Overview
The purpose of this document is to describe the guidelines Neighborhood Health Plan (NHP) utilizes to determine the medical appropriateness for genetic testing of BRCA 1 and BRCA 2 for hereditary breast\(^1\) and ovarian cancer syndrome. The treating specialist must request prior authorization.

Coverage Guidelines
NHP covers genetic testing for hereditary breast and ovarian cancer syndrome when it is recommended by the member’s provider and when the request meets the medical necessity criteria below.

BRCA 1 or BRCA 2 (Breast Cancer Susceptibility Gene) Analysis
NHP covers medically necessary BRCA 1 or BRCA 2 testing when either 1 & 2 are met or when 1 and another criteria element under 3 are met:

1. The member has met with a genetic counselor, medical geneticist, oncologist, surgeon, oncology nurse, or other health professional with expertise and experience in cancer genetics who has counseled the member and documented all of the following:
   a. The member’s understanding of benefits, risk, limitations, and goals of testing
   b. An individual cancer-risk assessment
   c. The limitations of testing (especially in an unaffected individual with a family history only)
   d. The likelihood of a positive result
   e. The impact that the test result will have on medical management
   f. In a family where no mutation is documented, a discussion regarding the importance of testing the family member with the highest likelihood for a positive test result first and the effort to obtain this testing; and
   g. A plan for post-test counseling and medical follow up

2. For specific site analysis:
   a. The member is from a family with a known BRCA 1 or BRCA 2 mutation, and the specific known mutation is being tested.

3. For full sequence analysis and/or duplication/deletion variants:\(^2\)
   a. Female member has been diagnosed with breast cancer and has one or more of the following (i-iv):
      i. Diagnosed at age 45 or younger

---

\(^1\) Breast Cancer includes ductal carcinoma in situ.  
\(^2\) If the member is of Ashkenazi Jewish descent, testing for the three founder mutations should be performed first. Full sequencing may be considered if ancestry also includes non-Ashkenazi Jewish relatives or if other criteria are met. Founder mutations also exist in other populations.
ii. Diagnosed at 50 or younger with:
   • an additional breast cancer primary\(^3\)
   • at least 1 close blood relative\(^4\) with breast cancer at any age; or
   • an unknown or limited family history\(^5\)

iii. Diagnosed at 60 or younger with a triple negative (ER-, PR-, HER2-) breast cancer

iv. Diagnosed at any age with:
   • at least 1 close blood relative\(^4\) with breast cancer diagnosed at 50 or younger
   • at least 2 close blood relatives\(^4\) with breast cancer at any age
   • at least 1 close blood relative\(^4\) with invasive ovarian\(^6\) cancer
   • at least 2 close blood relatives\(^4\) with pancreatic cancer and/or prostate cancer
     (Gleason score at least 7) at any age; or
   • with a close male blood relative\(^4\) with breast cancer

   Note: For individuals of ethnicity associated with a higher mutation frequency (e.g. Ashkenazi
   Jewish) no additional family history may be required\(^2\).

b. Member diagnosed with invasive ovarian cancer\(^6\)

c. Member diagnosed with male breast cancer

d. Member diagnosed with aggressive prostate cancer (Gleason score greater than or equal to 7) at
   any age with at least one close blood relative with breast cancer (at age 50 or younger), and/or
   invasive ovarian\(^6\) and/or pancreatic or prostate cancer (Gleason score greater than or equal to 7)

e. Member diagnosed with pancreatic cancer at any age with at least one close blood relative with
   breast (at age 50 or younger), and/or invasive ovarian\(^6\) and/or pancreatic cancer at any age

f. Member diagnosed with pancreatic cancer and Ashkenazi Jewish ancestry or

g. Member is unaffected but has one of the following:
   i. First- or second-degree blood relative meeting one of the above criteria (a-f); or
   ii. Third-degree blood relative with breast cancer and/or invasive ovarian cancer\(^6\) and who has
      at least 2 close blood relatives with breast cancer (at least one breast cancer diagnosed at
      age 50 or younger) and/or invasive ovarian\(^6\) in a lineage that could affect the
      member

   Note: Testing of unaffected members should only be considered when an appropriate affected
   family member is unavailable for testing

   Note: The significant limitations of interpreting test results for unaffected individual should be
   discussed.

   Note: Clinical judgment should be used to determine if the member has a reasonable likelihood
   of a mutation, considering the unaffected member’s current age and the age of female
   unaffected relatives who link the member with the affected relatives.

Exclusions

NHP does not provide coverage for:

1. Genetic testing for hereditary breast and ovarian cancer syndrome for any reason other than listed above.
2. Repeat genetic testing when a prior test has been negative or positive in its clinical significance.
3. Genetic testing for individuals under 18 years old.
4. Genetic testing considered experimental and investigational, including when the requested test has unproven
   validity and efficacy for population screening and risk management of carriers.

Definitions

\(^3\) Two breast primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors either synchronously or
   asynchronously.

\(^4\) Close blood relatives include first-, second-, and third-degree relatives on the same side of the family.

\(^5\) Limited family history is: fewer than two first- or second-degree female relatives or female relative surviving beyond 45 years in either lineage.

\(^6\) Invasive ovarian cancer includes: fallopian tube and primary peritoneal cancers. BRCA-related ovarian cancers are associated with epithelial non-
   mucinous histology. Other cancer genetic syndromes may be associated with epithelial mucinous ovarian cancer. Non-epithelial ovarian cancer
   may be associated with Peutz-Jeghers Syndrome. Ovarian/fallopian tube/primary peritoneal cancers are component tumors of lynch syndrome i.e.
   hereditary non- polyposis colorectal cancer.
**Close Blood Relative:** Close blood relatives include first-, second- and third-degree relatives on the *same side of the family.*

**Limited Family History:** Fewer than two first- or second-degree female relatives or female relative surviving beyond 45 years in either lineage.

**Related Policies**
- [Preventative Services Provider Payment Guideline](#)

**Effective**
February 2016: Annual update.
February 2015: Annual review, without substantial changes.
January 2014: Reorganized criteria.
October 2014: Annual review without substantial changes in medically necessary indicators.
September 2013: Effective date.

**References**