

<https://doi.org/10.29289/259453942025V36S11182>

1182 – Potential clinical impact of pembrolizumab incorporation for triple-negative breast cancer in Brazil's public health system: a 5-year survival modeling study

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Introduction: Triple-negative breast cancer (TNBC) is an aggressive subtype associated with poor outcomes and limited treatment options. Although pembrolizumab has demonstrated an overall survival benefit in early-stage TNBC, it has not yet been incorporated into Brazil's Unified Health System (SUS).

Objective: To estimate the potential clinical impact of pembrolizumab incorporation into the SUS for early-stage TNBC.

Methods: This retrospective observational modeling study used secondary DATASUS records to build a real-world SUS cohort and compared it with a counterfactual pembrolizumab cohort derived from published survival data. After deterministic linkage of hospitalization and outpatient datasets, 4,404 eligible patients composed the SUS cohort. For the 5-year survival analysis, 705 patients with adequate follow-up were included. A synthetic pembrolizumab cohort (n=784) was generated based on the phase III KEYNOTE-522 overall survival results. The primary outcome was 5-year overall survival. Cumulative mortality, absolute risk reduction, number needed to treat, and the number of additional lives preserved per 1,000 treated patients were also estimated.

Results: Five-year overall survival was 56.9% in the SUS cohort and 88.0% in the pembrolizumab cohort. The corresponding 5-year cumulative mortality was 43.1% *versus* 13.4%. Mean survival was 45.4 months in the SUS cohort and 55.1 months in the pembrolizumab cohort. The absolute reduction in mortality was 31.1%, with an estimated number needed to treat of 3.2. In a simulation per 1,000 treated patients, 570 patients were alive at five years under the current SUS scenario *versus* 864 with pembrolizumab, corresponding to 294 additional lives preserved over five years. Benefits were observed in both age subgroups.

Conclusion: The incorporation of pembrolizumab for TNBC in the SUS could substantially improve 5-year survival and translate into a major population-level survival gain, with nearly 300 additional lives preserved per 1,000 treated patients.

Ethics: Public data.

Keywords: triple-negative breast cancer; pembrolizumab; overall survival; public health; Brazil.