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Divergent Payor Medical Policy Leads to Gross Disparities in Access to Hereditary Breast and Ovarian Cancer Genetic Testing

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BACKGROUND

NCCN Criteria:
- The National Comprehensive Cancer Network (NCCN) has well-established and regularly-updated criteria for genetic testing for individuals at risk for Hereditary Breast/Ovarian Cancer (HBOC) [1].

Health Insurer Medical Policy:
- Some health insurers utilize NCCN criteria.
- Others develop custom criteria that deviate from NCCN.

Study Aims:
- To outline discrepancies among health insurer policies for HBOC testing.
- To document the impact on access to genetic testing and medical management.

METHODS

Identifying Discrepancies with NCCN Criteria:
- Three different payor policies were selected based on patient volume and partial alignment with NCCN.
  - Together these policies covered 24% of the overall patient cohort (and 36% of patients covered by commercial payors).
- Individual lines of criteria in each policy were compared to NCCN HBOC criteria (v.2.2021) to identify discrepancies.

Assessing Impact in a Clinical Testing Cohort:
- The study cohort consisted of 162,761 patients who underwent multi-gene panel testing that included *BRCA1*, *BRCA2* or *PALB2* from 2012-2016 at Ambry Genetics.
- Personal and family histories of cancer and mutation status in *BRCA1*, *BRCA2* and *PALB2* were assessed by line of NCCN criteria .

Figure 1. Payor Policy Alignment with NCCN Criteria

		Aetna	BS-CA/ Fed*	eviCore†	NCCN§
PERSONAL HISTORY CRITERIA					
KNOWN MUTATION	Individuals with any blood relative with known P/LP variant in a cancer susceptibility gene				
	Individual meeting below criteria + previous negative limited testing (e.g., single gene and/or del/dup) interested in MGPT				
BREAST	Breast cancer dx <=45				
	Breast cancer dx 46-50 + unknown or limited family history				
	Breast cancer dx 46-50 + a second breast cancer at any age				
	Breast cancer dx 46-50 + >=1 close blood relative with breast, ovarian, pancreatic, or prostate cancer at any age				
	Breast cancer dx <=60 + triple-negative breast cancer				
	Breast cancer + Ashkenazi Jewish ancestry				
	Breast cancer + >=1 close blood relative with breast <=50, ovarian, pancreatic, metastatic, intraductal/cribriform histology, or high-/very high-risk group prostate cancer at any age				
	Breast cancer + >=3 total diagnoses of breast cancer in patient and/or close blood relatives				
	Male breast cancer				
OVARIAN	Epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer) at any age				
PANCREATIC	Exocrine pancreatic cancer at any age				
PROSTATE	Metastatic, intraductal/cribriform histology, or high-/very high-risk group				
	Prostate cancer (any NCCN risk group) + AJ ancestry				
	Prostate cancer (any NCCN risk group) + >=1 close relative with breast <=50, ovarian, pancreatic, metastatic, or intraductal/cribriform prostate cancer at any age				
	Prostate cancer (any NCCN risk group) + >=2 close relatives with either breast or prostate cancer (any grade) at any age				
OTHER CRITERIA	Mutation identified on tumor genomic testing with clinical implications if also identified in the germline				
	Individual who meets LFS testing criteria or Cowden syndrome/*PTEN* hamartoma tumor syndrome testing criteria				
	To aid in systemic therapy decision making, such as for HER2- metastatic breast cancer				
FAMILY HISTORY CRITERIA					
	An affected or unaffected individual with a 1st/2nd-degree relative (FDR/SDR) meeting any of the above criteria				
BREAST	FDR/SDR with Breast cancer dx <=45				
	FDR/SDR with Breast cancer dx 46-50 + unknown or limited family history				
	FDR/SDR with Breast cancer dx 46-50 + a second breast cancer at any age				
	FDR/SDR with Breast cancer dx 46-50 + >=1 close blood relative with breast, ovarian, pancreatic, or prostate cancer at any age				
	FDR/SDR with Breast cancer dx <=60 + triple-negative breast cancer				
	FDR/SDR with Breast cancer + Ashkenazi Jewish ancestry				
	FDR/SDR with Breast cancer + >=1 close blood relative with breast <=50, ovarian, pancreatic, metastatic, intraductal/cribriform histology, or high-/very high-risk group prostate cancer at any age				
	FDR/SDR with Breast cancer + >=3 total diagnoses of breast cancer in patient and/or close blood relatives				
	FDR/SDR with Male breast cancer				
OVARIAN	FDR/SDR with Epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer) at any age				
PANCREATIC	FDR with Exocrine pancreatic cancer at any age				
PROSTATE	FDR with Metastatic, intraductal/cribriform histology, or high-/very high-risk group				
	FDR/SDR with Prostate cancer (any NCCN risk group) + AJ ancestry				
	FDR/SDR with Prostate cancer (any NCCN risk group) + >=1 close relative with breast <=50, ovarian, pancreatic, metastatic, or intraductal/cribriform prostate cancer at any age				
	FDR/SDR with Prostate cancer (any NCCN risk group) + >=2 close relatives with either breast or prostate cancer (any grade) at any age				
OTHER CRITERIA	FDR/SDR with Mutation identified on tumor genomic testing with clinical implications if also identified in the germline				
	FDR/SDR with Individual who meets LFS testing criteria or Cowden syndrome/*PTEN* hamartoma tumor syndrome testing criteria				
	FDR/SDR with To aid in systemic therapy decision making, such as for HER2- metastatic breast cancer				
	Does not meet above criteria but has >5% probability of *BRCA1/2* pathogenic variant based on prior probability models (e.g. TC, BRCAPro, CanRisk)				

Payor policy covers more than NCCN criterion
Payor policy is aligned with NCCN
Payor policy covers some of NCCN criterion
Payor policy covers less than NCCN criterion
Payor policy does not cover NCCN criterion

*Blue Shield of California/Federal Blue Cross-Blue Shield
†*eviCore (used by over 30 payors including AmeriHealth, Highmark and Horizon)*
§*NCCN criteria (used by Anthem, Cigna, Humana and others, and essentially match by United Healthcare)*

RESULTS

Subjects:
- 139,289 (86%) patients met NCCN testing criteria for HBOC and were included in this study.
- Of these, 6,567 (5%) were found to have PVs/LPVs in *BRCA1*, *BRCA2* or *PALB2*.

Criteria:
- Most policies either had criteria that were stricter than NCCN or only covered part of the NCCN criteria (Figure 1).
- Discrepancies were greatest for unaffected individuals with family histories of cancer, with 4% to 96% not being covered (Figure 2, top panel).
- Of the PV/LPV-positive patients covered by non-NCCN policies, 2% to 32% would not have been eligible for testing, depending on the payor policy (Figure 2, bottom panel).

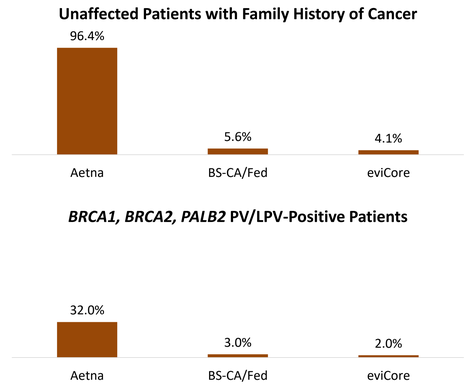

Figure 2. Percentage of Patients Meeting NCCN Not Covered by Payor Policy

TAKE HOME POINTS – Up to 32% Missed

Impact of Criteria Discrepancies
- Missed opportunities for cancer risk management (e.g., increased screening, chemoprevention and preventative surgery).
- Complicates the process of identifying patients appropriate for genetic testing.
- Potentially raises costs for the healthcare system.

Benefits of alignment with NCCN
- Simplifies identification of eligible patients for society at large.
- Reduces disparities in access to genetic testing.
- Increases the detection of patients with PVs and LPVs who may benefit from gene-specific screening and management.

Reference: 1. Daly MB, Pal T, Berry MP, et al.; NCCN Clinical Practice Guidelines in Oncology: NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic. Version 2.2021.Available at NCCN.org