

## REAL WORLD EVIDENCE AND LATE PHASE RESEARCH CASE STUDIES

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### Economic Impact of a Novel Qualitative In-Vitro in Sentinel Lymph Node Biopsy

Precise evaluation of the metastatic status of axillary lymph nodes can help guide staging and treatment choices for patients with early-stage breast cancer. Assessment of sentinel lymph nodes has been shown to accurately reflect the presence of metastases in axillary nodes. Based on the results of intraoperative evaluation of sentinel lymph nodes, the surgeon will choose to perform partial or complete dissection of the axillary nodes. Current intraoperative assessments are limited and postoperative pathological assessment of permanent sections often show different results, thus requiring patients with “false negative” intraoperative results to undergo a second surgical procedure for full axillary node dissection. This second surgical procedure involves substantially higher risk of complications such as lymphedema, pain, numbness and motion restriction. The objective of this study was to develop an economic model to assess the potential impact of a qualitative in vitro test for the rapid detection of clinically relevant ( $> 0.2$  mm) metastases in sentinel nodes on hospital reimbursements, costs, and net revenue.

The model compared four sentinel node strategies: (1) novel in vitro test; (2) frozen section; (3) imprint cytology; and (4) post-operative pathology only. The analysis was conducted from the perspective of a hospital performing inpatient and/or outpatient breast cancer surgeries on patients with breast cancer over a one-year timeframe. Hospital reimbursements for performing surgeries were derived from Medicare data. Hospital costs were estimated using Medicare cost-to-reimbursement ratios. The model estimated total hospital net revenue for each sentinel node strategy and calculated mean revenue per case, cost per case, and net revenue per case.