

Publication

Cost-effectiveness of palbociclib in early breast cancer patients with a high risk of relapse: Results from the PENELOPE-B trial.

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Patients with hormone receptor-positive, HER2-negative breast cancer who have residual invasive disease after neoadjuvant chemotherapy (NACT) are at a high risk of relapse. PENELOPE-B was a double-blind, placebo-controlled, phase III trial that investigated adding palbociclib (PAL) for thirteen 28-day cycles to adjuvant endocrine therapy (ET) in these patients. Clinical results showed no significant improvement in invasive disease-free survival with PAL.; We performed a pre-planned cost-effectiveness analysis of PAL within PENELOPE-B from the perspective of the German statutory health insurance. Health-related quality of life scores, collected in the trial using the EQ-5D-3L instrument, were converted to utilities based on the German valuation algorithm. Resource use was valued using German price weights. Outcomes were discounted at 3% and modeled with mixed-level linear models to adjust for attrition, repeated measurements, and residual baseline imbalances. Subgroup analyses were performed for key prognostic risk factors. Scenario analyses addressed data limitations and evaluated the robustness of the estimated cost-effectiveness of PAL to methodological choices.; The effects of PAL on quality-adjusted life years (QALYs) were marginal during the active treatment phase, increasing thereafter to 0.088 (95% confidence interval: -0.001; 0.177) QALYs gained over the 4 years of follow-up. The incremental costs were dominated by PAL averaging EUR 33,000 per patient; costs were higher in the PAL arm but not significantly different after the second year. At an incremental cost-effectiveness ratio of EUR 380,000 per QALY gained, PAL was not cost-effective compared to the standard-of-care ET. Analyses restricted to Germany and other subgroups were consistent with the main results. Findings were robust in the scenarios evaluated.; One year of PAL added to ET is not cost-effective in women with residual invasive disease after NACT in Germany.

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