

PBS Post-market Review workplan – September 2024

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.

Minor updates have been made following consideration of the PMR workplan by the PBAC at its September 2024 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 [PMR section](#).

Table 1: Current research projects being undertaken by the PMR section

Indication	Project title Background, Status and Next steps	Medicines
Type 2 diabetes mellitus (T2DM)	<p>PBS restrictions for T2DM medicines</p> <p>Background</p> <p>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, 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 risk, without a glycaemic requirement.</p> <p>The PBAC requested a subsequent utilisation analysis of T2DM medicines on the PBS, which identified high use of GLP-1 RAs outside of the PBS restrictions. The utilisation analysis also identified some use of SGLT2 inhibitors and dipeptidyl-peptidase 4 (DPP4) inhibitors outside of the PBS restrictions. The PBAC recommended a 15% price reduction to the cost of these medicines to account for use outside the restrictions, for which cost-effectiveness has not been considered. The PBAC recommended that if the 15% price reduction to SGLT2 inhibitors was implemented, then the March 2022 recommendation to expand the listings of SGLT2 inhibitors could be implemented without further price reductions or a financial cap.</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

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	<p>In July 2023, the PBAC recommended several changes to simplify the restrictions for pioglitazone, 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.</p> <p>On 1 June 2024, changes were made to the restrictions of several medicines listed on the PBS for the treatment of T2DM to implement recommendations made by the PBAC in March 2023, July 2023, and March 2024. These changes were accompanied by stakeholder communication and educational materials published on the PBS website. Price reductions to two PBS-listed DPP4 inhibitors were also implemented on this date.</p> <p>In July 2023, the PBAC considered that it may be appropriate to expand the PBS listings for GLP-1 RAs to include use in combination with metformin, a sulfonylurea or insulin, for T2DM patients with a body mass index (BMI) greater than 35 kg/m², without a requirement to trial an SGLT2 inhibitor. The PBAC requested that the Department provide financial estimates for this expanded listing to be considered at a future meeting.</p> <p>In July 2024, the PBAC considered updated financial estimates for the March 2022 recommendation to expand access to SGLT2 inhibitors for patients with T2DM and high cardiovascular risk and reaffirmed this recommendation.</p> <p>Next steps</p> <p>The Department will implement the March 2022 SGLT2 inhibitor restriction changes as part of routine monthly changes to the PBS schedule - subject to sponsor acceptance of price reduction.</p> <p>The Department will await potential sponsor re/submissions for GLP-1 RAs for obesity (semaglutide – Wegovy®) and T2DM (tirzepatide – Mounjaro®) before progressing further PMR work on GLP-1 RAs.</p> <p>It is anticipated that the Department/DUSC will review the utilisation of T2DM medicines approximately 2 years after the restriction changes.</p>	

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Heart failure (HF)	<p>Utilisation review of PBS listed heart failure (HF) medications</p> <p>Background</p> <p>In January 2023, the PBAC Executive noted that PBS expenditure for medicines used for the treatment of HF exceeded \$154 million in 2021. The PBAC recommended that a utilisation review be undertaken for PBS-listed medicines for HF to improve understanding of contemporary medicine treatment patterns in patients with HF in Australia, including switching between medicines, combination treatment and add-on therapy.</p> <p>Status</p> <p>The utilisation review of PBS-listed HF medicines was considered by the Drug Utilisation Sub-Committee (DUSC) at its June 2024 meeting and by the PBAC at its September 2024 intracycle meeting. The PBAC outcome was published on 18 October 2024.</p> <p>Next steps</p> <p>Project complete</p>	<ul style="list-style-type: none"> • Beta blockers (bisoprolol as fumarate, carvedilol, metoprolol as succinate, nebivolol) • eplerenone • dapagliflozin • empagliflozin • sacubutril+valsartan • ivabradine • vericiguat
Cancer	<p>Monitoring of final trial overall survival (OS) results in PBAC submissions for cancer medicines</p> <p>Background</p> <p>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>	<ul style="list-style-type: none"> • Oncology medicines

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	<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</p> <p>The Department has contracted a health technology assessment (HTA) evaluation 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. The project is currently in a pilot data collection phase.</p> <p>Next steps</p> <p>The Department will contact sponsors to request any unpublished trial data in late 2024. It is anticipated that a draft report will be provided to ESC/PBAC in mid-2025.</p> <p>The Department will continue to develop research proposals to review the use of surrogate outcomes and surrogate validity in other indications based on the ESC Advice for future PBAC consideration.</p>	
Epilepsy	<p>PBS restrictions for anti-epileptic drugs (AEDs)</p> <p>Background</p> <p>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</p>	<ul style="list-style-type: none"> • All PBS-listed AEDs

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	<p>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 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>Status</p> <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> <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>Next steps</p> <p>It is anticipated that evaluation group's report will be considered by the DUSC and/or PBAC in mid-2025.</p>	

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Various	<p data-bbox="539 276 1429 304">Review of PBS prescribing by nurse practitioners and endorsed midwives</p> <p data-bbox="539 328 689 357">Background</p> <p data-bbox="539 384 1675 722">The PMR Section is undertaking a review of items for Nurse Practitioner (NP) and Endorsed Midwife (EM) prescribing on the PBS, which 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. This work is in context of amendments to the <i>National Health Act 1953</i> occurring on 1 November 2024 to remove the legislated requirement for NPs and EMs to be in a specified collaborative arrangement with a medical practitioner to prescribe PBS-listed medicines.</p> <p data-bbox="539 770 1675 1026">At its December 2023 intracycle meeting, the PBAC noted that a review is being undertaken by the Department on PBS-listed medicines that may be appropriate for NP or EM prescribing. The Department published a consultation survey between 1 March-1April 2024 to collect data on which medicines are frequently being prescribed privately (i.e., non-PBS) by NPs and EMs that are PBS-subsidised for another prescriber type/s, and the settings in which this is occurring. The PMR Section is working closely with the Department’s Chief Nursing and Midwifery Officer Division (CNMO) on this review.</p> <p data-bbox="539 1042 622 1070">Status</p> <p data-bbox="539 1094 1675 1278">At its July 2024 meeting, the PBAC considered each PBS-listed benefit subject to a ‘Shared Care Model’ note for NP prescribing, and provided advice on whether it considered the amendment or removal of this note was required. At its September 2024 meeting, the PBAC considered and provided advice on PBS-listed medicines that were requested though consultation for prescribing by endorsed midwives.</p>	Various

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	<p>Next steps</p> <p>The Department will implement PBAC recommendations arising from the review as part of routine monthly changes to the PBS schedule.</p> <p>The Department will seek PBAC advice on PBS-listed benefits containing a ‘Continuing Therapy Only’ note for NP prescribing and whether this continues to be appropriate for those medicines.</p> <p>The PBAC will also be asked to provide advice on other PBS-listed medicines identified through consultation that may be suitable for NP prescribing on the PBS.</p>	
Severe dry eye	<p>PBS-listed ocular lubricants for treatment of severe dry eye</p> <p>Background</p> <p>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 from the external evaluation group to peak Australian optometry and ophthalmology representative groups and sponsors of PBS-listed ocular lubricants for a pre-PBAC response.</p> <p>Status</p> <p>The findings of the literature review and pre-PBAC responses were provided to the PBAC for consideration in July 2024.</p> <p>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 outcome was published on 23 August 2024.</p> <p>Next steps</p> <p>The PBAC requested that the Department develop an options paper to be considered by the Committee at a future meeting, taking into account current clinical practice and guidelines,</p>	PBS listed preservative containing and preservative free ocular lubricants

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	<p>while ensuring that PBS-listed ocular lubricants remain cost-effective for the eligible population. The PBAC requested information be prepared on the utilisation of ocular lubricants and associated costs to the PBS to support the Committee’s consideration of any potential changes to the PBS listings of these medicines.</p>	
Hypertension	<p>Utilisation analysis of antihypertensives</p> <p>Background</p> <p>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>Status</p> <p>The Department has contracted a HTA group to undertake this project. In addition to the utilisation analysis, the report will also include a literature review and costings analysis.</p> <p>Next steps</p> <p>It is expected that the draft report will be provided to the PBAC in December 2024. Sponsors will be consulted prior to committee consideration.</p>	PBS-listed antihypertensives
Hypercholesterolaemia	<p>Restriction review for ezetimibe and its fixed dose combinations</p> <p>Background</p> <p>Ezetimibe and its fixed dose combinations (FDCs) were identified as a potential medicine on the F2 formulary for a restriction review (see above). The PBS restrictions for ezetimibe and its FDCs are relatively complex and do not align with clinical guidelines. The PBS price has reduced to be similar to Unrestricted Benefit listings for the treatment of hypercholesterolaemia.</p>	<ul style="list-style-type: none"> • Ezetimibe • Ezetimibe fixed dose combinations

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	<p>A stakeholder also wrote to the Department to highlight that the PBS restrictions referenced an outdated cardiovascular risk calculator.</p> <p>Status</p> <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>Next steps</p> <p>The Department will implement restriction changes recommended by the PBAC as part of routine monthly changes to the PBS schedule.</p>	
Various	<p>Review of PBS restrictions for low-cost medicines</p> <p>Background</p> <p>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> <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</p>	Various PBS-listed antidepressants

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	<p>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>Next steps</p> <p>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</p> <p>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</p> <p>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</p> <p>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
Relapsing-remitting multiple sclerosis (RRMS)	<p>Treatments for RRMS</p> <p>Background</p> <p>Fingolimod was the first oral drug for the treatment of relapsing-remitting multiple sclerosis (RRMS) listed on the PBS. Other high-efficacy disease-modifying therapies (DMTs) for the treatment of RRMS (apart from alemtuzumab and natalizumab) have been recommended for a</p>	PBS-listed medicines for RRMS

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	<p>PBS listing on a cost-minimisation basis to fingolimod. All PBS-listed DMTs for RRMS are available as first-line treatment options.</p> <p>Status</p> <p>At its September 2024 meeting, the PBAC noted that the PBS prices of high-efficacy 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>Next steps</p> <p>The Department will undertake a utilisation analysis of the current market for PBS-listed medicines for RRMS.</p>	