

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MAY 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	
<p align="center"> ALECTINIB Capsule 150 mg Alecensa® ROCHE PRODUCTS PTY LTD Category 2 (Change to existing listing) </p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p align="center"> To request a General Schedule Authority Required (Telephone/Online) listing for the adjuvant treatment in adult patients following tumour resection of anaplastic lymphoma kinase (ALK)-positive NSCLC (tumour ≥4 cm or node positive). </p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule, Authority required (Telephone/Online) listing of alectinib for adjuvant treatment of adult patients following tumour resection (tumours ≥4 cm or node positive) of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). The PBAC considered there was a high clinical need for effective therapies in this uncommon NSCLC subtype, noting the rarity of this condition and that there are currently no targeted treatments available to patients with ALK-positive early-stage NSCLC. While the PBAC was uncertain if there was a survival benefit associated with alectinib, it was satisfied that alectinib provided, for some patients, a significant improvement in efficacy in terms of prolonging the time after treatment where there no signs of disease recurrence, over platinum-based chemotherapy. The PBAC considered alectinib would be cost-effective and that the uncertainties with the survival benefit estimated in the economic model would be mitigated, with a lower price for alectinib and with the updated inputs incorporated into the economic model.</p> <p>The PBAC considered that consistent with other high-cost adjuvant listings (e.g. osimertinib, immune checkpoint inhibitors), re-treatment in the metastatic setting should not be permitted. The PBAC would like to increase patient access in these situations but considered that evidence was required to determine a cost-effective price in the re-treatment setting. The PBAC noted flow-on changes to other PBS listings in locally advanced or metastatic disease (alectinib, brigatinib, crizotinib, ceritinib, and lorlatinib) to prevent treatment with ALK TKIs following recurrence after adjuvant treatment with alectinib would be required.</p>

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<p align="center">BIMEKIZUMAB</p> <p>Injection 160 mg in 1 mL single use pre-filled pen Injection 160 mg in 1 mL single use pre-filled syringe Injection 320 mg in 2 mL single use pre-filled pen Injection 320 mg in 2 mL single use pre-filled syringe</p> <p align="center">Bimzelx®</p> <p align="center">UCB AUSTRALIA PROPRIETARY LIMITED</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Hidradenitis suppurativa (HS)</p>	<p align="center">To request General Schedule Authority Required (Written) listings for new forms of bimekizumab, in addition to the currently listed form, for the treatment of patients with moderate to severe HS.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule, Authority Required (in writing) listing of bimekizumab for the treatment of moderate to severe hidradenitis suppurativa (HS). The PBAC's recommendation was based on, among other matters, its assessment that the cost effectiveness of bimekizumab would be acceptable if it were cost minimised to the least costly alternative therapy of either secukinumab or adalimumab. The PBAC noted flow-on restriction changes to secukinumab and adalimumab to include bimekizumab in the list of eligible therapies for the treatment of moderate to severe HS.</p>

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<p style="text-align: center;">DOSTARLIMAB</p> <p>Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p style="text-align: center;">Jemperli®</p> <p style="text-align: center;">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p style="text-align: center;">Standard re-entry (Change to existing listing)</p>	<p style="text-align: center;">Endometrial cancer</p>	<p style="text-align: center;">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for use in combination with platinum-containing chemotherapy for the treatment of primary advanced or first recurrent mismatch repair proficient endometrial cancer.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of dostarlimab (DOS) in combination with carboplatin and paclitaxel (CP) for the treatment of primary advanced or first recurrent (A/R) proficient mismatch repair (pMMR) endometrial cancer (EC). The PBAC noted that there is a high clinical need for effective first-line treatments for endometrial cancer but considered that the clinical benefit in the pMMR population remained unclear with updated data, and overall safety was inferior to current therapy. The PBAC noted that it was possible that these patients may benefit more from second-line treatment with pembrolizumab in combination with lenvatinib.</p> <p><u>Sponsor's Comment:</u> GSK is disappointed by the PBAC's decision not to recommend dostarlimab (Jemperli) for pMMR patients. GSK considers that subsequent follow-up from the RUBY trial has established the overall survival (OS) benefit for Jemperli plus CP in the overall primary advanced / first recurrent EC population (Powell et al., 2024). GSK considers that at least half of the women treated in the first-line setting would not be eligible for immunotherapy in the second-line setting (paragraph 7.10, Dostarlimab PSD, November 2023).</p>

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<p align="center">DURVALUMAB TREMELIMUMAB</p> <p>Solution concentrate for I.V. infusion 120 mg in 2.4 mL Solution concentrate for I.V. infusion 500 mg in 10 mL Solution concentrate for I.V. infusion 300 mg in 15 mL</p> <p align="center">Imfinzi® Imjudo®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Barcelona clinic liver cancer (BCLC) Hepatocellular carcinoma (HCC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for durvalumab in combination with tremelimumab for the first line treatment of patients with advanced (unresectable) Stage B BCLC or Stage C HCC.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (Streamlined) listing of durvalumab in combination with tremelimumab (referred to as Single Tremelimumab Regular Interval Durvalumab (STRIDE) regimen) for the treatment of patients with advanced (unresectable) Stage B Barcelona Clinic Liver Cancer (BCLC) or Stage C hepatocellular carcinoma (HCC) who have not received prior treatment or who are intolerant to prior treatment with a tyrosine kinase inhibitor. The PBAC considered that, despite the uncertainties associated with the clinical evidence comparing the STRIDE regimen to atezolizumab + bevacizumab, on balance it was likely that the STRIDE regimen was likely to be similarly effective and safe compared to atezolizumab + bevacizumab for this indication.</p> <p>The PBAC considered it was appropriate for the STRIDE regimen to be listed on a cost minimisation basis to atezolizumab + bevacizumab. The PBAC considered that the substantial difference in follow-up data available between the clinical trials for these therapies created additional challenges for determining the equi-effective doses and relied instead on PBS utilisation data for atezolizumab which resulted in more balanced treatment durations for determining the equi-effective doses compared to the available trial follow-up data for the STRIDE regimen.</p> <p>The PBAC noted flow-on changes to other PBS listings would be required to allow patients to be treated with lenvatinib or sorafenib where intolerance of a severity necessitating permanent treatment withdrawal occurs with the first-line use of the STRIDE regimen.</p>

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<p align="center">EMPAGLIFLOZIN</p> <p align="center">Tablet 10 mg</p> <p align="center">Jardiance®</p> <p align="center">BOEHRINGER INGELHEIM PTY LTD</p> <p align="center">Standard re-entry (Change to existing listing)</p>	<p align="center">Chronic kidney disease (CKD)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the CKD incremental population.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended expanding the eligible population for the current General Schedule, Authority Required (STREAMLINED) PBS listing for empagliflozin for the treatment of adult patients with chronic kidney disease (CKD) to include a larger population that is in line with the population from the pivotal clinical trial, EMPA-KIDNEY. The additional population for the expanded listing includes 4 distinct subgroups of patients with:</p> <ul style="list-style-type: none"> • estimated Glomerular Filtration Rate (eGFR) 20 to <25 mL/min/1.73 m² regardless of urinary albumin to creatinine ratio (UACR) • eGFR 25 to <45 mL/min/1.73 m² with UACR <200 mg/g • eGFR 25 to 75 mL/min/1.73 m² with UACR >5,000 mg/g • eGFR >75 to 90 mL/min/1.73 m² with UACR ≥200 mg/g <p>The PBAC considered that, despite the considerable diversity of the additional population and uncertainties with comparing clinical data across small subgroups, there was adequate clinical evidence that empagliflozin had a similar benefit in the additional population to that of the currently listed population.</p> <p>The PBAC's recommendation for expanding the eligible population for the current listing was based on its assessment that the cost-effectiveness of empagliflozin in the proposed additional population would be acceptable. The PBAC noted that the existing PBS price was recently reduced, which mitigated the significant uncertainties with the benefits estimated in the economic model.</p> <p>The PBAC recommended there be no flow-on changes to the PBS listing for dapagliflozin for the treatment of CKD to maintain alignment with its current Therapeutic Goods Administration approved indication.</p>

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<p align="center">ETONOGESTREL WITH ETHINYLESTRADIOL</p> <p>Vaginal ring containing etonogestrel 11.7 mg with ethinylestradiol 2.7 mg</p> <p align="center">NuvaRing®</p> <p align="center">ORGANON PHARMA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Contraception</p>	<p align="center">To request a General Schedule Restricted Benefit listing for contraception.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule PBS listing of etonogestrel with ethinylestradiol contraceptive vaginal ring (NuvaRing®). The PBAC welcomed input from consumers that PBS listing of NuvaRing® would enhance contraceptive choice by improving affordability and accessibility. The PBAC considered that NuvaRing® provides an additional contraceptive option and has similar contraceptive efficacy and safety compared to depot medroxyprogesterone acetate injection and PBS-listed oral contraceptives. The PBAC noted that the submission had asked for the PBS supply of NuvaRing® to be limited to women who either had difficulty swallowing tablets, gastrointestinal disturbances (e.g. malabsorption), or had experienced undesirable side effects with oral contraceptives. The PBAC considered that NuvaRing® could provide an additional contraceptive option for a wider population than these groups of women and that a broader listing would be appropriate. The PBAC therefore recommended listing NuvaRing® as an unrestricted benefit at a price consistent with the price per day of the PBS-listed oral contraceptive ethinylestradiol with drospirenone.</p>

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<p style="text-align: center;">FEDRATINIB</p> <p style="text-align: center;">Capsule 100 mg</p> <p style="text-align: center;">Inrebic®</p> <p style="text-align: center;">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p style="text-align: center;">Category 2 (New PBS listing)</p>	<p style="text-align: center;">Myelofibrosis (MF)</p>	<p style="text-align: center;">To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with intermediate-2/high-risk MF.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the PBS listing of fedratinib for the treatment of patients with intermediate-2 and high-risk myelofibrosis, post-polycythaemia vera myelofibrosis, or post-essential thrombocythaemia myelofibrosis who have had prior ruxolitinib treatment.</p> <p>The PBAC considered there was a clinical place for fedratinib, as an alternative or additional treatment option to or after ruxolitinib. However, the PBAC considered the incremental cost effectiveness ratio (ICER) to be unacceptably high and the listing would likely not be cost effective at the requested price.</p> <p>The PBAC noted there was clinical evidence supporting use in the first-line setting, and in conjunction with the clinical evidence presented in the submission supporting second-line therapy, considered it would be simpler for patients and clinicians if a potential future listing for fedratinib was line agnostic alongside ruxolitinib and momelotinib and expressed a preference for this approach.</p> <p>The PBAC considered the outstanding issues could be addressed in a standard resubmission.</p> <p><u>Sponsor's Comment:</u> Whilst disappointed with the outcome of the submission, BMS welcomes the opportunity to resubmit for a line agnostic PBS listing for fedratinib and remains committed to making this medicine accessible for patients living with intermediate or high-risk myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis.</p>

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<p align="center">GUSELKUMAB</p> <p align="center">Injection 100 mg in 1 mL single use pre-filled pen</p> <p align="center">Tremfya®</p> <p align="center">JANSSEN-CILAG PTY LTD</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Chronic plaque psoriasis (CPP)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of severe CPP.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule, Authority Required (in writing) listing of guselkumab 100 mg pre-filled pen (PFP), under the same arrangements as the currently listed guselkumab pre-filled syringe (PFS), for the treatment of severe chronic plaque psoriasis (CPP). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost effectiveness of guselkumab PFP would be acceptable if it were cost-minimised to the least costly alternative therapy of guselkumab PFS, bimekizumab, ixekizumab, tildrakizumab, risankizumab and secukinumab.</p> <p>Overall, the PBAC considered there was sufficient evidence presented to provide new advice and conclude that guselkumab provides, for some patients, a significant improvement in efficacy over adalimumab, etanercept and ustekinumab.</p>
<p align="center">INCOBOTULINUMTOXINA</p> <p align="center">Lyophilised powder for injection 100 units</p> <p align="center">Xeomin®</p> <p align="center">MERZ AUSTRALIA PTY LTD</p> <p align="center">Matters outstanding (Change to existing listing)</p>	<p align="center">Chronic sialorrhea</p>	<p align="center">To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of chronic sialorrhea due to neurological disorders.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing of incobotulinumtoxinA for the treatment of chronic sialorrhea due to neurological disorders, on the basis that it should be available only under special arrangements under Section 100 (Botulinum Toxin Program). The PBAC noted that the MSAC recommended the creation of a new codependent MBS item for the administration of botulinum toxin products for the treatment of chronic sialorrhea. The PBAC recalled that it had previously considered that incobotulinumtoxinA demonstrated an improvement in both the severity and frequency of sialorrhea compared with the nominated comparator, placebo. The PBAC recalled that listing was requested on the basis of a cost effectiveness analysis versus placebo.</p>

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<p align="center">NIRSEVIMAB</p> <p>Solution for injection 50 mg in 0.5 mL pre-filled syringe Solution for injection 100 mg in 1 mL pre-filled syringe</p> <p align="center">Beyfortus®</p> <p align="center">SANOFI-AVENTIS AUSTRALIA PTY LTD</p> <p align="center">Standard re-entry (New NIP listing)</p>	<p align="center">Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)</p>	<p align="center">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.</p>	<p align="center">Deferred</p>	<p>The PBAC deferred making a recommendation for nirsevimab, an immunisation product that prevents lower respiratory tract illness caused by respiratory syncytial virus (RSV). The PBAC advised that further information was required to support consideration of the proposed NIP listing of nirsevimab, including further input from the sponsor, and the Department.</p> <p>The requested listing was for infants in their first RSV season and children up to 24 months of age who have certain risk conditions for severe RSV disease in their second RSV season. Free access to nirsevimab is available through state and territory RSV infant protection programs.</p> <p>Under law, passive immunisation strategies such as nirsevimab cannot be included on the National Immunisation Program (NIP) at this time. The PBAC accepted that use of nirsevimab as an immunisation against disease, would be consistent with the goals of the NIP.</p> <p>The PBAC considered that the clinical evidence included in the submission demonstrated that nirsevimab is effective in reducing respiratory illness due to RSV and is acceptably safe. The PBAC considered no immunisation was the appropriate comparator for children in their second RSV season, but recombinant RSV pre-fusion F protein (RSVpreF) maternal vaccine (Abrysvo®) should be the main comparator for infants in their first RSV season since both products protect infants against RSV. The PBAC considered that the evidence provided in the resubmission did not support that nirsevimab is more effective than RSVpreF maternal vaccine. However, the PBAC noted in some infants, the use of nirsevimab would provide additional protection that could not be addressed by RSVpreF maternal vaccine, for example for infants whose mother received the RSVpreF vaccine but were born within two weeks from vaccination, which would result in impaired protection from the vaccine. The PBAC also acknowledged that nirsevimab would have additional value for infants at increased risk of severe disease from RSV during their first RSV season despite use of maternal RSVpreF vaccination, and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The PBAC advised that the cost-effective price would need to reflect the value of nirsevimab in each group and noted that the cost-effective price would be lower than the price requested by the sponsor. The PBAC noted the high cost to Government predicted by the resubmission.</p>
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				<p><u>Sponsor's Comment:</u> The primary objective of an RSV immunisation program is to achieve broad coverage that ensures protection for all infants. Nirsevimab plays an important role in avoiding the significant burden associated with RSV in infants. The success of nirsevimab immunisation has been demonstrated in state programs across Australia, in terms of vaccine effectiveness and cost effectiveness, and similar best practice programs continue to be rolled out overseas. We recognise the legislative complexities involved in listing nirsevimab on the National Immunisation Program. While these discussions are ongoing, Sanofi remains committed to ensuring infants remain protected through established state- and territory-funded nirsevimab programs.</p>
<p style="text-align: center;">NIVOLUMAB + IPILIMUMAB</p> <p style="text-align: center;">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL</p> <p>Injection concentrate for I.V. Infusion 100 mg in 10 mL</p> <p style="text-align: center;">Opdivo®</p> <p style="text-align: center;">IPILIMUMAB</p> <p>Injection concentrate for I.V. infusion 50 mg in 10 mL</p> <p style="text-align: center;">Yervoy®</p> <p style="text-align: center;">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p style="text-align: center;">(Change to existing listing)</p>	<p style="text-align: center;">Stage III melanoma</p>	<p>To request an amendment to the current PBS listings for nivolumab and ipilimumab to allow use in the neoadjuvant setting of stage III melanoma according to the protocol used in the NADINA (Neoadjuvant Ipilimumab plus Nivolumab versus Standard Adjuvant Nivolumab in Macroscopic Stage III Melanoma) trial.</p>	<p style="text-align: center;">Recommended</p>	<p>The PBAC recommended amending the PBS-listings of nivolumab and ipilimumab to allow their use in Stage III melanoma according to the protocol used in the NADINA trial. The PBAC noted the findings from the NADINA trial that showed superior 12-month event-free survival and 18-month distant metastases free survival with neoadjuvant therapy with nivolumab and ipilimumab compared to adjuvant therapy only with nivolumab. The PBAC advised that the use of nivolumab and ipilimumab as neoadjuvant therapy for Stage III melanoma is expected to result in a cost saving to the PBS/RPBS and MBS compared to current adjuvant therapy.</p> <p>The PBAC noted it had received correspondence from clinical groups supportive of these listing changes. The PBAC requested the Department provide the Melanoma Institute of Australia with the revised listings for nivolumab and ipilimumab to ensure they are clear for prescribers. The PBAC noted flow-on restriction changes to the PBS listings for nivolumab monotherapy, pembrolizumab 3-weekly and 6-weekly monotherapy, and nivolumab in combination with relatlimab for unresectable melanoma, to align with the proposed changes to the nivolumab and ipilimumab listings.</p>

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<p align="center">OMALIZUMAB</p> <p>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</p> <p align="center">Xolair®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 2 (Change to existing listing)</p>	<p align="center">Chronic rhinosinusitis with nasal polyps (CRSwNP)</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the initial treatment and an Authority Required (Telephone/Online) listing for the continuing treatment of patients with CRSwNP.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing of omalizumab for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of omalizumab would be acceptable if it had a cost per patient that was no more than the cost per patient of mepolizumab for the treatment of CRSwNP. The PBAC considered that access to omalizumab should be broadly in line with the current PBS listing for mepolizumab for the treatment of CRSwNP. However, the PBAC considered that the PBS listing for omalizumab should not include the blood eosinophilic count (BEC) threshold requirement for mepolizumab but should include an alternate threshold for immunoglobulin E (IgE) levels of ≥ 30 IU/mL, to reflect omalizumab's different mechanism of action.</p> <p>The PBAC advised the equi-effective doses were omalizumab 346.67 mg every 4 weeks is equivalent to mepolizumab 100 mg every 4 weeks.</p>

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<p style="text-align: center;">OSIMERTINIB</p> <p style="text-align: center;">Tablet 40 mg Tablet 80 mg</p> <p style="text-align: center;">Tagrisso®</p> <p style="text-align: center;">ASTRAZENECA PTY LTD</p> <p style="text-align: center;">Category 2 (Change to existing listing)</p>	<p style="text-align: center;">Non-small cell lung cancer (NSCLC)</p>	<p style="text-align: center;">To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of Stage IIIB (locally advanced) or Stage IV (metastatic) epidermal growth factor receptor mutation-positive (EGFRm) NSCLC in combination with pemetrexed and platinum-based chemotherapy.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the Authority Required PBS listing for osimertinib in combination with cisplatin or carboplatin, and pemetrexed for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with evidence in tumour material of an activating epidermal growth factor receptor mutation (EGFRm) known to confer sensitivity to EGFR tyrosine kinase inhibitors.</p> <p>The PBAC considered osimertinib in combination with chemotherapy (O+C) was associated with a moderate improvement in progression free survival compared to osimertinib monotherapy but overall survival data were immature and O+C was associated with increased toxicity.</p> <p>The PBAC considered the economic model was based on optimistic assumptions and overestimated the benefit of O+C. The PBAC considered the uptake rate of O+C in the submission to be substantially overestimated given the safety profile of the treatment.</p> <p>The PBAC considered the outstanding issues could be addressed in an early re-entry submission.</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>
<p style="text-align: center;">PEGCETACOPLAN</p> <p style="text-align: center;">Solution for subcutaneous infusion 1,080 mg in 20 mL</p> <p style="text-align: center;">Empaveli®</p> <p style="text-align: center;">SWEDISH ORPHAN BIOVITRUM PTY LTD</p> <p style="text-align: center;">Category 2 (Change to existing listing)</p>	<p style="text-align: center;">Paroxysmal nocturnal haemoglobinuria (PNH)</p>	<p style="text-align: center;">To request an amendment to the existing Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of PNH to allow initial treatment with pegcetacoplan in patients who are either treatment-naïve to complement 5 (C5) inhibitors or currently treated with a C5 inhibitor.</p>	<p>Recommended</p>	<p>The PBAC recommended an extension to the existing Section 100 Highly Specialised Drugs Program (HSD) Authority Required (in writing only via post/HPOS upload) listing of pegcetacoplan, to allow for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who are either treatment-naïve to complement 5 (C5) inhibitors or currently treated with a C5 inhibitor. The PBAC's recommendation for the extended listing was based on its assessment that the cost-effectiveness of pegcetacoplan would be acceptable if it were cost-minimised against ravulizumab. The PBAC noted flow-on changes would be required to the PBS listings for ravulizumab, eculizumab and iptacopan (when PBS listed) to allow for switching between treatments upon intolerance or contraindications.</p>

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<p align="center">PIOGLITAZONE</p> <p>Tablet 15 mg (as hydrochloride) Tablet 30 mg (as hydrochloride) Tablet 45 mg (as hydrochloride)</p> <p align="center">Actos®</p> <p align="center">CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p> <p align="center">Category 4 (New PBS listing)</p>	<p align="center">Type 2 diabetes mellitus (T2DM)</p>	<p>To request General Schedule Restricted Benefit listings for a new pack size of pioglitazone (Actos®), with an increased maximum quantity across all currently PBS-listed strengths of pioglitazone for the treatment of T2DM.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended General Schedule Restricted Benefit listings of pioglitazone 15 mg, 30 mg, and 45 mg 30-pack tablets for the treatment of type 2 diabetes mellitus (T2DM). Due to the new (larger) 30-pack across all strengths, the PBAC considered that the requested maximum quantities of 30 and 60 tablets would be appropriate for 30-day and 60-day maximum dispensed quantities (MDQ), respectively. The PBAC noted the current and anticipated shortages of pioglitazone, particularly the 30 mg strength, and that the new 30-pack of the Actos brand will replace the currently PBS-listed 28-pack size, which would help address the supply shortage.</p>
<p align="center">RANIBIZUMAB</p> <p>Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe Solution for intravitreal injection 2.3 mg in 0.23 mL</p> <p align="center">Lucentis®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">Category 1 (Change to existing listing)</p>	<p align="center">Proliferative diabetic retinopathy (PDR)</p>	<p>To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of patients with PDR without diabetic macular oedema.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended an Authority Required (Written) PBS listing for ranibizumab for the treatment of proliferative diabetic retinopathy (PDR) with or without diabetic macular oedema (DMO). As part of its recommendation, the PBAC recommended expanding the population originally requested in the submission (i.e. patients without DMO) to include patients not being treated with or patients who do not qualify for, PBS subsidised treatment for macular oedema secondary to diabetic retinopathy. This was based on unmet clinical need and to ensure continuous treatment for patients with PDR that progress to DMO and who have not developed serious vision impairment.</p> <p>The PBAC was satisfied that ranibizumab was adequately cost-effective compared to the current treatment option of panretinal laser photocoagulation (PRP) noting the sponsor offered a price reduction prior to the PBAC meeting. The PBAC considered the submission's claim of superior effectiveness to PRP had been demonstrated despite some limitations in the clinical evidence. The PBAC noted that, based on the clinical evidence, treatment with ranibizumab was associated with benefits including a reduction in neovascularisation, prevention of DMO and reduced surgeries for vitrectomy, compared to PRP. The PBAC also noted the significant impact of type 2 diabetes and the higher rates of vision threatening PDR in the Aboriginal and Torres Strait Islander population, and that the availability of ranibizumab would provide more treatment options for this high need population.</p>

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<p align="center">RAXTOZINAMERAN</p> <p>I.M. injection, suspension for injection containing raxtozinameran 30 micrograms</p> <p>Comirnaty® Omicron XBB.1.5</p> <p>PFIZER AUSTRALIA PTY LTD</p> <p align="center">Category 1 (New NIP listing)</p>	<p align="center">Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2</p>	<p align="center">To request a National Immunisation Program listing for the prevention of coronavirus disease 2019 (COVID-19) in adults with medical risk conditions, immunocompromised patients aged 18 and older, or adults aged 60 years and over.</p>	<p align="center">Deferred</p>	<p>The PBAC deferred making a recommendation for the raxtozinameran COVID-19 vaccine in relation to the requested National Immunisation Program (NIP) listing to prevent COVID-19 disease in adults at increased risk of severe COVID 19 disease. Raxtozinameran is currently available to Australians through the National COVID-19 Vaccination Program (NCVP). The PBAC advised that further information was required to support appropriate consideration of this submission, including further input from the sponsor, the Australian Technical Advisory Group on Immunisation (ATAGI) and the Department.</p> <p>The PBAC considered it would be better to retain access for Australians who can currently access this vaccine rather than limit access to a smaller group of people at higher risk of severe disease.</p> <p>The PBAC considered that the clinical evidence included in the submission demonstrated that raxtozinameran is effective and safe compared to no booster vaccine. However the vaccine was not cost-effective at the proposed price.</p> <p>The PBAC considered it was important to use vaccines that target current variants of the COVID-19 virus (SARS-CoV-2). As raxtozinameran does not target the main variants currently circulating in Australia, the PBAC did not support its listing.</p> <p>The PBAC, sponsor, and ATAGI supported an approach where future adaptations of the Comirnaty® (BNT162b2) vaccine that are updated to target the more recent versions of the virus could rely on existing PBAC advice for listing. This could occur after acceptable cost-effectiveness had been demonstrated. The PBAC advised that a revised proposal was needed from the sponsor to support the cost-effectiveness assessment. This will help provide access to the most current COVID-19 vaccines for the Australian community as soon as possible, when deemed appropriate by the TGA and ATAGI. The PBAC also requested advice from the Department of Health, Disability and Ageing about this approach.</p> <p>The PBAC noted the very high financial impact at the proposed price.</p>
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**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
				<p><u>Sponsor's Comment:</u> Pfizer welcomes the PBAC's acknowledgement of the continued burden of COVID-19 and a pragmatic approach to consider Comirnaty® (BTN162b2) as a platform for listing.</p> <p>Despite the considerable changes requested by the PBAC within the Minutes, Pfizer hopes that the PBAC deferral can be swiftly resolved in collaboration between the Department of Health, Disability & Aging, ATAGI, the PBAC and Pfizer, to achieve a smooth transition to the NIP.</p>
<p align="center">REPOTRECTINIB</p> <p align="center">Capsule 40 mg Capsule 160 mg</p> <p align="center">Augtyro™</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">Category 2 (New PBS listing)</p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p align="center">To request a General Schedule Authority Required (Written/Online) listing for the treatment of locally advanced (Stage IIIB) or metastatic (Stage IV) ROS proto-oncogene 1 (ROS1)-positive NSCLC.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended an Authority Required (Written/Online) PBS listing for repotrectinib for the treatment of adult patients with locally advanced (Stage IIIB) or metastatic (Stage IV) c-ROS proto-oncogene 1 (ROS1) positive non-small cell lung cancer (NSCLC). The PBAC considered that, despite the considerable heterogeneity and the uncertainties associated with the clinical comparison, on balance it was likely repotrectinib provided similar health outcomes to entrectinib in the proposed population. The PBAC's recommendation was based on, among other matters, its assessment that the cost effectiveness of repotrectinib would be acceptable if it were cost minimised to entrectinib.</p> <p>The PBAC recommended PBS listing at an equivalent cost per day based on the steady state dosing of entrectinib and repotrectinib, with the price of the repotrectinib dose reduction pack to be derived on a weighted dose approach to maintain an equivalent cost per day to the steady state pack.</p> <p>The PBAC noted flow on changes to the immunotherapy listings would be required to allow ROS1 positive NSCLC patients treated with repotrectinib, entrectinib or crizotinib as their first-line therapy to access immunotherapies as a potential second-line treatment upon disease progression.</p>

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<p align="center">TEPROTUMUMAB</p> <p align="center">Powder for I.V. infusion 500 mg</p> <p align="center">Tepezza®</p> <p align="center">AMGEN AUSTRALIA PTY LTD</p> <p align="center">Early resolution (New PBS listing)</p>	<p align="center">Thyroid Eye Disease (TED)</p>	<p align="center">To consider a resubmission for a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of teprotumumab for the treatment of active, moderate-to-severe Thyroid Eye Disease (TED).</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required (Streamlined) listing of teprotumumab for the treatment of active, moderate-to-severe thyroid eye disease. The PBAC reaffirmed its previous view that there is a high clinical need in the requested patient population, and that the evidence demonstrated that teprotumumab is more effective in improving proptosis and diplopia compared to current standard of care, which may also lead to a reduction in eye surgery. The PBAC considered that the economic model remained uncertain. However, the PBAC noted that changes to the economic evaluation and financial estimates had reduced uncertainty and addressed the Committee’s concerns. The PBAC considered that teprotumumab would be cost-effective at the price proposed in the resubmission. The PBAC noted that the resubmission proposed a Risk Sharing Arrangement and considered that the approach taken was reasonable, however required further revision. Overall, the PBAC considered that the resubmission had addressed the outstanding issues identified at the March 2025 PBAC meeting.</p>

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<p align="center">TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® ASTRAZENECA PTY LTD Category 2 (Change to existing listing)</p>	<p align="center">Gastric or gastroesophageal junction (G/GOJ) cancer</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of metastatic human epidermal growth factor receptor 2-positive (HER2+) G/GOJ cancer following trastuzumab therapy.</p>	<p align="center">Deferred</p>	<p>The PBAC deferred making a recommendation for trastuzumab deruxtecan (T-DXd for treatment of metastatic human epidermal growth factor receptor 2-positive (HER2+) gastric or gastroesophageal junction (G/GOJ) cancer following trastuzumab therapy to allow for further consultation with the sponsor about a potential pathway forward towards PBS listing. The PBAC considered it needed more information from the sponsor to be able to make its final recommendation. The PBAC accepted standard of care chemotherapy, consisting of paclitaxel, irinotecan, docetaxel or folinic acid, fluorouracil, and irinotecan combination (FOLFIRI), as the appropriate main comparator, as proposed by the submission. The PBAC also accepted the submission’s claim, that T-DXd has superior efficacy and inferior but manageable safety compared to SoC in patients with metastatic HER2-positive G/GOJ adenocarcinoma who have received a prior trastuzumab-based regimen. While the PBAC considered the claim of superior efficacy compared to SoC was supported by evidence included in the submission, it considered the extent of the improvements in time without disease progression and survival which would be observed in the proposed Australian population was uncertain, which has implications for the extent of benefit assumed in the economic model. The PBAC agreed with its Economics Sub Committee’s (ESC) advice that certain amendments should be made to the economic model. The PBAC considered that the cost-effectiveness of T-DXd estimated by the revised economic model which incorporates the amendments advised by ESC was still unacceptably high and uncertain at the price for T-DXd proposed in the submission.</p> <p><u>Sponsor’s Comment:</u> The sponsor had no comment.</p>

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<p style="text-align: center;">UBLITUXIMAB</p> <p>Solution concentrate for I.V. infusion 150 mg in 6 mL (25 mg per mL)</p> <p style="text-align: center;">Briumvi®</p> <p style="text-align: center;">KIRCHMANN ENTERPRISES PTY LTD</p> <p style="text-align: center;">Category 2 (New PBS listing)</p>	<p style="text-align: center;">Relapsing-remitting multiple sclerosis (RRMS)</p>	<p style="text-align: center;">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of RRMS.</p>	<p style="text-align: center;">Recommended</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required (Streamlined) listing of ublituximab for the treatment of relapsing-remitting multiple sclerosis (RRMS). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of ublituximab would be acceptable if it had a cost per patient that was no more than the least costly alternative therapy available on the PBS for RRMS within the 'higher' efficacy tier (fingolimod, cladribine, ozanimod, natalizumab, alemtuzumab, ocrelizumab and ofatumumab).</p> <p>The PBAC noted the submission claimed ublituximab was superior in effectiveness to fingolimod and at least as effective as ofatumumab and ocrelizumab. However, the Committee considered there were significant uncertainties when comparing ublituximab with fingolimod and ocrelizumab. This was because there was no clinical trial data comparing ublituximab with these treatments directly so the comparison was based on a comparison that used other studies to link the data. Some of these other studies had issues with how they were conducted which made the results less reliable, and those linking studies had additional issues. Therefore, the PBAC was not satisfied that the claim that ublituximab has superior effectiveness over fingolimod was adequately supported.</p> <p>However, the Committee considered four factors to be key to its deliberations:</p> <ol style="list-style-type: none"> 1. That the clinical trial evidence from the pivotal ublituximab trials (ULTIMATE I/II) supported a conclusion that ublituximab is likely superior in effectiveness compared to teriflunomide (an agent in the 'lower' efficacy tier); 2. That the comparison of ublituximab to ofatumumab was robust and supported a conclusion that ublituximab was similarly effective to ofatumumab, as it relied on a simpler indirect treatment comparison, based on high quality data from well-run clinical trials for both ublituximab (ULTIMATE I/II) and ofatumumab (ASCLEPIOS I/II); 3. The PBAC recalled it had considered a submission for ofatumumab in March 2024 that claimed superior effectiveness over fingolimod and requested the formation of a third ('mid') efficacy tier in RRMS and that it did not accept either of those claims/requests. The PBAC further noted the underlying fingolimod evidence and linking studies to inform the ofatumumab and ublituximab comparisons
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**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
			<p>were essentially the same in both submissions, so the claims of superiority compared to fingolimod for both ofatumumab and ublituximab were similarly uncertain and unreliable; and</p> <p>4. These issues notwithstanding, the PBAC considered that as, in its view, ublituximab was similarly effective to ofatumumab, it was reasonable to extend similar therapeutic relativities for ublituximab to the other higher efficacy tier RRMS therapies consistent for those established with ofatumumab when it first recommended ofatumumab in March 2021.</p> <p>Based on the above, the PBAC considered it was appropriate for ublituximab to be listed only on a cost minimisation basis with the least costly alternative higher efficacy tier therapy for RRMS, including fingolimod.</p>

Other agenda items

AGENDA ITEM, FORM(S), STRENGTH(S), SPONSOR, TYPE OF AGENDA ITEM	DRUG TYPE AND USE	PURPOSE OF AGENDA ITEM	PBAC OUTCOME
<p>ATAGI Recommendations regarding the Paediatric Pneumococcal Schedule</p> <p>Multiple forms and strengths</p> <p>Multiple brands</p> <p>MSD and Pfizer</p> <p>(Other matters)</p>	<p>Pneumococcal disease</p>	<p>To consider and endorse ATAGI recommendations for an updated Paediatric Pneumococcal Schedule.</p>	<p>The PBAC noted the updated Australian Technical Advisory Group on Immunisation (ATAGI) recommendations for the paediatric pneumococcal immunisation schedule on the NIP for those aged 17 years and under. The PBAC noted that its consideration of the vaccines was limited to the specific changes to the NIP schedule that were requested by the ATAGI. The PBAC recommended it would be appropriate to remove restrictions regarding location in specific states and territories in the listings for Aboriginal and Torres Strait Islander children receiving the three primary and a booster dose (3+1 schedule). The PBAC considered the changes would reduce ambiguity in the schedule, especially for patients residing close to state borders; will reduce administrative burden for prescribers; and provide equitable access to Aboriginal and Torres Strait Islander children nationally.</p> <p>The PBAC also noted the ATAGI's advice recommending the removal of the 23-valent pneumococcal polysaccharide vaccine (23vPPV) from the paediatric pneumococcal schedule when 20-valent pneumococcal conjugate vaccine (20vPCV) is used. The PBAC considered the 20vPCV vaccine would remain suitably cost-effective should the proposed changes to the schedule recommended by the ATAGI be implemented.</p>

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AGENDA ITEM, FORM(S), STRENGTH(S), SPONSOR, TYPE OF AGENDA ITEM	DRUG TYPE AND USE	PURPOSE OF AGENDA ITEM	PBAC OUTCOME
<p>Review of antiepileptic drugs (AEDs)</p> <p>Multiple Forms</p> <p>Multiple Brands</p> <p>Multiple Sponsors</p> <p>(PBS Post-market review)</p>	<p>Epilepsy</p>	<p>To consider amending the current PBS listings for the second-line AEDs, levetiracetam (LEV) and lamotrigine (LTG), to allow their first-line use in the general Australian population with epilepsy.</p>	<p>The PBAC noted the pre-sub-committee responses and pre-PBAC responses received from sponsors, stakeholders, and individual clinicians.</p> <p>Overall, the PBAC accepted the key findings from the Review of AEDs including the estimates of cost to the PBS of allowing first-line use of LEV and LTG in the general Australian population with epilepsy (the “proposed listings”).</p> <p>The PBAC noted the findings of the review of clinical guidelines that two Australian guidelines and most international guidelines recommend LEV and/or LTG as first-line antiseizure medications in adults with focal and/or generalised seizures.</p> <p>The PBAC considered the estimated cost to the R/PBS of allowing first-line use of LEV and LTG in the general Australian population with epilepsy was reasonable (\$1.2 million in 2025 increasing to \$4.4 million in 2030). In addition, the proposed listings were expected to have a minimal impact on the utilisation of the more expensive third-line antiseizure medications.</p> <p>The PBAC also noted the utilisation analysis of the private market which was used to estimate the current extent of private (non-PBS) use of LEV and LTG, and agreed the private market for LTG appears to be significantly larger than LEV; likely due to LTG use in conditions such as bipolar disorder and trigeminal neuralgia.</p> <p>The PBAC considered that while the cost-effectiveness of LEV and LTG as first-line agents for epilepsy had not been formally established by the Review, it was likely that these medicines now provide comparable value for money in this setting due to decreasing prices and improved safety/tolerability over older first-line antiseizure medications. The PBAC noted that the market for LEV and LTG was highly genericised which would assist in mitigating financial risk.</p> <p>The PBAC recommended amending the PBS restrictions for LEV (tablets and liquid forms) and LTG (tablets) to Restricted Benefit listings for “epileptic seizures” and removal of the following clinical criteria from the current listings: “The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR Patient must be a woman of childbearing potential.” This restriction change will allow the subsidised first-line use of these medicines in the general Australian population with epilepsy.</p> <p>The PBAC recommended the terms “focal onset seizures” replace “partial seizures” and “antiseizure medication/s” replace “anti-epileptic drug/s” to avoid prescriber confusion, and that this change should be flowed on to the terminology used in all other PBS restrictions including second- and third-line antiseizure medications.</p> <p>The PBAC considered there may be an unmet need to subsidise LTG for mental illnesses such as bipolar disorder. The PBAC recommended in principle extending subsidy of LTG to this indication and requested that the Department undertake further work to estimate the cost to the R/PBS of a separate Restricted Benefit listing for LTG for bipolar disorder for its consideration at a future meeting.</p>

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AGENDA ITEM, FORM(S), STRENGTH(S), SPONSOR, TYPE OF AGENDA ITEM	DRUG TYPE AND USE	PURPOSE OF AGENDA ITEM	PBAC OUTCOME
<p align="center">Review of PBS Prescriber Bag (PBS post-market review)</p>	<p align="center">Multiple types and uses</p>	<p>To seek the PBAC's advice on the purpose and intent of the Prescriber Bag Schedule, considering stakeholders' submissions, to ensure the listings reflect contemporary clinical need and to inform the Department's Prescriber Bag review for consideration at a future PBAC meeting.</p>	<p>The PBAC discussed issues raised in stakeholder submissions and reiterated that the purpose of the Prescriber Bag is to provide medicines for emergency care. The PBAC will further consider the utilisation of Prescriber Bag medicines and stakeholder submissions at a future meeting.</p>

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Submission category types

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

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Resubmission pathways

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