

AUGUST 2016 PBAC OUTCOMES – SUBSEQUENT DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>IBRUTINIB 140 mg capsules, 90</p> <p>Imbruvica®</p> <p>Janssen-Cilag Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p>	<p>Chronic lymphocytic leukaemia and small lymphocytic lymphoma</p>	<p>Re-submission to request Authority Required (STREAMLINED) listing for the treatment of relapsed or refractory chronic lymphocytic leukaemia and relapsed or refractory small lymphocytic lymphoma.</p>	<p>The PBAC did not recommend the listing of ibrutinib for the treatment of relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) because, at the price proposed by the submission, the incremental cost per quality adjusted life year (QALY) gained was unacceptably high. Additionally, the PBAC noted the financial impact of listing ibrutinib at the proposed price was high with a total net cost of more than \$100 million over the first five years of listing, and as such there would be a significant opportunity cost to the Commonwealth.</p> <p>In making this recommendation, the PBAC agreed that the broader restriction proposed by the sponsor and supported by clinical experts was appropriate, and reiterated its view that ibrutinib is an effective treatment for CLL and SLL based on the results of the RESONATE trial.</p> <p>However, the PBAC considered the incremental benefit of ibrutinib over its comparator (chlorambucil plus rituximab) as estimated in the economic model remained uncertain. This uncertainty resulted in part, from the adjustment required in the model to account for the comparator in the RESONATE trial being ofatumumab, which is likely to be inferior to chlorambucil plus rituximab in terms of overall survival. Additionally, even when the model is truncated at 10 years, a large proportion (87% prior to discounting and 84% post-discounting) of the estimated survival gain is from the extrapolated part of the survival curves. As a result, the extent of benefit is highly influenced by the approach taken to extrapolate the survival curves, and in particular the period over which the curves are converged.</p> <p>The PBAC considered a reduction in price would be required to achieve cost-effectiveness in the population preferred by the sponsor, clinicians and PBAC.</p>

AUGUST 2016 PBAC OUTCOMES – SUBSEQUENT DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
		<p align="center">Sponsor's Comment:</p>	<p>The sponsor is pleased the PBAC recognise that ibrutinib is an effective treatment for CLL and SLL and that they agreed with the sponsor and clinicians that the broader restriction is appropriate.</p> <p>The sponsor does not agree that ibrutinib is not cost-effective at the proposed price. Throughout the course of multiple submissions, the sponsor has agreed to increasingly conservative changes to the economic model in order to address PBAC's concern around uncertainty. However, the sponsor could not agree to all changes requested by PBAC as they represent a very conservative base case that underestimates the benefit and therefore value of ibrutinib. For example, in arriving at their decision that ibrutinib was not cost-effective, PBAC excluded any adjustment for the impact of cross-over, despite the fact that it was accepted during the course of the evaluation that bias existed due to cross-over (61% of patients in the comparator arm switched to active therapy). The sponsor therefore maintains that ibrutinib is a cost-effective treatment at the proposed price in the broader population preferred by the sponsor, clinicians and PBAC.</p> <p>The opportunity cost to the Commonwealth in approving ibrutinib at the proposed price is a separate consideration. The sponsor welcomes the opportunity to work with the Department of Health and the PBAC in order to ensure Australian patients achieve access to ibrutinib.</p>