

## Real-world comparative economics of a 12-gene assay for prognosis in stage II colon cancer

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Background: Prior economic analysis of a 12-gene assay (Oncotype DX), compared with patterns of care reported in the NCCN database of patients with stage II, T3, DNA mismatch repair proficient (MMR-P) colon cancer, predicted that the assay would save medical costs and improve patient well-being (Hornberger et al., Value Health, 2012). This study assessed the validity of those findings with actual adjuvant chemotherapy (aCT) recommendations. Methods: Outcomes and costs were estimated for patients with stage II, T3, MMR-P colon cancer using a Markov model. A study of 141 patients from 17 sites in the Mayo Clinic Cancer Research Consortium collected data on aCT recommended before and after knowledge of the 12-gene assay results (Srivastava et al. abstract). Quality-adjusted life years (QALY) and medical resource use after recurrence were computed using guideline-validated state-transition probability estimation methods. Risk of progression and incidence of adverse events with different aCT regimens were based on published literature. Drug and administration costs for aCT were obtained from 2012 Medicare fee schedules. One-way sensitivity analyses were conducted to evaluate parameter influence on economic impact. Results: After receiving the 12-gene assay results, physician recommendations in favor of aCT decreased 22% (95% CI 11%-32%; McNemar test  $p < 0.001$ ) from 73 (52%) to 42 (30%) patients. Oxaliplatin aCT and 5-FU monotherapy recommendations each declined 11%. Average aCT costs decreased \$5,738 for drugs, \$668 for administration, and \$3,268 for adverse events management. Overall, average total direct medical costs decreased \$4,203. The net effect on average patient well-being was a gain of 0.083 QALYs. Total medical costs are most influenced by change in aCT recommendations, 5-FU monotherapy efficacy, and oxaliplatin drug acquisition cost. Savings are expected to persist even if the cost of oxaliplatin dropped by >75% due to generic substitution. Conclusions: The 12-gene assay has been shown to alter aCT recommendations for patients with stage II, T3, MMR-P colon cancer. This study provides real-world confirmation that these changes in aCT reduce direct medical costs and improve patient well-being.