

PBS Post-market Review workplan – September 2025

There are currently no Post-market Reviews (PMRs) of medicines on the Pharmaceutical Benefits Scheme (PBS) underway. Table 1 includes information on current research projects being undertaken by the PMR section. In line with the [PMR Framework](#), these research projects may inform the Pharmaceutical Benefits Advisory Committee (PBAC) of potential PMR topics.

Updates have been made following consideration of the PMR workplan by the PBAC at its September 2025 intracycle meeting. Project timelines in the table are indicative and reflect the status at the time of publishing.

If you have any questions relating to the PMR workplan, please email the [Quality Use of Medicines \(QUM\) Reviews and Programs section](#).

Indication	Project title Background, Status and Next steps	Medicines
Type 2 diabetes mellitus (T2DM)	<p>PBS restrictions for T2DM medicines</p> <p>Background In September 2019, a stakeholder wrote to the PBAC requesting broader listings for sodium-glucose cotransporter-2 (SGLT2) inhibitors and glucagon-like peptide-1 receptor agonists (GLP-1 RAs) on the PBS. Following a series of cost-effectiveness analyses, in March 2022 and July 2024, the PBAC recommended that the listings for dapagliflozin and empagliflozin be revised to allow for use as add-on therapy to metformin in patients with T2DM and high cardiovascular (CV) risk, without a glycaemic requirement. The restriction changes were implemented on 1 December 2024, for dapagliflozin, and 1 April 2025, for empagliflozin, following acceptable price offers by the sponsors.</p> <p>In March 2023, July 2023, and March 2024, following an analysis of the utilisation of T2DM medicines through the PBS, the PBAC recommended several changes to simplify the restrictions for pioglitazone, dipeptidyl-peptidase 4 (DPP4) inhibitors, SGLT2 inhibitors and GLP-1 RAs. The PBAC recommended that GLP-1 RAs be made second-line to SGLT2 inhibitors and change to a telephone/electronic authority for therapy initiation. These changes were implemented on 1 June 2024, and were accompanied by stakeholder communication and educational materials published on the PBS restriction changes to type 2 diabetes mellitus (T2DM) medicines.</p> <p>Status This project is complete.</p>	<ul style="list-style-type: none"> • SGLT2 inhibitors: <ul style="list-style-type: none"> ○ dapagliflozin ○ empagliflozin • GLP-1 RAs: <ul style="list-style-type: none"> ○ semaglutide ○ dulaglutide • Pioglitazone • DPP4 inhibitors: <ul style="list-style-type: none"> ○ alogliptin ○ saxagliptin ○ sitagliptin ○ linagliptin ○ vildagliptin

Indication	Project title Background, Status and Next steps	Medicines
	<p>Next steps Review the utilisation of T2DM medicines approximately 2 years after the restriction changes.</p>	
Cancer	<p>Monitoring of final trial overall survival (OS) results in PBAC submissions for cancer medicines</p> <p>Background Surrogate end points have an increasingly important role in cancer medicine research, clinical practice, and evidence to support registration and subsidy of new medicines. In May 2022, the PBAC recommended a review of the use of surrogate outcome measures in PBAC submissions for cancer medicines between 2012-2021, including a literature review of the reliability of surrogate endpoints in various malignancies.</p> <p>The report on cancer surrogates was provided to the Economics Sub-Committee (ESC) in June 2023 and the PBAC in July 2023. The PBAC noted ESC Advice regarding potential further research and actions. The report was published on the PBS website and provided to relevant stakeholders in September 2023.</p> <p>The report found that for submissions and resubmissions that presented interim or immature OS trial data between January 2012 to May 2022, around 60% had not subsequently published final trial results (60/101 trials). The ESC noted that OS results, where published, were generally consistent with interim results but expressed concern over potential publication bias in trials reporting final results.</p> <p>In September 2023, the PBAC recommended a further project to develop a system to monitor final trial OS results for cancer medicines.</p> <p>Status The Department has contracted a health technology assessment (HTA) group to develop a report on final trial OS results for cancer medicines recommended by the PBAC between January 2012 and March 2024. The report aims to explore whether final trial OS results for cancer medicines align with the interim results considered by the PBAC and any reasons for trial results not being available.</p>	<ul style="list-style-type: none"> • Oncology medicines

Indication	Project title Background, Status and Next steps	Medicines
	<p>The report on final trial OS results for cancer medicines was considered by ESC in October 2025. Sponsors and other stakeholders were given an opportunity to provide pre-sub-committee responses and pre-PBAC responses.</p> <p>Next steps Provide the report on final trial OS results for cancer medicines to the PBAC in November 2025. The Department will undertake any next steps as requested by the PBAC.</p>	
Epilepsy	<p>PBS restrictions for anti-epileptic drugs (AEDs)</p> <p>Background At its September 2020 meeting, the PBAC recommended amending the PBS restrictions to allow for the first-line use of levetiracetam (LEV) and lamotrigine (LTG) in women of childbearing potential. These restriction changes took effect on 1 January 2021. These changes followed feedback from the Epilepsy Society of Australia (ESA) on best practice clinical management of epilepsy for women of childbearing potential. The PBAC noted that the previous PBS restrictions for LEV and LTG restricted access to those who had failed to have their epilepsy controlled with other AEDs and may have resulted in prescribers continuing to use sodium valproate among women of childbearing potential when safer options were available.</p> <p>Subsequently, the PBAC requested that the Department provide to the Drug Utilisation Sub-committee (DUSC):</p> <ul style="list-style-type: none"> • utilisation data and any further evidence on the broader use of other second-line AEDs, and • estimates of cost to the PBS of allowing first-line use of LEV and LTG in the remaining population with epilepsy (i.e. males and females of all ages). <p>This project was on hold for 24 months to allow for the collection of sufficient PBS utilisation data following the 1 January 2021 restriction changes to LEV and LTG.</p> <p>In September 2023, the DUSC considered the <i>Utilisation analysis of PBS-listed AEDs in a cohort of epilepsy patients</i>. The DUSC was also requested to advise the Department on the development of the cost estimates to the PBS of allowing first-line use of LEV and LTG in the remaining population with epilepsy (i.e. males and females of all ages).</p>	<ul style="list-style-type: none"> • All PBS-listed AEDs

Indication	Project title Background, Status and Next steps	Medicines
	<p>In April 2024, the Department contracted a HTA evaluation group to:</p> <ul style="list-style-type: none"> • undertake a systematic literature review to identify relevant clinical guidelines for the use of AEDs for the treatment of epilepsy and compare these to the PBS restrictions and Therapeutic Goods Administration (TGA)-approved indications for these medicines, and • estimate the cost to the PBS of expanding the restrictions for the second-line AEDs LEV and LTG to allow their first-line use in the general Australian population with epilepsy. <p>The evaluation group's report was considered by the DUSC in April 2025 and the PBAC in May 2025.</p> <p>Status This project is complete. Please refer to the <i>Review of clinical guidelines and cost estimates for the use of AEDs for the treatment of epilepsy</i> website for further information.</p> <p>Next steps Undertake further work to estimate the cost to the R/PBS of a separate Restricted Benefit listing for LTG for bipolar disorder for the PBAC's consideration at a future meeting. This additional work will be undertaken as a separate research project (see entry below).</p>	
Bipolar disorder	<p>Lamotrigine (LTG) for bipolar disorder</p> <p>Background At its <i>May 2025 Intracycle meeting</i> the PBAC considered the <i>Review of clinical guidelines and cost estimates for the use of anti-epileptic drugs (AEDs) for the treatment of epilepsy</i> report (see above entry).</p> <p>The PBAC recommended amending the PBS restrictions for levetiracetam (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>	<ul style="list-style-type: none"> • Lamotrigine

Indication	Project title Background, Status and Next steps	Medicines
	<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> <p>Status The Department has undertaken the modelling to estimate the financial impact to the R/PBS of a separate Restricted Benefit listing for LTG for bipolar disorder. It is anticipated that the findings of the modelling will be provided to the PBAC for consideration in November 2025. LTG sponsors and relevant clinical groups will be provided with the findings and invited to provide a pre-PBAC response prior to the PBAC's consideration.</p>	
Various	<p>Review of PBS prescribing by nurse practitioners and endorsed midwives</p> <p>Background The review of items for Nurse Practitioner (NP) and Endorsed Midwife (EM) prescribing on the PBS forms part of the Department's implementation of the Nurse Practitioner Workforce Plan released in May 2023. The purpose of the review is to identify PBS-subsidised medicines that are able to be privately prescribed by NPs and EMs (i.e. within their scope of practice and in accordance with state and territory regulations), but where these groups are not recognised as eligible prescribers on the PBS schedule. Between 1 March – 1 April 2024, the Department published a consultation survey to inform the Review, to collect data on which medicines are frequently being prescribed privately (i.e., non-PBS) by NPs and EMs that are subsidised through the PBS when prescribed by another prescriber type, and the settings in which this is occurring. The survey received feedback from consumers, carers, health professionals, consumer groups and peak representative organisations.</p> <p>Between July 2024 and July 2025, the PBAC considered and provided advice on five tranches of PBS medicines identified during consultation that may be suitable for prescribing by NPs or EMs.</p> <p>Status The Review is now complete. Please refer to the <i>Review of PBS items for prescribing by nurse practitioners and endorsed midwives</i> webpage for further information.</p>	Various

Indication	Project title Background, Status and Next steps	Medicines
	<p>Next steps PBAC recommendations arising from the PBS Review will be implemented as part of routine monthly changes to the PBS schedule. All authorised PBS prescribers are encouraged to check the Summary of Changes to the PBS that is published at the beginning of each new calendar month for changes to individual medicine listings.</p>	
Severe dry eye	<p>PBS-listed ocular lubricants for treatment of severe dry eye</p> <p>Background In March 2023, the PBAC requested that a systematic literature review be undertaken to compare the efficacy and safety of ocular lubricants containing preservatives (PC) versus ocular lubricants without preservatives (PF) in patients with severe dry eye. In late-2023, a contract was executed with an external evaluation group to undertake the review.</p> <p>The Department provided the final report, <i>Systematic literature review comparing the efficacy and safety of preservative-containing (PC) ocular lubricants versus preservative-free (PF) ocular lubricants in patients with severe dry</i> to peak Australian optometry and ophthalmology representative groups and sponsors of PBS-listed ocular lubricants for a pre-PBAC response.</p> <p>The PBAC considered the Report findings and pre-PBAC responses at its July 2024 meeting. Noting limitations in the literature, the PBAC considered that the Report did not find evidence to support the superior effectiveness or safety of PF products compared to PC products. The PBAC requested that an options paper be developed for its future consideration, taking current clinical practice and guidelines into account, while ensuring that PBS-listed ocular lubricants remain cost-effective for the eligible population. The PBAC also requested information on the utilisation of ocular lubricants and associated costs to the PBS of any potential changes to the PBS listings for ocular lubricants to support its consideration. For further information, please refer to the PBAC outcome from its July 2024 meeting.</p> <p>Status In November 2024, a HTA evaluation group was contracted to undertake a utilisation analysis of PBS ocular lubricants and develop financial estimates of costs to the PBS for potential</p>	PBS listed preservative containing and preservative free ocular lubricants

Indication	Project title Background, Status and Next steps	Medicines
	<p>changes to the PBS restrictions for ocular lubricants in patients with severe dry eye, for the PBAC's consideration.</p> <p>The evaluation group's Report, <i>Utilisation analysis and potential changes to the restrictions for PBS listings of ocular lubricants in patients with severe dry eye</i>, was considered by the DUSC in October 2025 and is expected to be considered by the PBAC in November 2025. Sponsors and other stakeholders were given the opportunity to provide a pre-PBAC response.</p> <p>Next steps The DUSC and PBAC advice will be provided to sponsors after the PBAC's consideration.</p>	
Hypertension	<p>Utilisation analysis of antihypertensives</p> <p>Background In September 2023, the PBAC recommended that the Department undertake a research project on the use of antihypertensive medications through the PBS, focussing on quantifying the potential underuse of fixed dose combination (FDC) medicines, and initiation of antihypertensive therapy with two or more medicines (including initiation with an FDC versus multiple single drug products). The PBAC noted that the PBS restrictions do not allow patients to initiate subsidised antihypertensive therapy with an FDC as recommended in some clinical guidelines.</p> <p>The Department contracted a HTA group to undertake this project. In addition to the utilisation analysis, the report included a literature review and costings analysis.</p> <p>Status The PBAC considered the report at the December 2024 meeting. The PBAC recommended changing the PBS restrictions for all antihypertensive dual therapy fixed dose combinations (FDCs) to unrestricted benefit listings, with the 60-day prescription items to remain Restricted Benefit listings with a single clinical criterion requiring the patient's condition to be stable.</p> <p>The PBAC considered that the recommended restriction changes were likely to result in cost savings for the PBS and consumers but considered the reported savings to be overestimated. The PBAC noted the Department's intention to revise the financial estimates, and that these would be brought back to the PBAC for consideration if a cost to the PBS was estimated.</p>	PBS-listed antihypertensives

Indication	Project title Background, Status and Next steps	Medicines
	<p>For further information please refer to the December 2024 PBAC Outcomes.</p> <p>Next steps The Department is revising the financial estimates and will either bring these back to PBAC for further consideration if a cost is estimated; or implement the restriction changes if a saving is estimated. Once the estimates are finalised, the report and outcomes of PBAC consideration will be published on the PBS website. The report findings will also be communicated to prescribers and consumers, including quality use of medicines issues identified, through relevant publications and peak bodies.</p>	
Hypercholesterolaemia	<p>Restriction review for ezetimibe and its fixed dose combinations</p> <p>Background Ezetimibe and its fixed dose combinations (FDCs) were identified as a potential medicine on the F2 formulary for a restriction review, on the basis that:</p> <ul style="list-style-type: none"> • the PBS restrictions were relatively complex and did not align with clinical guidelines. • the PBS price has reduced to be similar to Unrestricted Benefit listings for the treatment of hypercholesterolaemia • a stakeholder had written to the Department to highlight that the PBS restrictions referenced an outdated cardiovascular risk calculator. <p>In May 2024, the PBAC recommended that the ezetimibe and ezetimibe + HMG-CoA reductase inhibitor (statin) FDCs be changed from Authority Required (STREAMLINED) to Unrestricted benefit listings on the PBS. The PBAC considered that the clinical place of ezetimibe and its FDCs were well established and that the change to an Unrestricted PBS listing was unlikely to result in increased utilisation or expenditure.</p> <p>Status This project is complete. The recommended restriction changes were implemented on 1 November 2024. For further information please refer to the ‘PBS restrictions for ezetimibe and its fixed dose combinations’ website.</p>	<ul style="list-style-type: none"> • Ezetimibe • Ezetimibe fixed dose combinations
Relapsing-remitting multiple sclerosis	<p>Utilisation analysis of PBS-listed disease modifying therapies for relapsing-remitting multiple sclerosis (RRMS)</p> <p>Background</p>	<ul style="list-style-type: none"> • Alemtuzumab • Natalizumab • Ocrelizumab • Ozanimod

Indication	Project title Background, Status and Next steps	Medicines
	<p>In September 2024, the PBAC considered the PMR work plan and noted that the PBS prices of high-efficacy disease modifying therapies (DMTs) for RRMS have diverged since the price reduction of fingolimod on 1 December 2022. The PBAC recalled that there is currently no PBS requirement for patients to trial less costly medicines for RRMS before moving to more expensive therapies. The PBAC noted that an analysis of the PBS market for RRMS medicines has not been undertaken for some time and advised that a utilisation analysis of the current market for PBS-listed medicines for RRMS, including information around the market share of fingolimod, would be informative.</p> <p>Status In June 2025, the DUSC considered the utilisation analysis of PBS-listed disease modifying therapies for RRMS. DUSC considered the increasing use of newer generation DMTs (e.g. ocrelizumab, ofatumumab, natalizumab) were replacing older DMTs (e.g. fingolimod) and moderate efficacy DMTs was in line with current clinical practice, and noted the increasing market share of newer generation DMTs had not increased the overall benefits paid (based on effective prices) for PBS-listed DMTs. DUSC considered a data linkage process may lead to useful insights on why incident patients were declining in this cohort.</p> <p>The report was presented to PBAC at its July 2025 meeting. No further actions were requested by the committee.</p> <p>Next Steps This project is complete. A Public Release Document from the June 2025 DUSC consideration will be published.</p>	<ul style="list-style-type: none"> • Ofatumumab • Fingolimod • Cladribine • Siponimod • Teriflunomide • Peginterferon beta 1a • Interferon beta 1b • Glatiramer acetate • Dimethyl fumarate • Diroximel fumarate
Various	<p>Review of PBS restrictions for low-cost medicines</p> <p>Background In September 2023, as part of its consideration of the PMR workplan, the PBAC supported a proposal that the Department would consider on a rolling basis whether medicines that have moved to the F2 formulary would be suitable for a restriction review. The PBAC noted that this work may support the TGA's Medicines Repurposing Program (MRP).</p> <p>Status</p>	<ul style="list-style-type: none"> • Various PBS-listed antidepressants

Indication	Project title Background, Status and Next steps	Medicines
	<p>At its September 2024 meeting, the PBAC supported the Department's proposal to provide further information to inform its consideration of whether an unrestricted benefit PBS listing is appropriate for several PBS-listed antidepressants. The PBAC noted that for some Restricted Benefit listings, the TGA-approved indications are broader than the PBS-listed indications. In addition, Australian clinical guidelines recommend a wider range of uses beyond the PBS-listed and/or TGA-approved indication(s). The PBAC considered that because of the low cost of these medicines, there may be little incentive for sponsors to bring forward a TGA application or PBAC submission to change the indication or restriction.</p> <p>Restriction reviews for ezetimibe and antihypertensives have been undertaken (see above).</p> <p>Next steps The Department will undertake an analysis of several 'low cost' antidepressants with Restricted Benefit PBS listings to estimate the financial impact of changing these medicines to unrestricted benefits.</p>	
Palliative care	<p>Midazolam in palliative care</p> <p>Background In September 2020, the PBAC considered outcomes from the Palliative Care Schedule Review and considered there was a clinical need for PBS-subsidised midazolam in the palliative care setting.</p> <p>Status In September 2024, the PBAC agreed that the PMR section undertake research and stakeholder engagement activities to inform the committee's consideration of listing midazolam on the Palliative Care Schedule at a future meeting.</p> <p>Next steps The Department will consult with sponsors, clinical and consumer groups to inform PBAC's future considerations and estimate the financial impact of a potential Palliative Care Schedule listing for midazolam.</p>	<ul style="list-style-type: none"> • Midazolam
Pulmonary arterial hypertension (PAH)	<p>Pulmonary arterial hypertension</p> <p>Background</p>	<ul style="list-style-type: none"> • PBS-listed medicines indicated for pulmonary arterial hypertension

Indication	Project title Background, Status and Next steps	Medicines
	<p>At its March 2025 meeting the PBAC did not recommend a submission for sotatercept as add-on therapy in patients with pulmonary arterial hypertension (PAH) World Health Organisation (WHO) Functional class (FC) II-III. The PBAC noted the requested listing raised disconnections between currently available PAH medicines on the PBS and international PAH guidelines, 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 regarding consistency with international PAH treatment guidelines.</p> <p>Status On 12 August 2025, a stakeholder meeting was conducted to seek clinician input on therapy for patients with PAH and WHO FC II symptoms, including the role of sotatercept in the PAH treatment paradigm. An outcome statement was published on 23 September 2025.</p> <p>Next steps The outcomes of the stakeholder meeting will assist in informing the Department’s work and PBAC’s future considerations to better align PBS restrictions for PAH medicines with current clinical practice and/or international PAH treatment guidelines.</p>	<ul style="list-style-type: none"> • Sotatercept
Various	<p>Review of PBS Prescriber Bag</p> <p>Background At its August 2024 Executive meeting, the PBAC noted stakeholder views that current Prescriber Bag medicines were no longer suitable for use in the contemporary emergency medicine setting. The PBAC requested that the Department undertake a review of the PBS Prescriber Bag, which should include a utilisation analysis of Prescriber Bag medicines, and targeted consultation with key stakeholders on the medicines that would best support emergency care. The PBAC stated that the purpose of the Review is to ensure that the PBS Prescriber Bag supports emergency patient care through inclusion of pharmaceutical benefits that reflect contemporary best emergency practice and are efficacious and safe.</p> <p>In December 2024, the Department commenced the Review by writing to key stakeholders, seeking input to inform the Review. In parallel with the stakeholder consultation process, the Department conducted a utilisation analysis of Prescriber Bag items, using PBS data over the 2018-2024 period.</p>	<ul style="list-style-type: none"> • Medicines listed on the PBS Prescriber Bag Schedule

Indication	Project title Background, Status and Next steps	Medicines
	<p>At its May 2025 meeting, the PBAC's advice was sought 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. The PBAC discussed issues raised in stakeholder submissions and reiterated that the purpose of the Prescriber Bag is to provide medicines for emergency care.</p> <p>Status Stakeholder responses have been collated into tranches for the PBAC's consideration over two meetings.</p> <p>At its September 2025 meeting, the PBAC considered DUSC advice on the utilisation analysis of Prescriber Bag items (2018-2024) and considered stakeholder requests for removal of items, addition of new strengths of existing items, new items to replace current items increased maximum quantities and a request to add an authorised prescriber type. For further information, refer to the September 2025 PBAC Outcomes and the Review of PBS Prescriber Bag Schedule web page.</p> <p>Next steps At a future meeting, the PBAC will provide advice on the suitability of requested new items for inclusion in the Prescriber Bag, as identified through stakeholder consultation. PBAC recommendations arising from the PBS Review will be implemented as part of routine monthly changes to the PBS schedule. All authorised PBS prescribers are encouraged to check the Summary of Changes to the PBS that is published at the beginning of each new calendar month for changes to individual medicine listings.</p>	

Indication	Project title Background, Status and Next steps	Medicines
Attention Deficit Hyperactivity Disorder (ADHD)	<p>Attention Deficit Hyperactivity Disorder (ADHD) medicine review</p> <p>Background At its September 2025 intracycle meeting, the PBAC provided advice on a review proposed in Recommendation 4 of the report from the 2023 Senate Community Affairs References Committee (the Senate Inquiry report) on PBS subsidy arrangements for attention deficit hyperactivity disorder (ADHD) medicines.</p> <p>Status In September 2025, the PBAC noted the Government’s in-principle support for a review of PBS-listed ADHD medicines and considered the five action areas that had been raised by the Senate Inquiry report. The PBAC considered that a formal Post-market Review was not necessary to inform its future consideration of changes to PBS restrictions to improve access to subsidised ADHD medicines. The PBAC requested the Department to undertake a research project consistent with the Post-market Review framework to propose revised PBS restrictions in response to the action areas, as well as estimate changes in drug utilisation and financial implications. The PBAC requested that this work be undertaken as a priority for consideration at a future PBAC meeting. The PBAC requested that the Department consult with the Royal Australian and New Zealand College of Psychiatrists (RANZCP) and other relevant groups prior to PBAC’s consideration of any proposed changes to PBS listings. For further information, refer to the September 2025 PBAC Outcomes.</p> <p>Next steps The Department has commenced a project for future PBAC consideration to revise the PBS restrictions in response to the action areas, as well as estimate changes in drug utilisation and financial implications. The Department will consult with RANZCP and relevant stakeholders prior to PBAC’s consideration of any proposed changes to PBS listings.</p>	<ul style="list-style-type: none"> • PBS-listed medicines indicated for attention deficit hyperactivity disorder