ECONOMIC ANALYSIS OF ALTERNATIVE GENETIC TESTS FOR BRCA1 AND BRCA2 MUTATIONS

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BACKGROUND

Until recently, comprehensive BRCA1 and BRCA2 mutation testing was available in the United States through a single provider; Myriad Genetic Laboratories, BRACAnalysis®. However, a June 2013 U.S. Supreme Court decision ruled against the patentability of human genes including BRCA1/2.

Alternative tests are now available, and health insurers face decisions regarding test reimbursement based on differences in analytical sensitivity, rates of variants of unknown significance (VUS), variant classification accuracy and test cost, which ultimately impacts costs for preventive therapy and the occurrence and treatment of cancer. Therefore, economic analyses assessing competing tests are warranted.

METHODS

A decision analytic model was constructed in TreeAge using standard cost-effectiveness modeling methods for 35-year-old women with a high risk of hereditary breast and ovarian cancer (HBOC) undergoing BRCA testing with BRACAnalysis® compared to an alternative BRCA1/2 test. A 30-year time horizon and a U.S. third-party payer perspective were used.

Data inputs were derived from the literature and accuracy data were collected from data on file.

The list price for BRACAnalysis® is $4,040, and an estimated average list price was used for the alternative test.

Standard discounting off list price was used for both BRACAnalysis® and the alternative test (12% discount).
One-way sensitivity analyses of clinically meaningful variables were conducted.

RESULTS

Figure 1. Model Base Case Scenario of Populated Decision Analytic

Economic analysis of alternative genetic tests for BRCA1 and BRCA2 mutations
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RESULTS

The incremental cost-effectiveness ratio is dominant favoring BRACAnalysis®. Based on the model results, BRACAnalysis® testing resulted in prevention of 84.74% of cancer cases compared to 84.65% with an alternative test, preventing nine additional cancer cases in 10,000 women. The one-way sensitivity analyses identified the increased percentage of patients classified with a VUS, as a significant driver of the model results. Compared with alternative tests, using BRACAnalysis® would save $624,000 and prevent 9 BC and/or OC cases per year for a 1 million member health system.

LIMITATIONS

Assumed a fixed age of cancer occurrence (60 years) and cancer costs were included for 5 years after diagnosis.

Fixed 5 year survival estimates were used for BC and OC.

Assumed the risk of developing cancer was identical for BRCA1 and BRCA2 mutations.

The negative effects of preventive treatments received caused by false positive BRCA results were not considered.

The impact of BRCA testing in women with BC or OC was not considered.

CONCLUSIONS

The increased test performance of BRACAnalysis® translates into reduced overall costs for the prevention and treatment of additional cancer cases compared to alternative tests.

In determining the true costs between competing BRCA 1/2 tests, the performance of the test (analytic sensitivity and variant classification) and initial test price needs to be weighed against the overall impact on cancer occurrence, preventative treatment utilized and the overall costs.

Future research will address the limitations in current model to more accurately reflect the true benefit of more accurate testing.