

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
DECEMBER 2021 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	
<p>ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR</p> <p>Pack containing 56 tablets of elexacaftor 100 mg with tezacaftor 50 mg and ivacaftor 75 mg and 28 tablets of ivacaftor 150 mg</p> <p>Trikafta®</p> <p>Vertex Pharmaceuticals Australia Pty Ltd</p> <p>Early Re-entry Resubmission (New PBS listing)</p>	<p>Cystic fibrosis (CF)</p>	<p>Early re-entry submission to request PBS listing for CF in patients aged 12 years or older who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) for the treatment of CF patients aged 12 years and older who have at least one F508del mutation in the CFTR gene (F/any population).</p> <p>The PBAC noted that the resubmission was not consistent with the Committee's advice in March 2021 and May 2021 in relation to the F/any population with regard to the cost-effective price and the patient estimates. However, in making its recommendation, the PBAC noted that there was a high clinical need for ELX/TEZ/IVA especially for those patient populations that are not eligible for a currently PBS-subsidised CFTR modulator therapy. The PBAC considered that ELX/TEZ/IVA could be brought within an acceptable incremental cost effectiveness ratio range with a price reduction, and in the context of accepting the resubmission's proposed patient estimates as reflecting the upper end of the range of likely use.</p>
<p>LORLATINIB</p> <p>Tablet 25 mg Tablet 100 mg</p> <p>Lorviqua®</p> <p>Pfizer Australia Pty Ltd</p> <p>Category 2 submission (Change to PBS listing)</p>	<p>Locally advanced (stage IIIB) or metastatic (stage IV) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)</p>	<p>To request a General Schedule, Authority Required (Telephone/Electronic) listing for the treatment of locally advanced (Stage IIIB) or metastatic (Stage IV) ALK-positive NSCLC in patients who have not received prior treatment with an ALK inhibitor.</p>	<p>Recommended</p>	<p>The PBAC recommended the line-agnostic listing of lorlatinib for Stage IIIB (locally advanced) or Stage IV (metastatic) non-squamous or not otherwise specified type NSCLC with evidence of an ALK gene rearrangement in tumour material. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of lorlatinib would be acceptable if it were cost-minimised against the least costly alternative therapy.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
DECEMBER 2021 PBAC MEETING**

Non-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	
<p>CLOPIDOGREL</p> <p>Tablet 75 mg (as besilate) Tablet 75 mg (as hydrogen sulfate)</p> <p>CLOPIDOGREL + ASPIRIN</p> <p>Tablet 75 mg (as hydrogen sulfate)-100 mg</p> <p>Multiple brands and sponsors</p>	<p>Antithrombotic</p>	<p>To consider an unrestricted listing for clopidogrel and clopidogrel with aspirin.</p>	<p>Recommended</p>	<p>The PBAC recommended that the listing of clopidogrel and clopidogrel with aspirin be changed from Authority Required (STREAMLINED) listings to unrestricted listings. The PBAC noted clinician feedback received regarding the barriers that the current Authority Required (STREAMLINED) listings present in certain circumstances and how the place in therapy of clopidogrel has evolved over time. The PBAC considered that unrestricted listings would reduce the burden for prescribers and enable better access for patients in need of anti-platelet therapy.</p>
<p>HYDROXYCHLOROQUINE</p> <p>Tablet containing hydroxychloroquine sulfate 200 mg</p> <p>Multiple brands and sponsors</p>	<p>Antirheumatic</p>	<p>To consider reverting the listing of hydroxychloroquine to an unrestricted listing.</p>	<p>Recommended</p>	<p>The Committee recommended that hydroxychloroquine should be listed as an unrestricted benefit. The Committee noted the number of PBS prescriptions issued for this drug had reduced back to pre-COVID levels and remained stable since the implementation of the new listings.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
DECEMBER 2021 PBAC MEETING**

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p>IBRUTINIB</p> <p>Capsule 140 mg</p> <p>Imbruvica®</p> <p>Janssen-Cilag Pty Ltd</p> <p>VENETOCLAX</p> <p>Tablet 10 mg</p> <p>Tablet 50 mg</p> <p>Tablet 100 mg</p> <p>Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg</p> <p>Venclexta®</p> <p>AbbVie Pty Ltd</p> <p>IDELALISIB</p> <p>Tablet 100 mg</p> <p>Tablet 150 mg</p> <p>Zydelig®</p> <p>Gilead Sciences Pty Ltd</p>	<p>Multiple indications</p>	<p>To note that the restrictions for ibrutinib, venetoclax and idelalisib will be amended to allow 17p deletion to be detected by any Medical Benefits Schedule (MBS) listed test.</p>	<p>Noted</p>	<p>The PBAC noted that the PBS restrictions for ibrutinib, venetoclax and idelalisib would be updated on 1 January 2022 to state that 17p deletions can be detected using any MBS listed test.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
DECEMBER 2021 PBAC MEETING**

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p>LUMACAFITOR + IVACAFITOR</p> <p>Tablet containing lumacaftor 100 mg with ivacaftor 125 mg</p> <p>Orkambi</p> <p>Vertex Pharmaceuticals (Australia) Pty Ltd</p>	<p>Cystic fibrosis</p>	<p>To provide additional data as specified in the Managed Access Program</p>	<p>Advice provided</p>	<p>The PBAC noted the additional data and updated analyses included in the resubmission and advised that the updated point estimates for relative rate of decline (rROD,6+ years) provided (for up to 5 years of follow-up) were less than 42%. Specifically, for the new analysis that accounted for censoring, the point estimate of the rROD was 40%. While the submission asserted that the point estimate of 42% had been validated within acceptable margins of error, the PBAC noted that the updated US Cystic Fibrosis Foundation Patient Registry (CFFPR) analysis and the pre-specified US CFFPR (PASS108 IA4) analysis did not substantiate an assumption of a rROD in percent predicted forced expiratory volume in one second (ppFEV₁) for LUM/IVA compared to best supportive care of at least 42%. Therefore, the PBAC's advice to the Minister was that of the available estimates, and notwithstanding residual concerns about bias in the presented analyses, the most reasonable point estimate value for the rate of decline in lung function for LUM/IVA, for the purposes of the Managed Access Program, is 40%.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
DECEMBER 2021 PBAC MEETING**

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 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 High Added Therapeutic Value (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>