

# **Title: Cost-effectiveness evaluation of the Oncotype DX® breast cancer assay in clinical practice in the UK**

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**Objective:** Optimizing therapeutic regimens for breast cancer patients has an important role to play in improving outcomes and planning the best use of National Health Service resources. Oncotype DX testing has been shown to provide clinically valuable information in addition to traditional measurements (such as tumor size, tumor grade and lymph node status) to support chemotherapy treatment decision making, particularly in patients with 0–3 positive lymph nodes. The aim of this study was to evaluate the cost-effectiveness of Oncotype DX testing to support adjuvant therapy decision making versus current clinical practice in the treatment of patients with early-stage breast cancer in the UK.

**Methods:** A Markov model was developed to make long-term projections of distant recurrence, survival, quality-adjusted life expectancy and direct medical costs for patients with ER+, node-negative or up to 3 node-positive early-stage breast cancer. Scenarios using conventional diagnostic procedures (including Adjuvant! Online and the Nottingham Prognostic Index) or Oncotype DX testing to inform treatment recommendations for adjuvant therapy were modeled. The model relied on data from an ongoing study in Wales for treatment recommendations (with and without Oncotype DX), landmark Oncotype DX studies for the risk of recurrence, and UK-specific life tables for mortality. Costs were derived from published UK sources and expressed in 2010 Pounds Sterling (GBP). Future costs and clinical benefits were discounted at 3.5% annually. Probabilistic and deterministic sensitivity analyses were performed.

**Results:** Oncotype DX was projected to increase mean life expectancy by 0.16 years and mean quality adjusted life expectancy by 0.14 quality-adjusted life years (QALYs) compared with current clinical practice over a 30-year time horizon (see table). Clinical benefits were driven by optimized allocation of adjuvant chemotherapy in the Oncotype DX group. Direct medical costs were estimated to be higher with Oncotype DX testing, leading to an incremental cost-effectiveness ratio (ICER) of approximately GBP 6,232 per QALY gained for Oncotype DX versus current clinical practice in the UK. Sensitivity analysis showed that the cost-effectiveness of Oncotype DX testing was most sensitive to variations in patient age, the cost of the Oncotype DX assay, and net changes in chemotherapy in low risk patients.

	Current clinical practice	Oncotype DX testing	Difference
Life expectancy (years)	14.73	14.89	0.16
Quality-adjusted life expectancy (QALYs)	11.39	11.54	0.14
Cost (GBP)	11,847.24	12,734.93	887.69
ICER (GBP per QALY gained)	6,231.91		

GBP, pounds sterling; ICER, incremental cost-effectiveness ratio; QALYs, quality-adjusted life years; Values shown are per patient

**Conclusions:** Reallocation of adjuvant chemotherapy based on Oncotype DX test results was associated with improvements in survival and quality-adjusted life expectancy in this modeling analysis. At a willingness to pay threshold of GBP 20,000 per QALY (commonly quoted as representing good value for money in the UK), probabilistic sensitivity analysis showed that there was a 99.6% probability that Oncotype DX would be cost-effective versus current clinical practice.