



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 Review: 8/2007

Description of Procedure or Service

Genetic testing for breast and/or ovarian cancer is used to detect genetic mutations of the BRCA1 and the BRCA2 gene. This test is used for a patient who may be predisposed to breast and/or ovarian cancer through [heredity](#).

Families at risk of having [hereditary](#) breast and/or ovarian cancer may exhibit the following characteristics:

- ◆ breast or ovarian cancer occurs at an early age;
- ◆ breast or ovarian cancer occurs in multiple generations;
- ◆ breast or ovarian cancer often appears bilaterally (both breasts or both ovaries);
- ◆ breast or ovarian cancer appears in a pattern suggesting [autosomal dominant](#) inheritance (requires only one parent to have the trait to pass it to offspring).

Susceptibility may be transmitted through the mother or father's side of the family. Alterations in two genes, BRCA1 and BRCA2, are associated with an increased risk of breast and ovarian cancer. Alterations in these two genes do not account for all inherited forms of breast and ovarian cancer. It is possible, however, to test these two genes and provide future cancer risk information for those patients who show abnormalities in the BRCA1 and BRCA2 genes.

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.

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

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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

Genetic testing for breast and ovarian cancer is not covered when the criteria listed above is not met.

The following indications are considered investigational. BCBSNC does not cover investigational services:

1. Unaffected family members with no known BRCA1 or BRCA2 mutation;
2. For genetic testing on minors for BRCA1 and BRCA2 mutations.

Policy Guidelines

- Genetic testing should be performed in a setting with adequately trained health care providers who can provide appropriate pre-and post-test counseling.
- The facility should have a qualified laboratory to perform the test.
- 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.
- 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.

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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

Policy Key Words

Key Words: Breast Cancer, Genetic Testing, Ovarian Cancer, Breast, Ovaries, MED1170.

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

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

The American College of Medical Genetics, Policy Statement: Genetic Susceptibility to Breast and Ovarian Cancer: Assessment, Counseling and Testing Guidelines, 1999, Retrieved 2/23/09 from <http://>

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www.acmg.net/AM/Template.cfm?Section=Practice_Guidelines&Template=/CM/HTMLDisplay.cfm&ContentID=3701.

Senior Medical Director Review - 2/2009

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.
- 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 can-

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cer be considered cancers that occur in patients age 45 or younger." Policy returned to active review status. References added.

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.