year.

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ELACESTRANT Tablet 86 mg (as dihydrochloride) Tablet 345 mg (as dihydrochloride) Orserdu® A. MENARINI AUSTRALIA PTY LTD Category 1 (New PBS listing)	Estrogen receptor-positive (ER+) human epidermal growth factor receptor 2-negative (HER2-) locally advanced or metastatic breast cancer	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of ER+/HER2- locally advanced or metastatic breast cancer in patients who have progressed following at least one line of endocrine therapy administered with a cyclin dependent kinase 4/6 inhibitor and have a confirmed estrogen receptor 1 variant.	Not Recommended	The PBAC did not recommend the listing of elacestrant for the treatment of patients with ER+ HER2- locally advanced or metastatic breast cancer in patients whose tumours have evidence of activating *ESR1* variants. The PBAC considered that in the heavily pre-treated population included in the clinical trial for elacestrant, the control arm of fulvestrant was inappropriate for many patients, and was not representative of standard of care. The PBAC considered the outcomes from the pivotal trial are likely to overestimate the clinical benefit for elacestrant due to the inappropriate comparison. The PBAC considered that in some patients elacestrant may be useful as an oral alternative to intramuscular fulvestrant due to its different mode of administration. However the PBAC considered that, due to the patient population included in the trial, no clear PFS or OS benefit compared with fulvestrant was supported by the evidence and therefore at the proposed substantially higher cost, elacestrant was not considered cost-effective. <u>Sponsor's Comment:</u> The sponsor had no comment.

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ELAFIBRANOR Tablet 80 mg Iqirvo® IPSEN PTY LTD Category 1 (New PBS listing)	Primary Biliary Cholangitis (PBC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of PBC.	Recommended	The PBAC recommended elafibranor for the treatment of PBC. The PBAC considered that elafibranor was non-inferior in terms of effectiveness and safety compared to obeticholic acid (OCA) and therefore considered that a cost-minimisation approach versus OCA to be appropriate and that the equi-effective doses are: elafibranor 80 mg once daily is equivalent to obeticholic acid 5 or 10 mg once daily. The PBAC considered that a price premium for elafibranor would be reasonable given the potential reduction in PBC-relatedpruritus compared to OCA. The PBAC considered that elafibranor should join the risk sharing arrangement for OCA. The PBAC indicated that flow-on changes to the OCA restriction would be required. Specifically, removing reference to 'cholelithiasis' in the Administrative Advice and removal of unnecessary wording in the clinical criteria, including 'with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion' and 'following this authority application'. Further, a new criterion should be added to the OCA restriction excluding concomitant use with elafibranor and, if used as monotherapy, the restriction should reference contraindications, in addition to intolerances to ursodeoxycholic acid.

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ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg Pack containing 28 sachets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets ivacaftor 75 mg Pack containing 28 sachets elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets ivacaftor 59.5 mg Trikafta® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY LTD Category 2 (Change to existing listing)	Cystic fibrosis (CF)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of CF patients aged 2 years or older who have at least one mutation in the CF transmembrane conductance regulator (*CFTR*) gene responsive to Trikafta® based on clinical and/or in vitro assay data.	Recommended	The PBAC recommended that the listing of elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) for the treatment of CF be extended to include patients who have at least one mutation in the *CFTR* gene that is responsive to ELX/TEZ/IVA based on clinical and/or *in vitro* assay data. The PBAC welcomed the input from individuals and organisations and noted they strongly supported the proposed extension of the listing. The PBAC noted the clinical benefit was uncertain but it was reasonable for ELX/TEZ/IVA to be available for this population, some of whom do not currently have access to *CFTR* modulators. The PBAC considered ELX/TEZ/IVA was likely to be cost-effective for this population at the current PBS price, noting that this population should be included in the current risk sharing arrangement for *CFTR* modulators with no increase in expenditure caps.

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ELRANATAMAB Solution for subcutaneous injection 44 mg in 1.1 mL (40 mg per mL) Solution for subcutaneous injection 76 mg in 1.9 mL (40 mg per mL) Elrexfio® PFIZER AUSTRALIA PTY LTD Standard re-entry (New PBS listing)	Relapsed or refractory multiple myeloma (RRMM)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of RRMM in patients who have received at least three prior lines of therapy.	Recommended	The PBAC recommended elranatamab for the treatment of patients with RRMM who have received at least three prior lines of therapy. The PBAC welcomed input from individuals and organisations and noted that they highlighted the need for new, effective, and well tolerated therapies for patients with RRMM. The PBAC also noted the input supported use of elranatamab in the fourth line of therapy and advised that elranatamab could provide an alternative to CAR-T therapies. The clinical evidence presented in the submission had several limitations that created uncertainty about the extent to which elranatamab improved overall survival compared to standard of care. The PBAC considered that elranatamab was superior in terms of efficacy compared to standard of care, represented by carfilzomib plus dexamethasone, pomalidomide plus dexamethasone and selinexor plus dexamethasone, but inferior in terms of safety. The PBAC considered that the revised economic model was reliable for decision making and noted that elranatamab would be cost-effective with a price reduction. The PBAC considered that the estimated utilisation of elranatamab was uncertain and considered that a risk-sharing arrangement would be required. The PBAC noted the large number of treatments listed on the PBS for the treatment of multiple myeloma. The PBAC recommended that the Department undertake a utilisation analysis to understand the treatment pathways and duration of treatment for PBS-listed therapies for multiple myeloma.

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ESTETROL WITH DROSPIRENONE Pack containing 24 tablets estetrol 14.2 mg with drospirenone 3 mg and 4 inert tablets Nextstellis® MAYNE PHARMA INTERNATIONAL PTY LTD Category 2 (New PBS listing)	Contraception	To request a General Schedule unrestricted listing.	Recommended	The PBAC recommended listing estetrol with drospirenone (E4/DRSP) (Nextstellis®) on the PBS as an Unrestricted Benefit. The PBAC recalled comments from the oral contraceptives stakeholder meeting convened in October 2024 stating that it was important to have a range of hormonal contraceptive options available on the PBS as choice of therapy can be highly individualised. The PBAC also noted consumer comments that stated it was important that more affordable contraceptive options are available for women. The PBAC did not consider the evidence supported the claim that E4/DRSP is superior to PBS-listed contraceptives in terms of longer-term safety risks such as venous thromboembolism and the risk of myocardial infarction and stroke. The PBAC considered that E4/DRSP provides an additional combined oral contraceptive (COC) option for individuals, and has non-inferior contraceptive efficacy compared to other COCs listed. The PBAC advised the equi-effective doses are 28-day cycle of E4/DRSP ≡ 28-day cycle of ethinylestradiol 20 microgram/drospirenone 3 mg / 28-day cycle of ethinylestradiol 30 microgram/drospirenone 3 mg.
FARICIMAB Solution for intravitreal injection 21 mg in 0.175 mL (120 mg per mL) pre-filled syringe Vabysmo® ROCHE PRODUCTS PTY LTD Category 4 (New PBS listing)	Macular oedema secondary to retinal vein occlusion (RVO)	To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of a new form for macular oedema secondary to RVO.	Recommended	The PBAC recommended the General Schedule Authority Required (Written/online PBS authorities system) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of faricimab 21 mg in 0.175 mL pre-filled syringe (PFS) for the treatment of macular oedema secondary to RVO. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of faricimab PFS would be acceptable if it were cost-minimised to the lowest cost PBS-listed anti-vascular endothelial growth factor) treatment for the same indication. The PBAC advised that faricimab 28.8 mg in 0.24 mL vial and faricimab 24.0 mg in 0.2 mL PFS should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule). The PBAC considered that listing the new form of faricimab would not result in additional cost to the Government.

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FEZOLINETANT Tablet 45 mg Veoza® ASTELLAS PHARMA AUSTRALIA PTY LTD Category 1 (New PBS listing)	Moderate to severe menopause-related vasomotor symptoms (VMS)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe menopause-related VMS.	Not Recommended	The PBAC did not recommend fezolinetant for the treatment of moderate to severe menopause-related VMS for patients unsuitable for menopausal hormone therapy (MHT). The PBAC considered that there is a clinical need for non-hormonal treatments for VMS associated with menopause, and potentially perimenopause, in a small proportion of patients contraindicated to MHT. The PBAC considered that the clinical place for fezolinetant was not well-defined in the submission and the proposed population eligible for fezolinetant was broader than is clinically appropriate, including patients who could be treated with MHT. The PBAC noted that MHT, which is less costly than fezolinetant, is the most effective and current mainstay treatment for VMS and other symptoms associated with menopause. The PBAC noted the increasing safety concern of drug induced liver disease with the use of fezolinetant since TGA approval in May 2024. The PBAC noted that the testing, care and risks for these had not been adequately considered in the submission. The PBAC also noted a number of viable (off-label) non-hormonal treatments for patients contraindicated to MHT, that reduce menopause-related VMS, are available and in clinical use, but were not considered by the submission. <u>Sponsor's Comment:</u> Astellas is surprised and disappointed that the PBAC did not recommend fezolinetant for treating moderate to severe menopause-related vasomotor symptoms (VMS) in patients unsuitable for menopausal hormone therapy (MHT), thus leaving an unmet clinical need in this population who cannot be treated with MHT. Astellas acknowledges that MHT is the current mainstay treatment for VMS and other menopause-related symptoms, but it cannot be the mainstay for women unsuitable for MHT. Astellas will be evaluating the applicability of evaluating off-label non-hormonal treatments for the treatment moderate to severe menopause-related VMS for patients unsuitable for menopausal hormone therapy (MHT).

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				Astellas will be resubmitting and looks forward to enabling fezolinetant to urgently be available on the PBS for all suitable Australian women.
FUTIBATINIB Tablet 4 mg Lytgobi® TAIHO PHARMA OCEANIA PTY LTD Category 1 (New PBS listing)	Bile duct cancer (cholangiocarcinoma)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on systemic therapy and have a fibroblast growth factor receptor 2 (*FGFR2*) fusion or rearrangement.	Not recommended	The PBAC did not recommend the listing of futibatinib for the treatment of patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on systemic therapy and have a *FGFR2* fusion or rearrangement. The PBAC considered that there was a high clinical need for treatments for patients with locally advanced or metastatic cholangiocarcinoma, who have a poor prognosis. The PBAC noted that based on the available clinical evidence the magnitude of clinical benefit was highly uncertain. The PBAC considered the economic model would need to be amended to include a more conservative and realistic estimate of clinical benefit to increase the reliability of the incremental cost-effectiveness ratio (ICER). The PBAC considered futibatinib would be cost-effective with an ICER in the range of $55,000 to < $75,000 per QALY. The PBAC noted the estimated number of patients that would be treated with futibatinib was uncertain and would need revision to more accurately reflect the prevalence of cholangiocarcinoma and the number of patients with a *FGFR2* fusion or rearrangement. The PBAC considered the outstanding issues could be addressed in an early re-entry submission. The PBAC noted that if MSAC is not of a mind to recommend the proposed testing component, an integrated resubmission would be required, which would not be suitable for the early re-entry pathway. <u>Sponsor's Comment:</u> The Sponsor is pleased that the PBAC has acknowledged the high clinical need for treatments in the proposed patient population and is committed to working with the PBAC and the Department to facilitate sustainable patient access to futibatinib as soon as possible.

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GEMCITABINE Solution for injection 1 g (as hydrochloride) in 25 mL Solution for injection 2 g (as hydrochloride) in 50 mL Gemcitabine Sandoz® SANDOZ PTY LTD Category 4 (New PBS listing)	Various cancers	To request Section 100 (Efficient Funding of Chemotherapy Program) Unrestricted Benefit listings of new forms of gemcitabine.	Recommended	The PBAC recommended Section 100 (Efficient Funding of Chemotherapy Program) Unrestricted Benefit listings of two new forms of gemcitabine (1 g/25 mL injection and 2 g/50 mL injection), hereafter referred to as Gemcitabine Sandoz, under the same conditions and on a cost-minimisation basis to the existing gemcitabine listing (1 g/26.3 mL injection and 2 g/52.6 mL injection), hereafter referred to as DBL Gemcitabine. The PBAC advised the equi-effective doses to be 1 mg Gemcitabine Sandoz is equal to 1 mg DBL Gemcitabine.
INFLIXIMAB Solution for injection 120 mg in 1 mL pre-filled pen Solution for injection 120 mg in 1 mL pre-filled syringe Remsima® SC CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 3 (Change to existing listing)	Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis Severe Crohn disease, Complex refractory fistulising Crohn Disease Moderate to severe ulcerative colitis	To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the continuing treatment of the currently listed indications of Remsima® SC.	Recommended	The PBAC recommended changing the authority level of subcutaneous infliximab 120 mg in 1 mL subcutaneous injection (Remsima® SC) from Authority Required (Written or Telephone/Online) to Authority Required (STREAMLINED) for the continuing treatment listings of all the requested indications. The PBAC considered that there was no clinical reason to have Remsima SC listed at a higher authority level than the equivalent IV listings for the same indication and treatment phase, noting that Remsima is not the reference brand of infliximab. The PBAC also recommended the removal of reference to continuing treatment from the balance of supply restrictions and to retain its authority level. The PBAC noted that changing the restriction level of a continuing treatment restriction to Authority Required (STREAMLINED) permits prescribers to write subsequent prescriptions to complete a treatment course without requiring prior authority approval. The PBAC therefore did not consider it appropriate to have an Authority Required (STREAMLINED) balance of supply restriction as it would create inconsistencies with the current administration of balance of supply restrictions, which are all Authority Required.

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INFLIXIMAB Powder for I.V. infusion 100 mg Ixifi® PFIZER AUSTRALIA PTY LTD Category 3 (New PBS listing)	Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis Severe Crohn disease, Complex refractory fistulising Crohn Disease Moderate to severe ulcerative colitis	To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new infliximab biosimilar under the same conditions as other biosimilar brands of infliximab.	Recommended	The PBAC recommended Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new infliximab biosimilar (Ixifi®) on a cost-minimisation basis and under the same circumstances as the existing PBS-listed biosimilar brands of infliximab 100 mg powder for injection (Inflectra® and Renflexis®), for the same indications. The PBAC noted that the submission requested for the Ixifi listings to be consistent with the biosimilar uptake driver policy, that is, to have an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Ixifi listings encouraging use of the biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Ixifi would be clinically appropriate and would not impact cost-effectiveness.
IVACAFTOR Sachet containing granules 13.4 mg Kalydeco® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY LTD Category 2 (New PBS listing)	Cystic fibrosis (CF)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of CF patients aged 1 to 4 months who have a gating mutation or at least one mutation in the CF transmembrane conductance regulator (*CFTR*) gene.	Recommended	The PBAC recommended the listing of ivacaftor granules 13.4 mg for the treatment of CF in patients aged 1 month to less than 4 months who have at least one mutation in the *CFTR* gene that is responsive to ivacaftor based on clinical and/ or *in vitro* assay data. The PBAC welcomed the input from individuals and organisations and noted they strongly supported the proposed extension of the listing. The PBAC noted that, overall, the evidence supporting the clinical claim in the submission was very limited but acknowledged the difficulties in obtaining clinical data in this population. The PBAC considered ivacaftor was likely to be cost-effective for this population at the current PBS price. The PBAC advised this population could be included in the current risk sharing arrangement for *CFTR* modulators with no increase in expenditure caps.

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LUMASIRAN Solution for subcutaneous injection 94.5 mg in 0.5 mL Oxlumo® MEDISON PHARMA AUSTRALIA PTY LTD Category 1 (New PBS listing)	Primary hyperoxaluria type 1 (PH1)	To request a General Schedule Authority Required (STREAMLINED) listing PH1	Recommended	The PBAC recommended the listing of lumasiran for the treatment of PH1. In making this recommendation, the PBAC accepted there is a high unmet clinical need for treatment options for patients with PH1, and that lumasiran is effective in reducing urinary oxalate and plasma oxalate and may also lead to a reduction in the utilisation of dialysis and liver-kidney transplantation. The PBAC considered that the incremental cost-effectiveness ratio was high and that the economic model was not sufficiently reliable for decision making due to uncertainty related to the translation of trial evidence to final health outcomes and the use of optimistic assumptions, utilities, and structural relationships. The PBAC considered that in the context of this rare and life-limiting disease, lumasiran would be considered acceptably cost-effective with a price reduction that resulted in an acceptable cost per patient per year. The PBAC noted that the estimated utilisation of lumasiran had been corrected for errors in the Pre-PBAC Response. The PBAC considered that the remaining uncertainties regarding the cost-effectiveness, cost per patient per year and utilisation could be managed by a risk sharing arrangement.

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MIDOSTAURIN Capsule 25 mg Rydapt® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD Category 2 (Change to existing listing)	Advanced systemic mastocytosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with advanced systemic mastocytosis.	Recommended	The PBAC recommended the listing of midostaurin for treatment of adult patients with advanced systemic mastocytosis (aggressive systemic mastocytosis, systemic mastocytosis with an associated haematological neoplasm, or mast cell leukaemia). The PBAC welcomed input from consumers and acknowledged advanced systemic mastocytosis is rare and that people living with it have high unmet needs and that there is a need for new treatment options. The clinical evidence presented in the submission had several limitations that created uncertainty about the extent to which midostaurin improved quality of life and overall survival compared to the current standard of care. However, the PBAC also recognised the difficulty obtaining clinical data for this rare disease. The PBAC was satisfied that midostaurin provides, for some patients, a significant improvement in efficacy over supportive care (i.e., standard of care). The PBAC noted that limitations in the evidence meant that safety comparisons were difficult but considered it likely that midostaurin was similar in safety to current standard of care. The PBAC considered that estimates of the benefits of midostaurin in the economic model were overly optimistic, particularly estimates of overall survival and quality of life. The clinical evidence presented in the submission did not allow confidence that several of the benefits claimed in support of the proposed price would be realised. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of midostaurin would be acceptable with a price reduction using an economic model respecified by the ESC to include more realistic estimates (modified to remove condensing progression free health states).

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MOGAMULIZUMAB Solution concentrate for I.V. infusion 20 mg in 5 mL Poteligeo® KYOWA KIRIN AUSTRALIA PTY LTD Standard re-entry (New PBS listing)	Cutaneous T-cell lymphoma (CTCL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Written) listing for the treatment of relapsed or refractory CTCL (mycosis fungoides or Sezary syndrome) who have previously been treated with at least one prior systemic therapy.	Recommended	The PBAC recommended the Authority Required listing of mogamulizumab for the treatment of patients with CTCL that has returned after, or not responded to, initial treatment (relapsed or refractory CTCL). The PBAC welcomed input from individuals who described the impact of relapsed or refractory CTCL on their quality of life, and from health care professionals who highlighted that durable remissions are not attained with one line of treatment. The PBAC noted the input from clinicians in the sponsor hearing regarding the limitations of treatment options currently available. The PBAC acknowledged that mogamulizumab has a unique mechanism of action and agreed with clinician advice that this agent would be particularly useful in patients with blood compartment involvement. The PBAC noted that all input highlighted the need for new treatment options. Overall, the PBAC agreed with the input provided that there was a high clinical need for alternate therapy options for patients with this rare condition. The clinical evidence presented in the submission had several limitations that created uncertainty about whether patients who received mogamulizumab would have better outcomes or quality of life than patients who received the main alternative treatment, vorinostat. It did not allow confidence that benefits over vorinostat claimed in the submission would be realised. The PBAC considered instead that mogamulizumab was more likely to have similar effectiveness and safety to vorinostat. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of mogamulizumab would be acceptable if it had a cost per patient that was no more than the cost of vorinostat. The PBAC advised that the following equi-effective dosing over a 28-day cycle were appropriate for the cost-minimisation approach taken: • 400 mg vorinostat administered orally daily, adjusted for dose intensity (88.96%) • 80 mg of mogamulizumab administered IV on days 1 and 15 only, adjusted for dose intensity (94.41%).

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NATALIZUMAB Solution concentrate for I.V. infusion 300 mg in 15 mL Tyruko® SANDOZ PTY LTD Category 3 (New PBS listing)	Relapsing-remitting multiple sclerosis (RRMS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a natalizumab biosimilar for the treatment of RRMS under the same conditions as its reference biologic.	Recommended	The PBAC recommended the Section 100 (Highly Specialised Drug) Authority Required (STREAMLINED) listing of a new biosimilar brand of natalizumab 300 mg in 15 mL vial for intravenous infusion (Tyruko®) on a cost-minimisation basis and under the same circumstances as the PBS-listed reference biologic, Tysabri®, for the treatment of clinically definite RRMS. The PBAC considered that the inclusion of the 'Biosimilar prescribing policy' administrative note, encouraging use of the biosimilar brand (i.e., Tyruko) for treatment naïve patients, is clinically appropriate.
NIRSEVIMAB Solution for injection 50 mg in 0.5 mL pre-filled syringe Solution for injection 100 mg in 1 mL pre-filled syringe Beyfortus® SANOFI-AVENTIS AUSTRALIA PTY LTD Standard re-entry (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	Resubmission to request a National Immunisation Program listing for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season; and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.	Not Applicable	To be considered at a future PBAC meeting.

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ODEVIXIBAT Capsule 200 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms Bylvay® IPSEN PTY LTD Facilitated resolution (New PBS listing)	Progressive familial intrahepatic cholestasis (PFIC)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of PFIC.	Deferred	The PBAC deferred making a recommendation for odevixibat for the treatment of PFIC. The PBAC requested draft restrictions which considered revisions to the following aspects: prescriber type for adults, instrument used for assessing pruritus, and criteria for ceasing treatment if no response, for retreatment and for dose escalation. The PBAC requested a reduced price for odevixibat as it considered odevixibat was not cost-effective at the price proposed in the resubmission. The PBAC requested revised financial caps for the risk sharing arrangement as the financial estimates which informed the caps in the resubmission were overestimated and hence did not adequately manage the risk of dose escalation which would not be cost-effective, as well as continued use in non-responders. The PBAC, noting the high clinical need, stated that they would continue to work with the Sponsor to address the remaining issues. <u>Sponsor's Comment:</u> Ipsen looks forward to working with the PBAC and Department of Health and Aged Care on next steps to help address the needs of patients with PFIC as soon as possible.
OMALIZUMAB Injection 75 mg in 0.5 mL single dose pre-filled syringe Injection 150 mg in 1 mL single dose pre-filled syringe Omlyclo® CELLTRION HEALTHCARE AUSTRALIA PTY LTD Category 3 (New PBS listing)	Uncontrolled severe asthma Uncontrolled severe allergic asthma Severe chronic spontaneous urticaria	To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of an omalizumab biosimilar for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria, under the same conditions as its reference biologic.	Recommended	The PBAC recommended Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new biosimilar brand of omalizumab (Omlyclo®) in the forms of 75 mg in 0.5 mL and 150 mg in 1 mL pre-filled syringe (PFS) on a cost-minimisation basis and under the same circumstances as the PBS-listed reference biologic, Xolair®, for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria. The PBAC noted the submission requested that biosimilar uptake drivers be applied to Omlyclo, that is, to have an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Omlyclo listings encouraging use of the biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Omlyclo would be clinically appropriate and would not impact cost-effectiveness.

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OMALIZUMAB Injection 75 mg in 0.5 mL single dose pre-filled syringe Injection 150 mg in 1 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe Injection 75 mg in 0.5 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled pen Xolair® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Category 4 (New PBS listing)	Uncontrolled severe asthma(USA) Uncontrolled severe allergic asthma (USAA) Severe chronic spontaneous urticaria (CSU)	To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new strength and new forms of omalizumab for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria.	Recommended	The PBAC recommended listing a new 300 mg/2 mL strength and a new pre-filled pen (PFP) form of omalizumab (Xolair®) under the same conditions as the current PBS listings of the pre-filled syringe (PFS) form for the treatment of USA and CSU as a Section 100 (Highly Specialised Drugs Program) Authority Required listing. The PBAC considered it appropriate for the new PFS form with a new safety device in the 75 mg/0.5 mL and 150 mg/mL strengths to be listed under the same PBS item codes as the existing PFS form for the treatment of USA, CSU, and USAA. The PBAC advised that the PFS and PFP forms of omalizumab should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) for the treatment of USA and CSU. The PBAC noted that the 300 mg/2 mL PFS and all strengths of PFP are not intended for use in patients under 12 years of age and therefore advised that a caution stating "the 300 mg/2 mL pre-filled syringe and all dose strengths of the pen device are not intended for use in children under 12 years of age" should be included in the restriction for USAA. The PBAC considered that the new forms are expected to substitute for the currently PBS-listed PFS form of omalizumab, resulting in no net financial implications to the PBS/RPBS.

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OMAVELOXOLONE Capsule 50 mg Skyclarys® BIOGEN AUSTRALIA PTY LTD Category 1 (New PBS listing)	Friedreich's ataxia	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.	Not recommended	The PBAC did not recommend omaveloxolone for treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older. The PBAC noted the high clinical need for treatments for this condition but considered that the data presented did not convincingly support the claims that omaveloxolone was superior in terms of effectiveness compared to best supportive care. Further, the PBAC advised that omaveloxolone was not cost-effective with a very high incremental cost-effectiveness ratio. The PBAC noted that this was based on the proposed published price, and although the submission indicated the effective price would be lower, it was not provided by the sponsor. The PBAC considered that financial impact estimate of listing omaveloxolone on the PBS was very high (approximately $900 million to < $1 billion over 6 years), although this was also based on the proposed published price. <u>Sponsor's Comment:</u> Biogen welcomes the PBAC's acknowledgement of the high unmet clinical need for people living with Friedreich's ataxia. Biogen believes that the MOXIe trial demonstrated that omaveloxolone provides a clinical benefit to people with Friedreich's ataxia by slowing the progression of the disease. Biogen will continue to work collaboratively with the PBAC to deliver access to omaveloxolone for people with this rare condition in a timely manner. Biogen would like to take this opportunity to thank the Friedreich's ataxia community and healthcare professionals who supported the submission.

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PALOPEGTERIPARATIDE Solution for subcutaneous injection 168 micrograms in 0.56 mL pre-filled pen Solution for subcutaneous injection 294 micrograms in 0.98 mL pre-filled pen Solution for subcutaneous injection 420 micrograms in 1.4 mL pre-filled pen Yorvipath® SPECIALISED THERAPEUTICS PHARMA PTY LTD Category 1 (New PBS listing)	Chronic hypoparathyroidism	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of chronic hypoparathyroidism.	Not Recommended	The PBAC did not recommend palopegteriparatide for the treatment of patients with chronic hypoparathyroidism who are inadequately controlled on conventional therapy (i.e. active vitamin D and calcium supplements). The PBAC considered that palopegteriparatide was superior compared to the nominated comparator of conventional therapy in terms of efficacy and likely non-inferior in terms of safety. However, the PBAC considered that the economic model presented in the submission was highly uncertain and may not be suitable for decision making, given its reliance on chronic kidney disease (CKD) outcomes and, at the price proposed in the submission, that palopegteriparatide was not cost-effective. The PBAC considered that the estimated utilisation was likely overestimated and considered that a risk sharing arrangement would be required to mitigate the risk of usage in the first line setting. <u>Sponsor's Comment:</u> The sponsor had no comment.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Category 2 (Change to existing listing)	Cervical cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of high risk, locally advanced cervical cancer.	Recommended	The PBAC recommended pembrolizumab for the treatment of high-risk, locally advanced cervical cancer (LACC). The PBAC welcomed input from organisations advocating on behalf of patients with cervical cancer. The PBAC considered that pembrolizumab commenced in combination with chemoradiotherapy (CCRT) improved progression-free survival and overall survival compared to CCRT alone. The PBAC noted the magnitude of the benefit over CCRT was likely overestimated in the clinical trial given the underutilisation of subsequent pembrolizumab in patients who progressed following treatment with CCRT alone. The PBAC considered that revisions to the economic model were required and that pembrolizumab would be cost-effective with a price reduction. The PBAC considered that pembrolizumab should join the existing risk sharing arrangement (RSA) for pembrolizumab for advanced carcinoma of the cervix (persistent, recurrent or metastatic disease) on the basis that the cost-effectiveness of pembrolizumab for LACC will depend on the realisation of cost savings from reduced use of pembrolizumab in the advanced/metastatic setting.

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PERTUZUMAB Solution for I.V. infusion 420 mg in 14 mL Perjeta® ROCHE PRODUCTS PTY LTD Standard re-entry (Change to existing listing)	Human epidermal growth factor receptor 2-positive (HER2+) locally advanced, inflammatory or early stage breast cancer	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing, in combination with trastuzumab and chemotherapy, for the neoadjuvant treatment of HER2+ locally advanced, inflammatory or early stage breast cancer.	Recommended	The PBAC recommended the listing of pertuzumab for the neoadjuvant treatment of HER2+ high risk early breast cancer, on the basis that it should be available only under special arrangements under Section 100. The PBAC considered that the resubmission appropriately addressed its previous concerns regarding the clinical place for pertuzumab, and the incremental benefit from adding pertuzumab in the neoadjuvant setting was adequately supported by the evidence, which demonstrated that increasing the proportion of patients with pathological complete response is associated with improved disease free survival and OS. The PBAC considered that adjuvant treatment with pertuzumab would also be appropriate for a proportion of patients, consistent with international guidelines and the Australian Product Information for pertuzumab. The PBAC considered that the cost-effectiveness for pertuzumab would be acceptable with a price reduction and risk sharing arrangements that ensured that the cost of treatment in the adjuvant setting was contained to the patient population where there is evidence of treatment benefit.

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POLATUZUMAB VEDOTIN Powder for I.V. infusion 30 mg Powder for I.V. infusion 140 mg Polivy® ROCHE PRODUCTS PTY LTD Standard re-entry (New PBS listing)	Diffuse large B-cell lymphoma (DLBCL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing, in combination with rituximab, cyclophosphamide, doxorubicin and prednisone, for the treatment of previously untreated DLBCL.	Recommended	The PBAC recommended listing of polatuzumab vedotin in combination with rituximab plus cyclophosphamide, doxorubicin and prednisone (Pola+R-CHP) for the treatment of DLBCL in previously untreated patients with an international prognostic index (IPI) score of 3-5. The PBAC noted and welcomed the input from individuals and organisations and acknowledged (Pola+R-CHP) is recommended for the first-line treatment of DLBCL in a number of international guidelines. The PBAC was satisfied that Pola+R-CHP provides, for some patients, a modest improvement in progression-free survival over rituximab in combination with cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP). However, the PBAC noted that the clinical evidence presented in the submission showed no significant difference in overall survival. The economic model included in the submission however included claims of overall survival benefits in support of the proposed price. These estimated benefits were overly optimistic and not supported by the clinical evidence included in the submission. The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of polatuzumab vedotin would be acceptable using an economic model respecified by its Economic Sub-Committee to include more realistic estimates. The PBAC considered a risk-sharing arrangement, based on amended financial estimates, appropriate to mitigate the risk of use of polatuzumab vedotin in the broader DLBCL population.

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RAVULIZUMAB Solution concentrate for I.V. infusion 300 mg in 3 mL Solution concentrate for I.V. infusion 1,100 mg in 11 mL Ultomiris® ALEXION PHARMACEUTICALS AUSTRALIASIA PTY LTD Standard re-entry (Change to existing listing)	Generalised myasthenia gravis (gMG)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.	Recommended	The PBAC recommended the listing of ravulizumab for the treatment of gMG. The PBAC appreciated the input provided by patients, carers and clinicians and found the comments very informative for understanding the high and unmet clinical need for new effective treatments and the potential use of the new therapies in practice. The comments outlined the significant impact that gMG can have on quality of life, including the impact on patient's families. The comments also described the limitations of currently available treatment options including adverse events and lengthy administration times. The clinical evidence presented in the submission had several limitations that created uncertainty as to whether ravulizumab would improve patient outcomes compared with intravenous immunoglobulin or plasma exchange. Overall, the PBAC considered there was insufficient evidence to suggest ravulizumab would be more effective or safer than these treatments. Further, the PBAC considered that there was no evidence to suggest that ravulizumab was superior in terms of efficacy or safety compared with the other three therapies for gMG that were considered at the March 2025 meeting (zilucoplan, efgartigimod and rozanolixizumab). Overall, the PBAC advised that the four therapies should be considered to have similar efficacy and safety compared with each other and with intravenous immunoglobulin. The recommendation to list ravulizumab on the PBS was made on the basis of a cost-comparison versus intravenous immunoglobulin, supported by a cost-per-responder analysis versus placebo. The PBAC considered that the new gMG therapies should substitute for intravenous immunoglobulin and plasma exchange rather than be added on to or used in combination with these modalities. The PBAC advised that the prescribing criteria for intravenous immunoglobulin should be revised to ensure use remains appropriate in the context of the availability of the new therapies.

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ROZANOLIXIZUMAB Solution for subcutaneous infusion 280 mg in 2 mL (140 mg per mL) Rystiggo® UCB AUSTRALIA PTY LTD Category 1 (New PBS listing)	Generalised myasthenia gravis (gMG)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.	Recommended	The PBAC recommended the listing of rozanolixizumab for the treatment of gMG. The PBAC appreciated the input provided by patients, carers and clinicians and found the comments very informative for understanding the high and unmet clinical need for new effective treatments and the potential use of the new therapies in practice. The comments outlined the significant impact that gMG can have on quality of life, including the impact on patient's families. The comments also described the limitations of currently available treatment options including adverse events and lengthy administration times. Overall, the PBAC considered there was insufficient evidence to suggest rozanolixizumab would be more effective or safer than intravenous immunoglobulin or plasma exchange. Further, the PBAC considered that there was no evidence to suggest that rozanolixizumab was superior in terms of efficacy or safety compared with the other three therapies for gMG that were considered at the March 2025 meeting (zilucoplan, efgartigimod and ravulizumab). Overall, the PBAC advised that the four therapies should be considered to have similar efficacy and safety compared with each other and with intravenous immunoglobulin. The recommendation to list rozanolixizumab on the PBS was made on the basis of a cost-comparison versus intravenous immunoglobulin, supported by a cost-per-responder analysis versus placebo. The PBAC considered that the new gMG therapies should substitute for intravenous immunoglobulin and plasma exchange rather than be added on to or used in combination with these modalities. The PBAC advised that the prescribing criteria for intravenous immunoglobulin should be revised to ensure use remains appropriate in the context of the availability of the new therapies.

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RUXOLITINIB Tablet 5 mg Tablet 10 mg Tablet 15 mg Tablet 20 mg Jakavi® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD Standard re-entry (Change to existing listing)	Polycythemia vera (PV)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adult patients with PV who are resistant to or intolerant of hydroxycarbamide (hydroxyurea).	Recommended	The PBAC recommended the listing of listing for ruxolitinib for the treatment of adult patients with PV who are resistant to or intolerant of hydroxycarbamide (hydroxyurea). The PBAC welcomed the input from individuals, health care professionals and organisations that highlighted the impact of PV on patients' quality of life and noted the issues associated with current treatment options. The PBAC noted the resubmission provided updated data which reported significant improvements in major event-free survival, reductions in venesections and improvements in duration of response that were clinically relevant. As such, the PBAC is satisfied that ruxolitinib provides, for some patients, a significant improvement in efficacy over best available therapy. The PBAC noted that while no statistically significant differences in progression-free survival or overall survival were reported in the clinical trial evidence, differences in these outcomes were assumed in the economic model and maintained throughout the 20 year time horizon. Despite revisions to the economic model inputs in the pre-PBAC response the PBAC considered the resulting incremental cost-effectiveness ratio remained uncertain. The PBAC noted a cost-per-overall response was determined and advised that, together with the economic model, it adequately supported the cost-effectiveness of ruxolitinib at the price proposed in the pre-PBAC response.
SACITUZUMAB GOVITECAN Powder for injection 180 mg Trodelvy® GILEAD SCIENCES PTY LIMITED Category 3 (Change to existing listing)	Breast cancer	To request a definition for human epidermal growth factor receptor 2 (HER2) status be added to the clinical criteria for the initial treatment of unresectable locally advanced or metastatic triple-negative breast cancer.	Not Recommended	The PBAC did not recommend an amendment to the listing of sacituzumab govitecan for the treatment of patients with unresectable locally advanced or metastatic triple negative breast cancer to include a definition for HER2 status in the clinical criteria of the initial treatment phase restriction. The PBAC considered that "triple negative breast cancer" is a well understood term by clinicians in oncology. The PBAC considered that the restriction wording effectively enables prescribers to exercise clinical discretion to determine patient eligibility and prescribe the most appropriate treatment for their patients. <u>Sponsor's Comment:</u> The sponsor had no comment.

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SOTATERCEPT Powder for subcutaneous injection 45 mg (50 mg per mL) Powder for subcutaneous injection 60 mg (50 mg per mL) Winrevair® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Category 1 (New PBS listing)	Pulmonary arterial hypertension (PAH)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing as add on therapy for the treatment of Group 1 PAH.	Not Recommended	The PBAC did not recommend sotatercept as add-on therapy for the treatment of patients with Group 1 PAH. The PBAC recognised the unmet clinical need in this population and that treatment guidelines in PAH have continued to evolve. While the PBAC considered that the clinical claim of superior effectiveness of sotatercept vs placebo is supported for WHO FC II patients when added to existing dual or triple background therapy, there was minimal evidence supporting sotatercept added to monotherapy in this population. The PBAC noted that the relevant comparator is dual therapy with ERA + PDE5i, not placebo as nominated by the submission. The PBAC considered that the clinical claim of superior effectiveness of sotatercept vs selexipag is potentially supported, but the magnitude of any benefit is uncertain. The PBAC noted the submission's acknowledgement of this uncertainty in its proposal of an overall weighted price of sotatercept, with the sotatercept price at parity to selexipag in WHO FC III patients. The PBAC advised that the economic model would require revision to the inputs and considered that the incremental cost-effectiveness ratio was very high at the proposed price. The PBAC considered the submission's financial estimates to be uncertain and overestimated. The PBAC noted that the requested listing (for sotatercept treatment in combination with standard therapy in patients with WHO FC II or III) raised several disconnections in terms of currently available PAH medicines on the PBS and international guidelines for the treatment of PAH, which in turn informs the potential clinical place of sotatercept on the PBS. The PBAC requested that the Department undertake a review of the restrictions for currently listed PAH medicines with regard to the consistency with international PAH treatment guidelines. <u>Sponsor's Comment:</u> MSD is committed to working with the PBAC to bring this new treatment to Australian PAH patients as soon as possible.

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TARLATAMAB Powder for injection 10 mg Imdelltra® AMGEN AUSTRALIA PTY LTD Category 1 (New PBS listing)	Small cell lung cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the third-line plus treatment of extensive-stage small cell lung cancer.	Not Applicable	To be considered at a future PBAC meeting.
TEPROTUMUMAB Powder for I.V. infusion 500 mg Tepezza® AMGEN AUSTRALIA PTY LTD Category 1 (New PBS listing)	Thyroid eye disease (TED)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of active, moderate-to-severe TED.	Not Recommended	The PBAC did not recommend teprotumumab for the treatment of active, moderate-to-severe TED. The PBAC considered there was a high clinical need in the requested patient population, and the evidence presented demonstrated that teprotumumab was more effective in reducing proptosis and diplopia compared to the current standard of care, which may lead to a reduced utilisation of eye surgery. However, the PBAC considered that due to the limited data available, the complexity of the economic model led to a high degree of uncertainty. The PBAC considered that revision to model inputs and a price reduction would be required to address residual uncertainty and achieve a cost-effective listing, together with a risk sharing arrangement. <u>Sponsor's Comment:</u> Amgen is committed to working with the PBAC and Department of Health and Aged Care to enable timely access to teprotumumab for patients with active, moderate-to-severe thyroid eye disease.

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TORIPALIMAB Solution concentrate for I.V. infusion 240 mg in 6 mL (40 mg per mL) Zytorvi® DR REDDY'S LABORATORIES AUSTRALIA PTY LTD Category 2 (New PBS listing)	Nasopharyngeal carcinoma	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of recurrent or metastatic nasopharyngeal carcinoma.	Recommended	The PBAC recommended the Authority Required listing of toripalimab for the treatment of recurrent or metastatic nasopharyngeal carcinoma The PBAC welcomed input from organisations advocating on behalf of patients with nasopharyngeal carcinoma. The PBAC acknowledged that patients with nasopharyngeal carcinoma have a poor prognosis and face significant financial burden. The PBAC recognised there was a high clinical need for additional treatment options for patients with this condition. The PBAC considered it reasonable for toripalimab to be available for patients being treated for recurrent or metastatic nasopharyngeal carcinoma, regardless of whether patients have received prior treatment. The clinical evidence presented demonstrated that toripalimab improved progression-free and overall survival in patients who participated in the trials when added to existing treatment with cisplatin and gemcitabine. However, the evidence did not allow confidence about the extent to which this benefit would be realised in Australia. In particular, the clinical trials included a very small number of patients with the keratinising squamous cell variant of nasopharyngeal carcinoma, which is more common in Australia, and is associated with poorer prognosis. Further, the clinical evidence did not support the claim in the submission that the safety of toripalimab was no worse than standard of care chemotherapy. The PBAC noted that patients in the toripalimab arm of the JUPITER-02 trial experienced over twice as many immune related adverse events and a higher number of treatment emergent adverse events that led to treatment discontinuation compared to the placebo arm. Because of these uncertainties, the PBAC considered that the benefits estimated in the economic model, in support of the proposed price, were overly optimistic, particularly the duration of benefit. The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of toripalimab would be acceptable with a price reduction using an economic model respecified by its Economic-Sub-Committee to include more realistic estimates.

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USTEKINUMAB Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Solution concentrate for I.V. infusion 130 mg in 26 mL (5 mg per mL) Epyztek® SAMSUNG BIOEPIS AU PTY LTD Category 3 (New PBS listing)	Severe chronic plaque psoriasis (CPP) Severe psoriatic arthritis (PsA) Severe Crohn disease (CD) Complex refractory fistulising CD (fCD) Moderate to severe ulcerative colitis (MSUC)	To request General Schedule and Section 100 (Highly Specialised Drugs Program) listings of an ustekinumab biosimilar for the treatment of CPP, PsA, CD, fCD and MSUC.	Recommended	The PBAC recommended General Schedule and Section 100 (Highly Specialised Drugs Program) listings of a new biosimilar brand of ustekinumab (Epyztek®) in the forms of injection 45 mg in 0.5 mL in 0.5 mg pre-filled syringe (PFS), injection 90 mg in 1 mL PFS, and solution for I.V. infusion 130 mg in 26 mL on a cost-minimisation basis and under the same circumstances as the PBS-listed reference biologic, Stelara®, for the same indications. The PBAC noted the biosimilar uptake driver policy, that is, an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Epyztek listings encouraging use of the biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Epyztek would be clinically appropriate and would not impact cost-effectiveness.

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ZILUCOPLAN Solution for injection 16.6 mg in 0.416 mL (as tetrasodium) pre-filled syringe Solution for injection 23 mg in 0.574 mL (as tetrasodium) pre-filled syringe Solution for injection 32.4 mg in 0.810 mL (as tetrasodium) pre-filled syringe Zilbrysq® UCB AUSTRALIA PTY LTD Standard re-entry (New PBS listing)	Generalised myasthenia gravis (gMG)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for initial treatment and a General Schedule Authority Required (Written) listing for continuing treatment of gMG.	Recommended	The PBAC recommended the listing of zilucoplan for the treatment of gMG. The PBAC appreciated the input provided by patients, carers and clinicians and found the comments very informative for understanding the high and unmet clinical need for new effective treatments and the potential use of the new therapies in practice. The comments outlined the significant impact that gMG can have on quality of life, including the impact on patient's families. The comments also described the limitations of currently available treatment options including adverse events and lengthy administration times. Overall, the PBAC considered there was insufficient evidence to suggest zilucoplan would be more effective or safer than intravenous immunoglobulin or plasma exchange. Further, the PBAC considered that there was no evidence to suggest that zilucoplan was superior in terms of efficacy or safety compared with the other three therapies for gMG that were considered at the March 2025 meeting (ravulizumab, efgartigimod and rozanolixizumab). Overall, the PBAC advised that the four therapies should be considered to have similar efficacy and safety compared with each other and with intravenous immunoglobulin. The recommendation to list zilucoplan on the PBS was made on the basis of a cost-comparison versus intravenous immunoglobulin, supported by a cost-per-responder analysis versus placebo. The PBAC considered that the new gMG therapies should substitute for intravenous immunoglobulin and plasma exchange rather than be added on to or used in combination with these modalities. The PBAC advised that the prescribing criteria for intravenous immunoglobulin should be revised to ensure use remains appropriate in the context of the availability of the new therapies.

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ZOLBETUXIMAB Powder for I.V. infusion 100 mg (20 mg per mL) Vyloy® ASTELLAS PHARMA AUSTRALIA PTY LTD Category 1 (New PBS listing)	Gastric or gastroesophageal junction (G/GOJ) cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of locally advanced unresectable or metastatic epidermal growth factor receptor 2-negative G/GOJ adenocarcinoma.	Deferred	The PBAC deferred making a recommendation for the listing of zolbetuximab with fluoropyrimidine- and platinum-containing chemotherapy, for the targeted first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative G/GOJ adenocarcinoma whose tumours are CLDN18.2- positive (CLDN18.2+). The PBAC was of a mind to recommend zolbetuximab pending MSAC consideration of immunohistochemistry (IHC) testing for Claudin 18.2 (CLDN18.2) expression and presentation of revised restriction criteria and cost-minimisation approach (CMA). The PBAC considered that there is a moderate clinical need for new treatments for advanced G/GOJ as there are few effective treatment options for this population and the associated prognosis is poor. The PBAC considered that while no evidence was presented in the submission to support treatment effect modification of CLDN18.2 expression, it would be reasonable to accept the claim for codependence due to the strong biological rationale. The PBAC considered that the efficacy of zolbetuximab was non-inferior compared to nivolumab, but due to the additional gastrointestinal toxicity safety was inferior, which would limit uptake, and this should be reflected in the CMA. <u>Sponsor's Comment:</u> Astellas Pharma Australia welcomes the deferral for zolbetuximab and looks forward to its inclusion on the PBS. Despite recent medical advancements, gastric and GOJ adenocarcinoma remains a significant clinical problem because a majority of patients continue to present with incurable locally advanced or metastatic disease on diagnosis.

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ALIROCUMAB Injection 300 mg in 2 mL single dose autoinjector Praluent® SANOFI-AVENTIS AUSTRALIA PTY LTD	Familial heterozygous hypercholesterolaemia Non-familial hypercholesterolaemia	To request the PBAC review its March 2023 recommendation that has not yet been accepted by the applicant.	The PBAC rescinded the March 2023 recommendation for this drug.
BEVACIZUMAB Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL Zirabev® PFIZER AUSTRALIA PTY LTD	Various cancers	To request the PBAC review its July 2020 recommendation that has not yet been accepted by the applicant.	The PBAC rescinded the July 2020 recommendation for this drug.
IXEKIZUMAB Injection 80 mg in 1 mL single dose pre-filled pen Taltz® ELI LILLY AUSTRALIA PTY LTD	Non-radiographic axial spondyloarthritis	To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.	The PBAC rescinded the November 2021 recommendation for this drug.
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 syringe Injection 300 mg in 2 mL pre-filled pen Cosentyx® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD	Paediatric psoriasis	To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.	The PBAC rescinded the November 2021 recommendation for this drug.

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Review of PBS items for nurse practitioner and endorsed midwife prescribing Various forms and strengths Various brands Various sponsors (Other matters)	Various	To request the PBAC consider a tranche of PBS-listed medicines which do not include nurse practitioners and endorsed midwives as authorised prescribers but may be suitable for prescribing by these health professionals.	The PBAC considered and provided advice on PBS listings identified by stakeholders, that may be suitable for prescribing by nurse practitioners and endorsed midwives. The PBAC recommended a number of PBS listings be amended to include nurse practitioners as authorised prescribers, in some instances under a shared care and/or as continuing therapy only. For endorsed midwives, the PBAC recommended amending all PBS listings for combined oral contraceptives to include endorsed midwives as authorised prescribers.
MIGALASTAT Capsule 123 mg Galafold® AMICUS THERAPEUTICS PTY LTD Other matters (Change to existing listing)	Fabry disease	Request to increase the number of repeats specified in the PBS listing for migalastat.	The PBAC recommended amending the existing PBS listing of migalastat for initial, continuing and grandfather (LSDP transition arrangements). The PBAC noted this request followed correspondence from clinicians stating the existing PBS maximum repeats provided only 5.5 months' of therapy per prescription. The PBAC noted the change to the maximum repeats would facilitate 6 monthly patient review. The PBAC considered that the change was unlikely to affect overall utilisation or result in a financial impact to Government.

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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.

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 High Added Therapeutic Value (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 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.