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August 15, 2024

Dear Drs. Gratias and Castle:

The undersigned organizations, advocates for individuals and families affected by hereditary cancer, are writing to express our concern with EviCore's misuse of the "most informative family member" recommendation to deny coverage of germline genetic testing for individuals who otherwise meet established testing criteria for a hereditary cancer syndrome. Over the past few years, our unaffected, at-risk patients have experienced a significant increase in EviCore coverage denials when the provider's clinical notes do not specifically document why the "most informative family member" was not tested first. This is a significant barrier to appropriate care.

EviCore's "Hereditary Cancer Syndrome Multigene Panels" policy (Mol.TS.182.A v2.0.2024) for germline testing cites American Society of Breast Surgeons (ASBrS) and National Comprehensive Cancer Network (NCCN) guidelines regarding testing the most informative family member:

> *Genetic testing should be made available to patients without a history of breast cancer who meet NCCN guidelines. Unaffected patients should be informed that testing an affected relative first, whenever possible, is more informative than undergoing testing themselves. When it is not feasible to test the affected relative first, then the unaffected family member should be considered for testing if they are interested, with careful pre-test counseling to explain the limited value of "uninformative negative" results.* [1,2]

Despite its incorporation into consensus guidelines for cancer prevention and care, germline genetic testing remains vastly underutilized. Overly burdensome coverage requirements impede the diagnosis of hereditary cancer risk in patients (and their family members), exacerbate health disparities, and hinder the implementation of precision medicine.

In an ideal world, the affected or next most informative relative would be tested first. In a real-world setting, however, that is often not practical or possible because:

- extended family members may live in other areas of the country or world and may not be in contact;
- family members lack health insurance or coverage of genetic testing; and,
- medical confidentiality and limited time prevent clinicians from contacting other family members to facilitate testing.

Thus, it falls on the patient to reach out and encourage their more informative relatives to pursue genetic testing. This is often easier said than done.

A literature review to determine the frequency of and factors associated with genetic testing of first-degree relatives of Lynch syndrome probands shows that even in families with a known genetic mutation, where relatives have a low-cost test available, more than 50% of family members fail to pursue testing.[3] A more recent study shows that even when a genetics clinic directly contacted at-

risk relatives about testing for a known familial mutation, it did not increase the uptake rate, even for first-degree relatives.[4] In situations where testing in a family has not begun, the likelihood of a more informative relative pursuing genetic testing independently is even lower than in families with a known mutation.

It's important to note that some patients may wish to keep their desire to undergo genetic testing confidential. Likewise, relatives may wish to maintain confidentiality about whether they have tested and if so, the results. Furthermore, there are numerous potential reasons for the low uptake of genetic testing. Some relatives may be uninformed and unmotivated. Lack of insurance coverage and/or the inability to afford out-of-pocket costs, long wait times for a genetic counseling/testing appointment, travel requirements, and administrative burdens can present additional barriers. In some cases, the next most informative relative (affected or unaffected) may be of Medicare age and does not qualify for coverage. Finally, family members may make an informed decision not to test.

For these reasons, we believe it is prudent to offer genetic testing to a patient while they are in the practitioner's office, assuming the patient's personal and/or family history meets established evidence-based guidelines. With the use of terms such as "should" (rather than "must"), NCCN and ASBrS indicate that this guidance is a recommendation rather than a strict prerequisite. We feel that EviCore has inappropriately interpreted this guidance as a "requirement," as stated in its Hereditary Cancer Syndrome policy:

> *"If the member is not the most informative person to test, documentation must be provided by the ordering physician's office clearly documenting that it is impossible to test the most informative family member and describing the reason the unaffected member is being tested at this time, AND…"*

Our organizations are concerned that EviCore case reviewers are using this policy to deny coverage for otherwise eligible patients based on the absence of statements about the "most informative" family member in the clinical notes. This is a misinterpretation of the guidance's intent. Additionally, provider clinical notes vary greatly and may not include a written description of a discussion about the potential availability of their relative(s) for testing, even when such a conversation took place. When all other criteria are met, documentation of why each family member is unavailable to test presents an unreasonable burden and should not be used to deny patient access to testing.

We respectfully request that EviCore revise its policy to ensure that patients who meet NCCN guidelines for genetic testing are approved based on their clinical and family presentation, regardless of "most informative" family member documentation in the medical chart. Thank you for your consideration of this important matter. Please contact Lisa Schlager, Vice President of Public Policy at FORCE, with any questions – lisas@facingourrisk.org.

Sincerely,

Academy of Oncology Nurse & Patient Navigators
AliveandKick'n
Alliance for Patient Access
American Association of Clinical Urologists (AACU)
American College of Gastroenterology
American College of Medical Genetics and Genomics
Association for Molecular Pathology

BRCA Research & Cure Alliance (CureBRCA)
Brem Foundation to Defeat Breast Cancer
Colon Cancer Coalition
Debbie's Dream Foundation: Curing Stomach Cancer
Fight Colorectal Cancer
JScreen
Let's Win Pancreatic Cancer
Living Beyond Breast Cancer
Male Breast Cancer Global Alliance
National Ovarian Cancer Coalition
NothingPink
Ovarian Cancer Research Alliance
Patient Empowerment Network
Sharsheret
Society of Gynecologic Oncology
Susan G. Komen
The National Association of Nurse Practitioners in Women's Health (NPWH)
Triage Cancer
UC Santa Cruz Genomics Institute
ZERO Prostate Cancer

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[1] The American Society of Breast Surgeons. Official Statement: Consensus guideline on genetic testing for hereditary breast cancer. 2019. Available at: https://www.breastsurgeons.org/docs/statements/Consensus-Guideline-onGenetic-Testing-for-Hereditary-Breast-Cancer.pdf

[2] National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic. Version 3.2023. Available at: NCCN.org.

[3] Sharaf RN, Myer P, Stave CD, Diamond LC, Ladabaum U. Uptake of genetic testing by relatives of lynch syndrome probands: a systematic review. Clin Gastroenterol Hepatol. 2013 Sep;11(9):1093-100. doi: 10.1016/j.cgh.2013.04.044. Epub 2013 May 10. PMID: 23669308. (https://pubmed.ncbi.nlm.nih.gov/23669308/)

[4] Menko FH, van der Velden SL, Griffioen DN, Ait Moha D, Jeanson KN, Hogervorst FBL, Giesbertz NAA, Bleiker EMA, van der Kolk LE. Does a proactive procedure lead to a higher uptake of predictive testing in families with a pathogenic BRCA1/BRCA2 variant? A family cancer clinic evaluation. J Genet Couns. 2024 Jun;33(3):615-622. doi: 10.1002/jgc4.1767. Epub 2023 Aug 21. PMID: 37605508.