Genetic Testing for Cancer Susceptibility and Hereditary Cancer Syndromes

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Description

Genetic testing for cancer susceptibility and hereditary cancer syndromes is performed in people with known risk factors for an inherited form of cancer. Testing may be used in people diagnosed with cancer when there are "red flags" in the individual's personal medical and/or family history for a hereditary form. Predictive genetic testing may also be performed for this group of conditions, in people known to be at increased risk of developing an inherited condition based on their family history. This testing is generally limited to adult individuals; however, it may be considered for minors if the results will be of medical and/or psychosocial benefit.[1-3] A positive genetic test result increases the risk for cancer (types vary by the gene involved) and, therefore, impacts medical management decisions around screening, prevention, and treatment.

- For information on tests used to screen for or make a diagnosis of cancer, please refer to the guideline *Genetic Testing for the Screening, Diagnosis, and Monitoring of Cancer,* as this testing is not addressed here.
- For information on diagnostic or predictive testing for conditions other than hereditary cancer, please refer to the guideline *Genetic Testing to Diagnose Non-Cancer Conditions and Genetic Testing to Predict Disease Risk,* as this testing is not addressed here.

Note:

This benefit/harm statement only applies to those jurisdictions that do not have Medicare guidance. Based upon the clinical policy, following EviCore's criteria for genetic testing for cancer susceptibility and hereditary cancer syndromes will ensure that testing will be available to those members most likely to benefit from a genetic diagnosis. For those not meeting criteria, it ensures alternate diagnostic/management strategies are considered. However, it is possible that some members who would benefit from the testing, but do not meet criteria, will not receive an immediate approval for testing.

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Criteria

Introduction

Genetic testing for cancer susceptibility and hereditary cancer syndromes are reviewed using the following criteria.

Criteria: General Coverage Guidance

Genetic testing for hereditary cancer syndromes is medically necessary when **ALL** of the following conditions are met:

- **Technical and clinical validity**: The test must be accurate, sensitive and specific, based on sufficient, quality scientific evidence to support the claims of the test.
- **Clinical utility**: Healthcare providers can use the test results to provide significantly better medical care for the individual.
- **Reasonable use**: The usefulness of the test is not significantly offset by negative factors, such as expense, clinical risk, or social or ethical challenges.

Limits:

- Testing will be considered only for the number of genes or tests necessary to establish carrier status. A tiered approach to testing, with reflex to more detailed testing and/or different genes, will be required when clinically possible.
- Genetic testing is medically necessary once per lifetime per condition. Exceptions may be considered if technical advances in testing demonstrate significant advantages that would support a medical need to retest.

Criteria: Special Circumstances

The following policies address a group of tests that are used for similar purposes. Because a variety of tests may be used, but the circumstances that justify testing are the same, individual test-specific policies are not necessary.

Predictive testing for at-risk people with known familial mutations

The genetic mutation(s) associated with a hereditary cancer syndrome can often be defined in an affected family member, allowing for testing of at-risk relatives for those specific mutations. Testing for known familial mutations is medically necessary when **ALL** of the following conditions are met:

- The mutation(s) in the family have been **clearly defined** by previous genetic testing and **information about those mutations can be provided** to the testing lab.
- **Technical and clinical validity**: The test must be accurate, sensitive and specific to the familial mutation(s).

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- **Clinical utility**: Healthcare providers can use the test results to provide significantly better medical care for the individual.
- **Reasonable use**: The usefulness of the test is not significantly offset by negative factors, such as expense, clinical risk, or social or ethical challenges.

Limits:

- Testing will be considered only for the known familial mutations when clinically possible.
- Predictive genetic testing is reimbursable once per lifetime per condition.
- Predictive genetic testing will be considered only for adult individuals (age 18 and over). Exceptions may be considered if there are medical management and/or significant psychosocial benefits to testing prior to adulthood.

Criteria: Test-specific Guidelines

Test-specific guidelines are available for some hereditary cancer syndrome tests. For tests without a specific guideline, use the General Coverage Guidance above.

References

1. Ross LF, Saal HM, David KL, Anderson RR. Technical report: ethical and policy issues in genetic testing and screening of children. *Genet Med.* 2013;15:234–245. Available at: **http://www.nature.com/gim/journal/v15/n3/pdf/gim2012176a.pdf**
2. National Society of Genetic Counselors Position Statement. Genetic testing of minors for adult-onset conditions. Adopted 2012. Updated April 2018. Available at: **https://www.nsgc.org/Policy-Research-and-Publications/Position-Statements/Position-Statements/Post/genetic-testing-of-minors-for-adult-onset-conditions**
3. Botkin, JR, Belmont JW, Berg JS, et al. Points to consider: ethical, legal, and psychosocial implications of genetic testing in children and adolescents. *Am J Hum Genet*. 2015;97:6-21.