



Corporate Medical Policy

Genetic Testing for Breast and Ovarian Cancer

File Name: genetic_testing_for_breast_and_ovarian_cancer
Policy Number: MED1170
Origination: 8/1997
Last CAP Review: 8/2009
Next CAP Review: 8/2011
Last Review: 8/2009

Description of Procedure or Service

Several genetic syndromes with an autosomal dominant pattern of inheritance that feature breast cancer have been identified. Of these, hereditary breast and ovarian cancer (HBOC) and some cases of hereditary site-specific breast cancer have in common causative mutations in BRCA genes. Families suspected of having HBOC syndrome are characterized by an increased susceptibility to breast cancer occurring at a young age, bilateral breast cancer, male breast cancer, and ovarian cancer at any age. Other cancers, such as prostate cancer, pancreatic cancer, gastrointestinal cancers, melanoma, laryngeal cancer, occur more frequently in HBOC families. Hereditary site-specific breast cancer families are characterized by early onset breast cancer with or without male cases, but without ovarian cancer. For this policy, both will be referred to collectively as hereditary breast and/or ovarian cancer.

Germline mutations in the BRCA1 and BRCA2 genes are responsible for the cancer susceptibility in the majority of HBOC families, especially if ovarian cancer or male breast cancer are features. However, in site-specific breast cancer, BRCA mutations are responsible for only a proportion of affected families, and research to date has not yet identified other moderate or high-penetrance gene mutations that account for disease in these families. BRCA gene mutations are inherited in an autosomal dominant fashion through either the maternal or paternal lineage. It is possible to test for abnormalities in BRCA1 and BRCA2 genes to identify the specific mutation in cancer cases, and to identify family members with increased cancer risk. Family members without existing cancer who are found to have BRCA mutations can consider preventive interventions for reducing risk and mortality.

*****Note: The Medical Policy on genetic testing for breast and ovarian cancer is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Genetic Testing for Breast and Ovarian Cancer when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

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Members must have benefits for the anticipated surgery and meet the guidelines for the testing to be covered.

When Genetic Testing for Breast and Ovarian Cancer is covered

- A. Genetic testing of cancer-affected individuals may be medically necessary under **any** of the following circumstances:
 - 1. Women who are affected with breast or ovarian cancer and are from families with a high risk of BRCA1 or BRCA2 mutation as defined in the Policy Guidelines, OR;
 - 2. Women affected with early onset breast or ovarian cancer, or with breast or ovarian cancer and multiple primary cancers, or with bilateral breast or ovarian cancer, but who do not have a known family history of breast or ovarian cancer, OR;
 - 3. Women affected with both breast and ovarian cancer, OR;
 - 4. Men affected with breast cancer at any age, OR;
 - 5. Those affected with breast or ovarian cancer and who are from an ethnic background, e.g., Ashkenazi Jewish descent, associated with deleterious founder mutations
- B. Genetic testing of unaffected adults may be considered medically necessary under any of the following circumstances:
 - 1. Unaffected individuals (male or female) from families with a known BRCA1 or BRCA2 mutation, OR;
 - 2. Unaffected individuals from families with a high risk of BRCA1 or BRCA2 mutation based on a family history (See Policy Guidelines), where it is not possible to test an affected family member for a mutation, OR;
 - 3. Unaffected individuals in populations at risk for specific founder mutations due to ethnic background, e.g., Ashkenazi Jewish descent, with one or more relatives with breast or ovarian cancer at any age.

When Genetic Testing for Breast and Ovarian Cancer is not covered

- 1. Genetic testing for breast and ovarian cancer is considered investigational for either those affected with breast or ovarian cancer or for unaffected individuals when the criteria listed above is **not** met.
- 2. Genetic testing on minors for BRCA1 and BRCA2 mutations is considered investigational.

Policy Guidelines

- 1. The US Preventative Services Task Force (USPSTF) recommends the following in identifying families with a high risk for mutation in the BRCA1 and BRCA2 gene, both the maternal and paternal family histories are important and each lineage must be considered separately. For non-Ashkenazi Jewish women, high risk includes the following:
 - a. Three or more first or second degree relative with breast cancer regardless of age at diagnosis, or
 - b. Two first-degree relatives with breast cancer, one of whom was diagnosed at age 50 years or younger, or
 - c. Combination of both breast and ovarian cancer among first- and second degree relatives, or

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- d. First degree relative with bilateral breast cancer, or
 - e. A combination of two or more first or second degree relatives with ovarian cancer regardless of age at diagnosis, or
 - f. A first or second degree relative with both breast and ovarian cancer at any age, or
 - g. A history of breast cancer in a male relative.
2. Genetic testing should be performed in a setting with adequately trained health care providers who can provide appropriate pre-and post-test counseling.
 3. The facility should have a qualified laboratory to perform the test.
 4. Families at high risk for harboring a BRCA1 or BRCA2 mutation are those in which the incidence of breast or ovarian cancer in first or second degree relatives suggests an **autosomal dominant** inheritance, i.e., about half the family members are affected.
 5. The American College of Medical Genetics recommends that "early onset" breast or ovarian cancer be considered cancers that occur in patients age 45 or younger.
 6. The American Society of Clinical Oncology (ASCO) recommends that cancer predisposition testing be offered when 1) the person has a strong family history of cancer or very early age of onset of disease, 2) the test can be adequately interpreted, and 3) the results will influence the medical management of the patient or family member.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: S3818, S3819, S3820, S3822, S3823, 83890, 83891, 83892, 83893, 83894, 83896, 83897, 83898, 83901, 83902, 83903, 83904, 83905, 83906, 83912

Medical Term Definitions

Autosomal dominant

requires only one affected parent have the trait to pass it to offspring.

Hereditary

the genetic transfer of a specific trait from parent to offspring.

Scientific Background and Reference Sources

MEDLINE database search from 1/97 through 7/97

Consultant Review, August 1997

Plan Medical Director Review, August 1997

BCBSA Medical Policy Reference Manual, 7/31/97

Medical Policy Advisory Group, 5/28/98

Specialty Matched Consultant Advisory Panel 11/1999

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Medical Policy Advisory Group 12/2/1999

Hematology/Oncology Clinics of North America. *"Breast Cancer Genetics: Implications for Clinical Practice"*. Volume 14, Number 3, June, 2000. W.B. Saunders Company.

Specialty Matched Consultant Advisory Panel 11/2001

Specialty Matched Consultant Advisory Panel - 10/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.02, 12/17/2003.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.02, 11/9/2004.

Specialty Matched Consultant Advisory Panel - 9/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.02, 9/27/2005.

Specialty Matched Consultant Advisory Panel - 8/2007

Senior Medical Director Review - 2/2009

American Society of Clinical Oncology. Policy Statement Update: Genetic Testing for Cancer Susceptibility (posted online April 11, 2003). *J Clin Oncol* 2003; 21(12):1-10.

The US Preventive Services Task Force (USPSTF). 2005. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility. Retrieved 6/3/08 from <http://www.ahrq.gov/clinic/uspstf05/brcagen/brcagenrs.htm>.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.02, 2/14/08.

Specialty Matched Consultant Advisory Panel - 8/28/09

Policy Implementation/Update Information

- 8/97 Original policy: Investigational
- 6/98 Reviewed: changed from investigational to medically necessary in cases where the member is considering prophylactic surgery and will be using the results of genetic testing as a decision factor. The member must meet the criteria for genetic testing. Recommended by MPAG.
- 6/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 3/01 Codes 83890-83906, 83912 added to policy.
- 11/01 Specialty Matched Consultant Advisory Panel - 11/2001. Format changes. Criteria revised. Typos corrected.
- 11/03 Specialty Matched Consultant Advisory Panel - 11/2003. Added information in Benefit Application and Billing/Coding sections. Reformatted policy.
- 4/04 Individual CPT codes listed for CPT code ranges 83890-83906 under Billing/Coding section.
- 8/12/04 Added HCPCS codes S3818, S3819, S3820, S3822, S3823 to Billing/Coding section.
- 9/23/04 Revised Description of Procedure or Service section. Revised When Covered section to include those with early onset breast cancer, members of high-risk populations without an affected family members, and included ovarian cancer in #1. Removed from When Not Covered section, "unaffected individuals from potentially high risk populations (e.g. Ashkenazi Jewish descent)".
- 10/8/05 Specialty Matched Consultant Advisory Panel review 9/19/2005. No changes to criteria. References added.

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- 9/24/07 Specialty Matched Consultant Advisory Panel review 8/23/2007. No changes to policy statement. References added. Policy status changed to: "Active policy, no longer scheduled for routine literature review."
- 3/16/09 Reviewed with Senior Medical Director 2/19/09. Reworded the "When Covered" section and added three additional indications. "A. Genetic testing of cancer-affected individuals may be medically necessary under **any** of the following circumstances: 1.) Women who are affected with breast or ovarian cancer and are from families with a high risk of BRCA1 or BRCA2 mutation as defined in the Policy Guidelines, OR; 2.) Women affected with early onset breast or ovarian cancer, or with breast or ovarian cancer and multiple primary cancers, or with bilateral breast or ovarian cancer, but who do not have a known family history of breast or ovarian cancer, OR; 3.) Women affected with both breast and ovarian cancer, OR; 4.) Men affected with breast cancer at any age, OR; 5.) Those affected with breast or ovarian cancer and who are from an ethnic background, e.g., Ashkenazi Jewish descent, associated with deleterious founder mutations. B. Genetic testing of unaffected adults may be considered medically necessary under any of the following circumstances: 1.) Unaffected individuals (male or female) from families with a known BRCA1 or BRCA2 mutation, OR; 2.) Unaffected individuals from families with a high risk of BRCA1 or BRCA2 mutation based on a family history (See Policy Guidelines), where it is not possible to test an affected family member for a mutation, OR; 3.) Unaffected individuals in populations at risk for specific founder mutations due to ethnic background, e.g., Ashkenazi Jewish descent, with one or more relatives with breast or ovarian cancer at any age." Added to the "Policy Guidelines" section; "The American College of Medical Genetics recommends that "early onset" breast or ovarian cancer be considered cancers that occur in patients age 45 or younger." Policy returned to active review status. References added. (btw)
- 10/12/09 Specialty Matched Consultant Advisory Panel review 8/28/09. Description revised. No change to policy statement. Reformatted wording in the "When Not Covered" section, no change to intent. Added information under "Policy Guidelines" to indicate; "1. The US Preventative Services Task Force (USPSTF) recommends the following in identifying families with a high risk for mutation in the BRCA1 and BRCA2 gene, both the maternal and paternal family histories are important and each lineage must be considered separately. For non-Ashkenazi Jewish women, high risk includes the following: a. Three or more first or second degree relative with breast cancer regardless of age at diagnosis, or b. Two first-degree relatives with breast cancer, one of whom was diagnosed at age 50 years or younger, or c. Combination of both breast and ovarian cancer among first- and second degree relatives, or d. First degree relative with bilateral breast cancer, or e. A combination of two or more first or second degree relatives with ovarian cancer regardless of age at diagnosis, or f. A first or second degree relative with both breast and ovarian cancer at any age, or g. A history of breast cancer in a male relative." and "6. The American Society of Clinical Oncology (ASCO) recommends that cancer predisposition testing be offered when 1) the person has a strong family history of cancer or very early age of onset of disease, 2) the test can be adequately interpreted, and 3) the results will influence the medical management of the patient or family member." References added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.