

POLICY # 08-01	BRCA1 / BRCA2 GENE ANALYSIS	EFFECTIVE DATE December 1, 2013
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DESCRIPTION

BRCA1 and BRCA2 are human genes that belong to a class of genes known as tumor suppressors. Mutation of these genes has been linked to hereditary breast and ovarian cancer. A woman's risk of developing breast and/or ovarian cancer is greatly increased if she inherits a deleterious BRCA1 or BRCA2 mutation. Men with these mutations also have an increased risk of breast cancer.

POLICY

BRCA1/BRCA2 testing services for individuals without a personal history of breast and/or ovarian cancer should be provided to high risk individuals as defined below, or as otherwise defined by the US Preventive Services Task Force (USPSTF).

BRCA1/BRCA2 testing services for women with a personal history of breast and/or ovarian cancer and for men with a personal history of breast cancer should be provided as defined below, or as otherwise defined by National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines.

Genetic counseling must precede genetic testing for hereditary cancer.

If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered, while a full sequence BRCA 1 and 2 analyses is not. An exception to this can be considered if a Certified Genetic Counselor presents sufficient justifiable need.

If the individual is of Ashkenazi Jewish descent, test the three common mutations first. Then if negative, consider comprehensive ("Reflex") testing based on assessment of individual and family history as if the individual is of non-Ashkenazi Jewish descent.

PRIOR AUTHORIZATION: YES ☒ NO ☐

COVERAGE AND LIMITATIONS:

Frequency is limited to once-in-a-lifetime.

BRCA1/BRCA2 gene analysis is covered for individuals meeting the following criteria:

1. For individuals without diagnosis of breast or ovarian cancer:
 - Two first-degree relatives with breast cancer, one of whom was diagnosed at age 50 or younger; OR
 - A combination of three or more first or second-degree relatives with breast cancer regardless of age at diagnosis; OR
 - A combination of both breast and ovarian cancer among first and second-degree relatives; OR

- A first-degree relative with bilateral breast cancer; OR
- A combination of two or more first or second degree relatives with ovarian cancer, regardless of age at diagnosis; OR
- A first or second-degree relative with both breast and ovarian cancer at any age; OR
- History of breast cancer in a male relative; OR
- For women of Ashkenazi Jewish descent, any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer; OR
- 2. A family history of breast or ovarian cancer that includes a relative with a known deleterious BRCA mutation; OR
- 3. A personal history of breast cancer plus one or more of the following:
 - Diagnosed at age ≤ 45 ; OR
 - Diagnosed at age ≤ 50 with ≥ 1 close blood relative with breast cancer diagnosed at any age or with a limited family history; OR
 - Two breast primaries when first breast cancer occurred at age ≤ 50 ; OR
 - Diagnosed at age ≤ 60 years with a triple negative breast cancer; OR
 - Diagnosed at age ≤ 50 with a limited family history; OR
 - Diagnosed at any age, with ≥ 1 close blood relative with breast cancer diagnosed ≤ 50 ; OR Diagnosed at any age with ≥ 2 close blood relatives with breast cancer at any age OR
 - Diagnosed at any age with ≥ 1 close blood relative with epithelial ovarian cancer
 - Diagnosed at any age with ≥ 2 close blood relatives with pancreatic cancer or aggressive prostate cancer (Gleason Score ≥ 7) at any age; OR
 - Close male blood relative with breast cancer; OR
 - For an individual of ethnicity associated with higher mutation frequency (e.g., Ashkenazi Jewish,) no additional family history may be required
- 4. Personal history of epithelial ovarian cancer OR
- 5. Personal history of male breast cancer; OR
- 6. Personal history of pancreatic cancer or aggressive prostate cancer (Gleason Score ≥ 7) at any age with ≥ 2 close blood relatives with breast and/or ovarian and/or pancreatic cancer or aggressive prostate cancer (Gleason Score ≥ 7) at any age with at any age.

1. The NCCN Clinical Practice Guidelines in Oncology Breast Cancer (Version 3.2013). 2013 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp. Accessed August 20, 2013.
2. U.S. Preventive Services Task Force. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility recommendation statement. Available at: <http://www.uspreventiveservicestaskforce.org/uspstf05/brcagen/brcagenrs.htm>. Accessed June 8, 2013.