

**ITEMS RECOMMENDED OUT OF SESSION BETWEEN ORDINARY PBAC MEETINGS (NOVEMBER 2022 – MARCH 2023)**

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">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">Category 2 submission (Change to PBS listing)</p>	<p align="center">Chronic heart failure</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic heart failure (NYHA classes II, III or IV) in patients with a left ventricular ejection fraction greater than 40%.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended extending the existing listing of empagliflozin to include a General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic heart failure in patients with a left ventricular ejection fraction greater than 40%. The PBAC considered there was a high unmet clinical need for effective treatments for patients with this condition. The PBAC noted that empagliflozin when added to standard care provided a statistically significant improvement in efficacy over standard care alone in the proposed population based on the primary composite outcome in EMPEROR-Preserved (time to first cardiovascular death or hospitalisation for heart failure).</p> <p>The PBAC considered that the sponsor had addressed the substantive outstanding issues identified at the November 2022 PBAC meeting via the proposed price reduction and risk sharing arrangement.</p>
<p align="center">ENFORTUMAB VEDOTIN</p> <p align="center">Powder for I.V. infusion 20 mg Powder for I.V. infusion 30 mg</p> <p align="center">Padcev®</p> <p align="center">Astellas Pharma Australia Pty Ltd</p> <p align="center">Early re-entry submission (New PBS listing)</p>	<p align="center">Urothelial cancer</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer who have progressed on or after treatment with a platinum-containing chemotherapy regimen and either a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing of enfortumab vedotin for the treatment of patients with locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer (Ia/mUC) who have progressed on or after a platinum-containing chemotherapy regimen and either a PD-1 inhibitor or a PD-L1 inhibitor. The PBAC was satisfied that enfortumab vedotin provides, for some patients, a significant improvement in efficacy over docetaxel or paclitaxel, administered as single agents. The PBAC considered that the sponsor had addressed the outstanding issues identified at the November 2022 meeting via the proposed price reduction and the proposed Special Revenue Arrangement.</p>

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<p align="center">NIRMATRELVIR AND RITONAVIR</p> <p>Pack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5</p> <p align="center">Paxlovid®</p> <p align="center">Department of Health (Commonwealth)</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Mild to moderate COVID-19</p>	<p align="center">To review current Pharmaceutical Benefits Scheme (PBS) eligibility for nirmatrelvir and ritonavir; consider whether broader eligibility is appropriate while the Commonwealth is the Responsible Person; and recommend any changes to restrictions.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended to expand patient eligibility for PBS nirmatrelvir and ritonavir to include people aged 60-69 years with mild to moderate COVID-19 and one additional risk factor. The PBAC was satisfied that clinical benefit and safety exists for use of nirmatrelvir and ritonavir in the proposed new patient group. The PBAC considered that the listing will be cost effective in the expanded population for so long as pharmaceutical benefits dispensed are sourced from the stock already purchased by the Commonwealth, and which might otherwise expire unused. As such, the PBAC recommended that this expansion of patient eligibility only apply until the Commonwealth purchased stock is exhausted or has expired.</p>

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**Submission category types**

<b>Category 1</b>	<p>A request for PBS or NIP listing of one or more of the following:</p> <ul style="list-style-type: none"> <li>• A first in class medicine or vaccine, and/or a medicine or vaccine for a new population. OR</li> <li>• A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC. OR</li> <li>• A drug or designated vaccine with a TGA Provisional determination related to the proposed population.</li> </ul>
<b>Category 2</b>	<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>
<b>Category 3</b>	<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>
<b>Category 4</b>	<p>A request for one or more of the following:</p> <ul style="list-style-type: none"> <li>• Listing of a new pharmaceutical item of a listed medicine.</li> <li>• Consideration as an exempt item (Exempt item as per subsection 84AH of the <i>National Health Act 1953</i>).</li> <li>• Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing.</li> <li>• A change/new manner of administration of a listed medicine.</li> <li>• A change to the maximum quantity and/or number of repeats of a listed medicine.</li> <li>• A change or addition to the prescriber type(s) of a listed medicine.</li> </ul>
<b>Committee Secretariat</b>	<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"> <li>• New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk</li> <li>• Pharmaceutical benefits that can no longer be supplied early</li> <li>• New brand of glucose indicator pharmaceutical item.</li> </ul>