MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

Policy Number: PA.055.MH
Last Review Date: 06/08/2021
Effective Date: 09/01/2021

PA.055.MH – Molecular Susceptibility Testing for Breast Cancer and/or Ovarian Cancer (BRCA and BART Testing)

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **BRCA and BART Testing** medically necessary for the following indications:

BRCA1/ BRCA2 Testing Indications

1. Individual from a family with a known deleterious BRCA1/BRCA2 mutation,
2. Personal History of Breast Cancer and one or more of the following:
    a. Diagnosed age ≤ 45 years,
    b. Two breast primaries, when first breast cancer was diagnosed age ≤ 50 years,
    c. Diagnosed age ≤ 50 years with an additional breast cancer primary, one or more close blood relative with breast cancer at any age or with an unknown or limited family history,
    d. Diagnosed age ≤60 years with a triple negative breast cancer,
    e. Diagnosed at any age with one or more close blood relative breast cancer diagnosed ≤ 50 years,
    f. Diagnosed at any age with two or more close blood relatives with breast cancer diagnosed any age,
    g. Diagnosed at any age with one or more close blood relative with epithelial ovarian cancer,
    h. Diagnosed at any age with two or more close blood relatives with pancreatic cancer or prostate cancer (Gleason score ≥7) at any age,
    i. Close male blood relative with breast cancer.
    j. For an individual of an ethnicity associated with a higher mutation frequency (e.g. Ashkenazi Jewish) no additional family history may be required.
3. Personal history of epithelial ovarian, fallopian tube, or primary peritoneal cancer,
4. Male with personal history of breast cancer,
5. Personal history of pancreatic cancer or prostate cancer (Gleason score ≥7) at any age with ≥1 close blood relatives with breast (≤50 years) and/or ovarian and/or pancreatic or aggressive prostate cancer (Gleason score ≥7) at any age,
6. Personal history of pancreatic cancer at any age with ≥1 close blood relative with breast (≤50 years) and/or invasive ovarian and/or pancreatic cancer at any age,

7. Personal history of pancreatic cancer, and Ashkenazi Jewish ancestry,
8. Family history only (significant limitations of interpreting test results for an unaffected individual should be discussed):
   a. 1st or 2nd degree relative who meets any of the above criteria (1-5),
   b. 3rd degree relative with breast cancer and/or ovarian cancer with ≥ 2 close blood relatives with breast cancer (at least one with breast cancer ≤50 years) and/or ovarian cancer,
   c. Clinical judgment should be used to determine if the patient has a reasonable likelihood of a mutation, considering the unaffected patient's current age and the age of female unaffected relatives who link the patient with the affected relatives.
   d. Testing of unaffected individuals should only be considered when an appropriate affected family member is unavailable for testing.

Testing Family Members

Occasionally, blood or tissue samples from other non-covered family members are required to provide the medical information necessary for the proper medical care of a member. **Such molecular-based testing for BRCA and other specific heritable disorders in non-members will be reviewed for medical necessity when all of the following conditions are met:**

1. The information is needed to adequately assess risk in the member
2. The information will be used in the immediate care plan of the member
3. The non-covered family member's benefit plan (if any) will not cover the test and the denial is based on specific plan exclusion.

Limitations/Exclusions

1. Members post bone marrow transplant (allogeneic and autologous) should not have testing via blood or buccal samples (due to contamination of donor DNA). In these cases, DNA should be extracted from a fibroblast culture.

2. <u>Exclusions</u>

- BRCA testing for assessment of risk of cancers other than breast or ovarian cancers is considered **<u>Experimental and Investigational</u>** and therefore not covered.
- The following are not medically necessary and therefore not covered:
  - BRCA testing of members less than 18 years old.
  - ***BRCA testing performed primarily for the medical management of other family members that are not covered by an Evolent Health managed product is not a covered benefit for any Evolent Health managed product.

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Background

Breast cancer is the second leading cause of cancer-related deaths for women. Between 5% and 10% of women with breast cancer develop the disease due to the inheritance of a mutated copy of the BRCA1 or BRCA2 gene. BRCA1 and BRCA2 are human genes that produce tumor suppressor proteins. These proteins help repair damaged DNA and, therefore, play a role in ensuring the stability of the cell's genetic material. Specific inherited mutations in *BRCA1* and *BRCA2* increase the risk of female breast and ovarian cancers, accounting for 20-25% hereditary breast cancers

About 12 percent of women in the general population will develop breast cancer sometime during their lives. By contrast, according to the most recent estimates, 55 to 65 percent of women who inherit a harmful BRCA1 mutation and around 45 percent of women who inherit a harmful BRCA2 mutation will develop breast cancer by age 70 years. About 1.3 percent of women in the general population will develop ovarian cancer sometime during their lives. By contrast, according to the most recent estimates, 39 percent of women who inherit a harmful BRCA1 mutation and 11 to 17 percent of women who inherit a harmful BRCA2 mutation will develop ovarian cancer by age 70 years.

Mutations in BRCA1 and BRCA2 are more common in certain racial/ethnic populations than others, including higher prevalence of mutations in Norwegian, Dutch, Icelandic and Ashkenazi Jewish peoples.

Definitions:

Breast cancer	Invasive breast cancer or ductal carcinoma in situ
Close blood relative	First-, second-, or third-degree relative
First-degree relative	Parent, sibling, or child of an individual
Second-degree relative	Grandparent, aunt, uncle, half-sibling, niece, nephew, or grandchild of an individual

Third-degree relative	Great-grandparent, great-uncle, great-aunt, first cousin, grand-niece, grand-nephew, or great-grandchild of an individual
Fourth-degree relative	Includes great-great-grandparents, great-great-grandchildren, and first cousins once-removed (i.e., children of the individual's first cousin)

Codes:

CPT Codes	
Code	Description
81212	BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81215	BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (ie, detection of large gene rearrangements)
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis

81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)

References

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Disclaimer:
MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.