

## **Title:** Divergent Payor Medical Policy leads to Gross Disparities in Access to Hereditary Breast and Ovarian Cancer Genetic Testing

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**Background:** The National Comprehensive Cancer Network (NCCN) has well-established and routinely updated criteria for genetic testing for individuals at risk for Hereditary Breast/Ovarian Cancer (HBOC). While some health insurers utilize these criteria when setting their medical policy, others develop custom criteria that deviate from NCCN criteria. We sought to identify and describe discrepancies among health insurer policies for HBOC testing and document the resultant impact on access to genetic testing and medical management.

**Methods:** We reviewed 4 different sets of payor testing criteria: Aetna, Blue Shield of California/Federal Blue Cross-Blue Shield, eviCore (used by over 30 payors including AmeriHealth, Highmark and Horizon) and NCCN criteria (used by Anthem, Cigna, Humana and others, and essentially match by United Healthcare). Payors were selected based on proportion of overall coverage in a cohort of patients who underwent panel testing which included BRCA1, BRCA2 or PALB2. Together these policies covered 24% of the overall patient cohort (and 36% of patients covered by commercial payors).

Using NCCN as the baseline, payor policies were compared by individual lines of criteria to identify discrepancies. Then, personal and family histories of cancer, as reported by ordering clinicians, were compared to NCCN testing criteria for HBOC (v.2.2021) and to the corresponding criteria set by each payor group in this study. The number and percent of patients meeting NCCN testing criteria (NCCN-eligible) who did or did not meet each payor's testing criteria were tabulated for each NCCN criterion. The number and percent of NCCN-eligible patients testing positive for pathogenic variants (PV) and likely pathogenic variants (LPV) in BRCA1, BRCA2, and PALB2 were calculated for each criterion and compared across payors.

**Results:** Among 162,761 patients tested, 86% met NCCN testing criteria for HBOC and were included in this study. Of these, 6567 (5%) were found to have PVs/LPVs in BRCA1, BRCA2 or PALB2. By study design, 100% of these positive patients had coverage under policies following NCCN guidelines. Testing criteria were most consistent across non NCCN payor policies for patients with early-onset, triple negative and male breast cancers, ovarian cancer and pancreatic cancer. Major discrepancies arose for women with breast cancers over age 50 who also had relatives affected with breast, ovarian, pancreatic or metastatic prostate cancers. Most policies either had criteria that were stricter than NCCN or only covered part of these NCCN criteria. Similarly, most non-NCCN policies offered limited, if any, coverage for individuals with prostate cancer, relative to NCCN. Of positive patients covered by non NCCN policies, 2% to 32% would not have been eligible for testing, depending on the payor policy. Discrepancies among non NCCN policies were greatest for those criteria addressing unaffected individuals with family histories of cancer, with 2% to 96% of patients not being covered for testing

**Discussion:** Our data indicate that 2% to 32% of patients meeting NCCN testing criteria for HBOC do not have coverage under the non-NCCN payor policies selected for review. These patients represent missed opportunities for cancer risk management, including increased screening and preventative surgery or

other measures. These discrepancies in criteria among payors also complicate the process of identifying patients appropriate for genetic testing and potentially raise costs for the healthcare system. Our data suggest that payors should reevaluate their criteria used for genetic testing eligibility and consider alignment with NCCN criteria in order to simplify identification of eligible patients and reduce disparities in access to genetic testing. In turn this will also increase detection of patients with PVs and LPVs who may benefit from gene-specific screening and management recommendations.