PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
SEPTEMBER 2024 PBAC MEETING

The PBAC outcomes and recommendations are presented in alphabetical order by drug name.

Submission items

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
FRUQUINTINIB Capsule 1 mg Capsule 5 mg Fruzaqla® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (New listing)	Metastatic colorectal cancer (mCRC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with mCRC who have been previously treated with or who are not considered candidates for available therapies.	Recommended	The PBAC recommended the listing of fruquintinib as an Authority Required (STREAMLINED) benefit for metastatic colorectal cancer (mCRC) patients who have been previously treated with or who are not considered candidates for available therapies. The PBAC noted the high clinical need for alternative treatments in this patient group and that fruquintinib would provide an additional option with a modest benefit to patients in both the third- and fourth-line settings. The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of fruquintinib would be acceptable if it were cost-minimised to trifluridine/tipiracil (TRI/TIP) based on equi-effective doses. The PBAC considered that fruquintinib 5 mg/day for 21 days of each 28-day cycle (total 105 mg) is equi-effective to TRI/TIP 60 mg twice daily on days 1-5 and 8-12 of each 28-day cycle (total 1,200 mg).
OSILODROSTAT Tablet 1 mg Tablet 5 mg Isturisa® RECORDATI RARE DISEASES AUSTRALIA PTY. LTD. (New listing)	Cushing syndrome	Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of endogenous Cushing syndrome.	Recommended	The PBAC recommended the General Schedule Authority Required (Telephone/Online) listing of osilodrostat for the treatment of endogenous Cushing's syndrome (CS) in adults. The PBAC was satisfied that osilodrostat provides, for some patients, a significant improvement in efficacy over placebo. In making this recommendation, the PBAC acknowledged the high unmet clinical need for effective treatments for CS. The Committee also recalled it had previously considered that osilodrostat was superior to placebo in normalising cortisol in the majority of treated patients. The PBAC noted the information presented in the early resolution resubmission to support the value of a reduction in cortisol levels over the short, medium-, and long-term. The PBAC agreed with the early resolution resubmission that, over time, osilodrostat may positively impact multiple patient relevant outcomes, and that this value proposition was a point of difference to other chronic therapies that had been recommended on the basis of incremental cost per responder analyses. Overall, the PBAC accepted osilodrostat would be cost-effective based on the incremental cost per responder as presented in this resubmission. The PBAC noted no additional information was available to support the estimated duration of therapy and that, notwithstanding factors that may necessitate discontinuation, use is expected to be lifelong in patients who respond to treatment. The PBAC considered the expected duration of use remained uncertain and, as such, a risk sharing arrangement would be required to manage the estimated cost to Government.

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PBS Restrictions of Hepatitis C medicines Multiple strengths Multiple brands Multiple sponsors (Change to listing)	Hepatitis C	To consider amending the treatment criteria in the PBS General Statement for Hepatitis C infection.	Advice provided	The PBAC advised that it would be appropriate to clarify the treatment criteria in the PBS General Statement for Drugs for the Treatment of Hepatitis C (General Statement) to specify only a single positive hepatitis C antibody test was required, in combination with other eligibility criteria. The PBAC considered the proposed amendment would not result in a financial impact to the Government as the proposed changes to the treatment criteria of the General Statement would align with current clinical practice and not increase the eligible population.
Gap analysis of opioids listed on the PBS (Other business)	Opioid analgesia	To provide the PBAC with an overview of the current opioid analgesic medicines listed on the PBS, highlighting potential gaps in therapeutic options due to current shortages and those that may arise from future delists (or shortages) of opioid products.	Advice provided	The PBAC considered a gap analysis of opioid analgesic medicines currently listed on the Pharmaceutical Benefits Scheme (PBS). The PBAC noted clinical input from the Australian New Zealand Society of Palliative Medicine (ANZSPM), Palliative Care Australia, Advanced Pharmacy Australia (AdPha), the Australian New Zealand College of Anaesthetists Faculty of Pain Medicine (ANZCA) and the Royal Australian College of General Practitioners (RACGP). The PBAC advised that it was important to maintain a range of opioid medicines (and dose forms) on the PBS to ensure prescribers have access to suitable therapeutic options for pain management that can be tailored to a patient's individual circumstances. The PBAC advised that most withdrawals of individual opioid products can be managed without a significant impact on patient care. However, when multiple discontinuations of products from a similar class occur, this has a substantial impact, particularly on special patient populations with specific requirements. The PBAC advised that it favours sourcing a reliable supply of opioid products under these circumstances, rather than bridging gaps with the temporary PBS listings of s19A products. The PBAC noted the significant concerns regarding the shortages and discontinuations of opioids raised in correspondence from the ANZSPM (supported by Palliative Care Australia and AdPha), Palliative Care Australia, ANZCA and RACGP. In particular, the PBAC noted concerns from ANZSPM that the net effect of discontinuations and shortages is severe compromise in the ability of clinicians to tailor pain relief to individual patient need. The PBAC noted that ANZCA also raised concerns about the vulnerability of the supply of opioids to disruptions in Australia.

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				The PBAC noted that there is a gap in the availability of a number of opioid products, including: • Immediate release oral morphine products. The PBAC considered the supply disruptions of the only TGA approved oral morphine liquid product, Ordine, to be the most significant concern, and advised that a reliable supply of a TGA registered morphine oral liquid product of multiple strengths was critical. It noted correspondence from stakeholders raising concerns about the impact that the supply disruption is having on patients and prescribers. The PBAC noted that although there are s19A oral morphine liquid products available on the PBS, input from clinical stakeholders indicates that use of these products in clinical practice is problematic. • Controlled release morphine for patients with swallowing difficulties. The PBAC noted that with the discontinuation of MS Contin Suspension and MS Mono® capsules, Kapanol would be the only morphine CR product that may be suitable for patients with swallowing difficulties or enteric feeding tubes. The PBAC noted clinical input advised the discontinuation of MS Contin Suspension has created a gap in effective pain management for paediatric patients and others who are unable to swallow tablets. • Hydromorphone. The PBAC noted that there are currently no hydromorphone oral liquid or hydromorphone controlled release products with TGA registration, and while there are s19A hydromorphone oral liquids currently PBS-listed, no controlled release hydromorphone products are listed on the PBS. The PBAC noted input from stakeholders that hydromorphone had a role in people with palliative care needs and patients with renal impairment.

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Post-market Review (PMR) Workplan Update	N/A	To: - consider the PMR workplan, including the status of current research projects and the implementation of recently completed work. - seek advice on potential PMR topics or research projects.	Advice provided	The PBAC noted the status of current research projects and the implementation of recently completed work outlined in the PMR workplan. The PBAC noted that there are currently no PMRs underway and did not recommend any new PMR topics. The PBAC recalled that the PMR Framework provides for preliminary research projects to be undertaken by the Department to inform its consideration of potential PMR topics, with the aim of ensuring the ongoing quality and cost-effective use of PBS-listed medicines. The PBAC noted that suggestions for new topics could be provided to the PMR or PBAC Secretariats at any time. The Department may also undertake consultation with Health Technology Assessment (HTA) or clinical groups to identify potential PMR topics. The PBAC agreed that the Department proceed with the following research projects for inclusion in the published PMR workplan: • Review of PBS restrictions for low-cost medicines • Midazolam in palliative care • Treatments for relapsing-remitting multiple sclerosis
Programmed cell death protein 1/death ligand 1 (PD-(L)1) inhibitors Multiple strengths Multiple brands Multiple sponsors (Other business)	Multiple indications	To provide initial guidance on parameters that need to be considered for future broad PBS listing proposals for PD-(L)1 inhibitors, and to advise on next steps to seek broader stakeholder input.	Advice provided	Available here

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Review of PBS items that may be suitable for endorsed midwife (EM) prescribing Multiple strengths Multiple brands Multiple sponsors (PBS review)	Multiple indications	To consider a list of PBS items that may be suitable for prescribing by endorsed midwives.	Recommended	The PBAC considered approximately 50 PBS-listed medicines identified through consultation that were requested for prescribing by endorsed midwives. The PBAC recommended that the majority of these medicines be amended to allow PBS prescribing by endorsed midwives without any further conditions beyond those that may already specified in PBS restrictions. For a subset of medicines, the PBAC recommended that PBS listings be amended to allow PBS prescribing by endorsed midwives under certain circumstances where the care of a patient is shared with a medical practitioner and, in some instances, for continuing treatment only. The PBAC did not recommend adding endorsed midwives as authorised prescribers of PBS-listed medicines where: the medicine is not TGA registered for the proposed use, the medicine is currently withdrawn from the market, or clinical guidelines do not support use of the medicine during pregnancy.
Utilisation review of PBS listed medicines for heart failure Multiple strengths Multiple brands Multiple sponsors (PBS review)	Medicines with the PBS indication of heart failure	To note the utilisation review of PBS listed medicines for heart failure, consider advice on the review from the Drug Utilisation Sub Committee, and advise the Department on any further work that may be required.	Advice provided	The PBAC considered the utilisation analysis of PBS listed medicines for HF, advice from the Drug Utilisation Sub Committee advice, and sponsor comments received through the pre-sub-committee and pre-PBAC responses. The PBAC considered that a Post-Market Review (PMR) of HF medicines is premature, given the relative recency of changes to clinical guidelines for the management of HF and the immaturity of the current market due to several recent new medication listings. The PBAC also noted that the PBS restrictions of HF medicines do not prohibit quadruple drug therapy. The PBAC advised it would consider stakeholder input on revising PBS restrictions for HF medicines to align with clinical guidelines in the context of a future PMR. The PBAC was cognisant that the discordance between PBS restrictions and clinical treatment guidelines is likely to reflect clinical scenarios in which HF treatments have not been demonstrated to be cost-effective.

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Resubmission pathways

*There are four different resubmission pathways available to applicants following a 'not recommended' PBAC outcome. Resubmission pathways are not available for submissions that receive a positive recommendation from the PBAC. The resubmission pathways are classified into the following categories:	
Standard re-entry	The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where: • an applicant chooses not to accept the PBAC nominated resubmission pathway; or • an Early Re-entry or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or • an applicant decides to lodge later than the allowable timelines for the other pathways.
Early re-entry pathway	An Early Re-entry Pathway may be nominated by the PBAC where the PBAC considers that the remaining issues could be easily resolved and the medicine or vaccine does not represent High Added Therapeutic Value (HATV) for the proposed population. Applicants who accept this pathway are eligible for PBAC consideration at the immediate next meeting.
Early resolution pathway	For medicines or vaccines deemed by the PBAC to represent HATV AND where the PBAC considers that the remaining issues could be easily resolved, including when: • new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and • a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission. Applicants who accept this pathway are eligible for PBAC consideration out-of-session (before the main meeting), unless the department, in consultation with the PBAC Chair, identifies an unexpected issue such that the resubmission needs consideration at the next main PBAC meeting.
Facilitated resolution pathway	A Facilitated Resolution Pathway may be nominated by the PBAC where the PBAC considers the issues for resolution could be explored through a workshop AND where the medicine or vaccine meets the HATV criteria. Applicants who accept this pathway are eligible for a solution-focussed workshop with one or more members of the PBAC. The workshop agenda will be based on the issues for resolution outlined in the PBAC Minutes. This can be further clarified during the post-PBAC meeting with the Chair.