

NOVEMBER 2019 PBAC OUTCOMES – SUBSEQUENT DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>NERATINIB</p> <p>Tablet 40 mg</p> <p>Nerlynx®</p> <p>Specialised Therapeutics Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Neratinib is indicated for the extended adjuvant treatment of adult patients with early-stage human epidermal growth factor receptor-2 (HER2) overexpressed/ amplified breast cancer, to follow adjuvant trastuzumab based therapy.</p>	<p>Neratinib is not currently listed on the PBS.</p>	<p>Resubmission to request an Authority Required listing for the extended adjuvant treatment of patients with HER2+, hormone receptor positive (HR+) early breast cancer (eBC) who have received prior adjuvant trastuzumab therapy within the past 12 months.</p> <p>Comparator: usual care/placebo</p>	<p>The PBAC did not recommend an Authority Required listing for neratinib for extended adjuvant treatment of adult patients with HER2+ eBC who have completed prior adjuvant trastuzumab-based therapy.</p> <p>The PBAC considered that for part of the proposed population, there were no or limited data and therefore the clinical benefit could not be demonstrated. In the remaining population, the clinical benefit of neratinib would be small and the effect was likely to be lower than observed in a broader trial population. Overall, the PBAC considered the clinical place of neratinib was reduced to a limited and diminishing population given the changing landscape for treatment of HER2+ eBC.</p> <p>The main comparator was unchanged from the previous submission (March 2019 PBAC meeting). The PBAC previously accepted the nominated main comparator as being appropriate.</p>

NOVEMBER 2019 PBAC OUTCOMES – SUBSEQUENT DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
			<p>Clinical claim: neratinib was superior in terms of effectiveness compared with placebo in patients with HER2+ eBC but inferior in terms of safety to placebo.</p>	<p>The PBAC maintained its view from its previous consideration that the claim of superior comparative effectiveness was not supported by the data. The PBAC considered the difference in invasive disease-free survival to be small and uncertain given the potential for a high risk of bias. Further, the PBAC noted in the absence of overall survival data, the long term benefits of neratinib therapy are unknown.</p> <p>The PBAC considered that the claim of inferior comparative safety was reasonable and consistent with the data. The PBAC noted that the patient support program appears to have helped patients and oncologists manage the adverse events associated with neratinib. However, the PBAC maintained its view from its previous consideration that the adverse events experienced with neratinib therapy compared to placebo were significant and may outweigh the small benefit for some patients.</p>
			<p>Economic claim: cost-utility analysis comparing neratinib to usual care/placebo.</p>	<p>The PBAC considered the base case presented in the resubmission was highly optimistic due to assumptions and inputs that favoured neratinib. The PBAC considered that the economic evaluation did not reflect use in the relevant population likely to use neratinib in clinical practice and therefore was not a reliable basis for estimating the cost-effectiveness of neratinib. The PBAC also considered that the financial estimates remained substantially overestimated.</p>
			<p align="center">Sponsor's comment:</p>	<p>No comment</p>