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# Discrepancies Between Payer Coverage and Consensus Guidelines for Personalizing Hereditary Cancer Risk

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## BACKGROUND

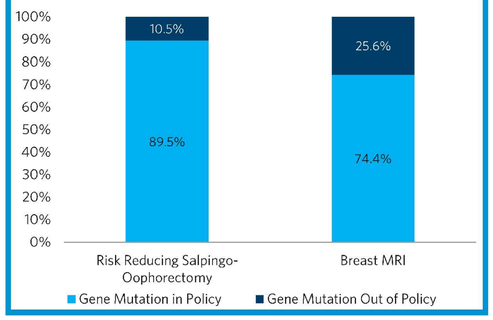
- Next generation sequencing has allowed diagnostic laboratories to offer multigene panel testing (MGPT) for hereditary breast and ovarian cancer (HBOC).
- MGPT is preferred by many clinicians for HBOC testing due to increased clinically actionable diagnostic yield.
- Clinician adoption of MGPT has outpaced insurance policies, which have drastically variable medical policy for genes beyond *BRCA1* & *BRCA2*.
- This study aims to compare HBOC genetic testing policies from three US insurers to NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) for HBOC gene mutation carriers, which typically guide patient management.

## METHODS

- Management guidelines for breast and/or ovarian cancer were identified in NCCN Guidelines® for Genetic/Familial High-Risk Assessment: Breast and Ovarian V2.2019 for patients with mutations in 16 genes commonly found on MGPT:
  - *ATM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MLH1, MSH2, NBN, NF1, PALB2, PTEN, RAD51C, RAD51D, STK11,* and *TP53*.[1]
- MGPT orders were assessed for patients with insurer A, B, or C in the year 2017 at a single diagnostic testing laboratory.

## Figure 1

Overall Breast MRI or RSSO Consideration for Positive Patients By Genes In vs. Out of Policy




## RESULTS

- 6(37.5%), 8(50.0%) and 15(93.8%) of the 16 genes were covered by insurer A, B, & C, respectively.
- Limiting genetic testing to payer coverage would have resulted in unidentified mutations in 48.1%, 19.5% and 3.1% of patients with Insurers A, B, and C, respectively (Fg. 2).
- Had the laboratory strictly tested for genes under each insurer's medical policy:
  - 25.6% (range 3.4-45.2%) of patients who should consider breast MRI screening per NCCN would have been missed (Fg. 1 & Fg. 3).
  - 10.5% (range 0-14%) of patients who should consider risk reducing salpingo-oophorectomy (RRSO) per National Comprehensive Cancer Network® (NCCN®) would have been missed (Fg. 1 & Fg. 3).
  - All patients who should consider risk-reducing mastectomy (RRM) would have been identified, as all three insurers cover *BRCA1, BRCA2, PTEN* and *TP53*.

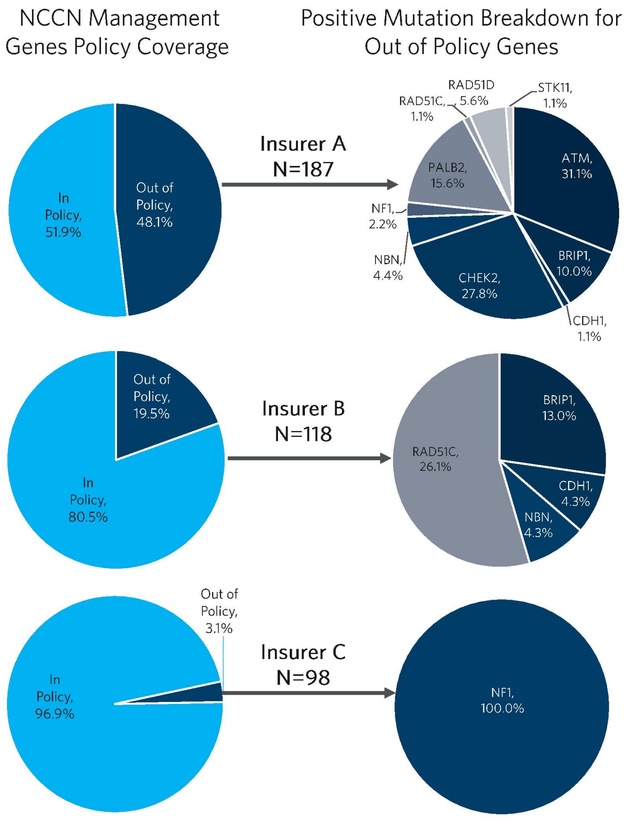
## Table 1. Mutation Spectrum for Positive Patients by Insurer

| Type of management | Gene Covered by Insurer A? | Insurer A # of patients with gene positive | Insurer A % patients in each management group | Gene Covered by Insurer B? | Insurer B # of patients with gene positive | Insurer B % patients in each management group | Gene Covered by Insurer C? | Insurer C # of patients with gene positive | Insurer C % patients in each management group |
|---|---|---|---|---|---|---|---|---|---|
| RRM | | 91 | | | 60 | | | 43 | |
| *BRCA1* | Yes | 43 | 47.3% | Yes | 27 | 45.0% | Yes | 20 | 46.5% |
| *BRCA2* | Yes | 43 | 47.3% | Yes | 31 | 51.7% | Yes | 20 | 46.5% |
| *PTEN* | Yes | 2 | 2.2% | Yes | 0 | 0.0% | Yes** | 0 | 0.0% |
| *TP53* | Yes* | 3 | 3.3% | Yes* | 2 | 3.3% | Yes** | 3 | 7.0% |
| RRSO | | 107 | | | 70 | | | 51 | |
| *BRCA1* | Yes | 43 | 40.2% | Yes | 27 | 38.6% | Yes | 20 | 39.2% |
| *BRCA2* | Yes | 43 | 40.2% | Yes | 31 | 44.3% | Yes | 20 | 39.2% |
| *BRIP1* | No | 9 | 8.4% | Not mentioned | 3 | 4.3% | Yes** | 2 | 3.9% |
| *MSH2* | Yes | 4 | 3.7% | Yes | 3 | 4.3% | Yes** | 5 | 9.8% |
| *MLH1* | Yes | 2 | 1.9% | Yes | 0 | 0.0% | Yes** | 0 | 0.0% |
| *RAD51C* | No | 1 | 0.9% | Not mentioned | 6 | 8.6% | Yes** | 3 | 5.9% |
| *RAD51D* | No | 5 | 4.7% | Not mentioned | 0 | 0.0% | Yes** | 1 | 2.0% |
| Breast MRI | | 166 | | | 106 | | | 87 | |
| *ATM* | No | 28 | 16.9% | No* | 12 | 11.3% | Yes | 9 | 10.3% |
| *BRCA1* | Yes | 43 | 25.9% | Yes | 27 | 25.5% | Yes | 20 | 23.0% |
| *BRCA2* | Yes | 43 | 25.9% | Yes | 31 | 29.2% | Yes | 20 | 23.0% |
| *CDH1* | No* | 1 | 0.6% | No* | 1 | 0.9% | Yes** | 2 | 2.3% |
| *CHEK2* | No | 25 | 15.1% | Yes | 16 | 15.1% | Yes** | 18 | 20.7% |
| *NBN* | No | 4 | 2.4% | Not mentioned | 1 | 0.9% | Yes** | 0 | 0.0% |
| *NF1* | Not mentioned | 2 | 1.2% | Not mentioned | 0 | 0.0% | Not mentioned | 3 | 3.4% |
| *PALB2* | No | 14 | 8.4% | Yes | 16 | 15.1% | Yes** | 12 | 13.8% |
| *PTEN* | Yes | 2 | 1.2% | Yes | 0 | 0.0% | Yes** | 0 | 0.0% |
| *STK11* | No* | 1 | 0.6% | No* | 0 | 0.0% | Yes** | 0 | 0.0% |
| *TP53* | Yes* | 3 | 1.8% | Yes* | 2 | 1.9% | Yes** | 3 | 3.4% |

*Medical policy has specific requirements not related to HBOC for coverage of testing for that gene.
**Payer may cover in conjunction with another relevant gene on panel testing.

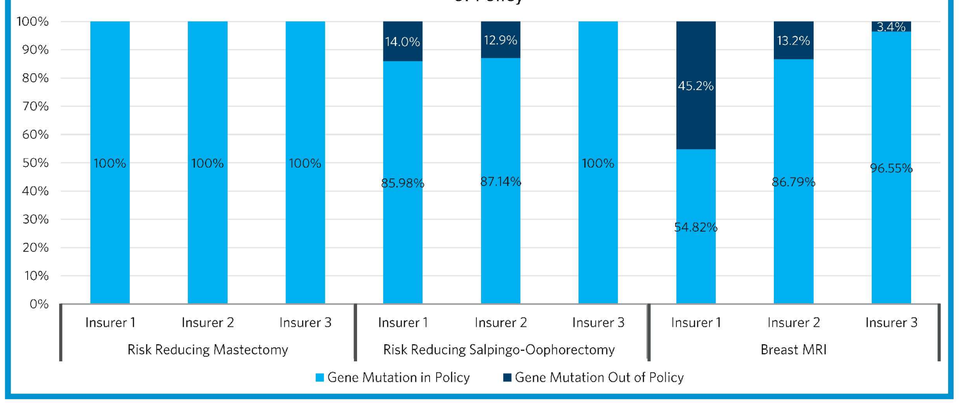
## Figure 2

Mutation Distribution By Insurer for Genes In vs. Out of Policy




## Figure 3

Medical Management Consideration for Positive Patients by Insurer and Genes In vs. Out of Policy




## TAKE-HOME POINTS

- Overall, at least 1 in 4 patients who should consider breast MRI and 1 in 10 who should consider RRSO would be missed, had testing been limited to genes which insurers cover with medical policy.
- This data demonstrates discrepancies between insurer coverage policies for HBOC genetic testing and medical management recommendations by the NCCN*.
- This data highlights the need for payers to expand gene coverage policies to ensure that patients at high-risk of HBOC are identified and afforded the opportunity for early detection and prevention of associated cancers.

* NCCN management recommendations may be dependent on patient age.

## REFERENCES

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Genetic/Familial High-Risk Assessment: Breast and Ovarian V.2.2019. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed [October 4, 2018]. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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