The Impact of Discrepant Payor Policies from One Lab Benefits Manager on Patient Access to Genetic Testing

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BACKGROUND

The determination of medical necessity for hereditary cancer genetic testing is complex and does not easily lend itself to automation and/or scalability. To address this, health plans are increasingly contracting lab benefits managers (LBMs) to perform these services, aiming to control unnecessary testing and lower costs. This increased reliance on LBMs has raised concerns about the transparency of the processes and the resultant impact on patient access to care. While National Comprehensive Cancer Network (NCCN) testing criteria are widely accepted by both clinicians and health plans as the standard for hereditary cancer testing, some medical policies diverge significantly, with a resultant impact on patient access to testing.

We sought to quantify the impact of NCCN-discrepant payor policies from one LBM.

NCCN BOPP criteria selected for comparison[#]:

- Breast cancer patients over 50 with a first (FDR), second (SDR) or third degree relative with metastatic or high- or very-high risk group prostate cancer
- Unaffected people with:
  - SDR with breast cancer ≤50
  - FDR/SDR with triple negative breast cancer
  - FDR/SDR with breast cancer dx at any age and a close blood relative with metastatic, or high- or very-high risk group prostate cancer

[#]Criteria not included in LBM policy

NCCN colon cancer criteria selected for comparison[##]:

- Personal history of any Lynch syndrome-related cancer AND:
  - Diagnosed <50y
  - A second Lynch syndrome cancer at any age
  - FDR or SDR with a Lynch syndrome cancer diagnosed <50y
  - ≥2 FDR or SDR with Lynch syndrome cancers at any age

[##]Only colon and endometrial cancers qualify in LBM policy, not ANY Lynch syndrome cancer

TAKE HOME POINTS

Restricted Eligibility — Testing criteria adopted by one large LBM resulted in a significant decrease in patients eligible for genetic testing (5.7% meeting NCCN BOPP criteria and 26% meeting NCCN colon criteria).

LBM Misses Positives — 8.75% of those not covered by the LBM's BOPP criteria and 7.24% of those not covered by their colon criteria tested positive in a moderate or high penetrance gene.

Access to Care — This study highlights that eligibility restrictions implemented by an LBM, without supporting evidence, significantly decreased access to standard-of-care genetic testing for hereditary cancer.

METHODS

Participants referred for hereditary cancer panel testing at one commercial laboratory

- Dates of Study: 1/1/24 to 5/31/24
- Histories obtained from ordering provider's clinical notes, pedigrees, test requisitions etc.

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Trained data curators determined if participants met NCCN criteria [1,2] ("NCCN-eligible")

Four LBM breast/ovarian/pancreatic/prostate cancer (BOPP) criteria and four colon cancer criteria that most-impactfully differed from NCCN were selected.

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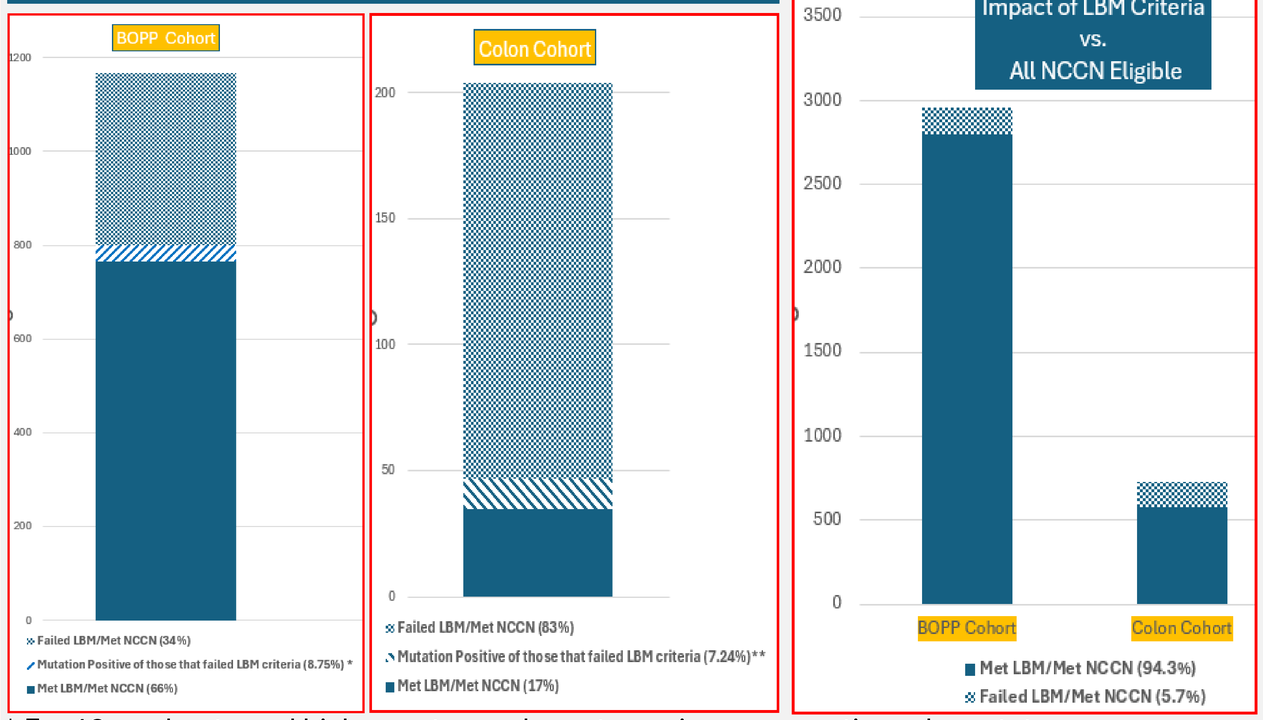
Histories of NCCN-eligible patients were mapped to the corresponding LBM criteria.

- Participants not meeting LBM criteria (and denied access to testing) were identified.
- The impact of these criteria was then extrapolated to our entire testing cohort.

RESULTS

Four Selected LBM Criteria Compared to Corresponding NCCN Criteria



* For 12 moderate and high penetrance breast, ovarian, pancreatic and prostate cancer genes included in the analysis: *ATM, BRCA1, BRCA2, CDH1, CHEK2, NBN, NF1, PALB2, PTEN, RAD51C, RAD51D, TP53.*

** For 19 moderate and high penetrance colon cancer genes included in the analysis: *APC, AXIN2, BMPR1A, CDH1, EPCAM, GREM1, MLH1, MSH2, MSH3, MSH6, MUTYH, NTHL1, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53.*

REFERENCES

1) National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic (v3.2024). National Comprehensive Cancer Network .
2) National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Colon (v3.2023). National Comprehensive Cancer Network .