Genetic Testing for Breast and Ovarian Cancer

BRCA1 and BRCA2 are human genes that produce tumor suppressor proteins. Louisiana Medicaid considers genetic testing for BRCA1 and BRCA2 mutations in cancer-affected individuals and cancer-unaffected individuals to be medically necessary if the recipient meets the following published criteria. Prior authorization is required through the fiscal intermediary's Prior Authorization Unit (PAU).

Eligibility Criteria

Patients with Cancer Diagnosis

Genetic testing for BRCA1 and BRCA2 mutations in cancer-affected individuals may be medically necessary under any of the following circumstances:

- Individual from a family with a known BRCA1/BRCA2 mutation;
- Personal history of breast cancer and ≥1 of the following:
    - Diagnosed age ≤45 years;
    - Two primary breast cancers when the first breast cancer diagnosis occurred age ≤50 years;
    - Diagnosed age ≤50 years AND: ≥1 1st-, 2nd-, or 3rd-degree relative with breast cancer at any age;
    - Unknown or limited family history;
    - Diagnosed age ≤60 years with a triple negative (ER–, PR–, HER2–) breast cancer;
    - Diagnosed any age AND ≥1 1st-, 2nd-, or 3rd-degree relative with breast cancer diagnosed ≤ 50 years;
    - Diagnosed any age AND ≥2 1st-, 2nd-, or 3rd-degree relatives with breast cancer at any age;

- Diagnosed any age AND ≥1 1st-, 2nd-, or 3rd-degree relative with epithelial ovarian/fallopian tube/primary peritoneal cancer;
- Diagnosed any age AND ≥2 1st-, 2nd-, or 3rd-degree relatives with pancreatic cancer or prostate cancer at any age;
- 1st-, 2nd-, or 3rd-degree male relative with breast cancer; or
- Ethnicity associated with deleterious founder mutations (e.g., Ashkenazi Jewish);

- Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer;
- Personal history of male breast cancer; or
- Personal history of pancreatic cancer or prostate cancer at any age AND ≥2 1st-, 2nd-, or 3rd-degree relatives with any of the following at any age. For pancreatic cancer, if Ashkenazi Jewish ancestry, only one additional affected relative is needed.
  - Breast cancer;
  - Ovarian/fallopian tube/primary peritoneal cancer; or
  - Pancreatic or prostate cancer.

Patients without cancer (Testing unaffected individuals)

Genetic testing for BRCA1 and BRCA2 mutations of cancer-unaffected individuals may be considered medically necessary under any of the following circumstances:

- Individual from a family with a known BRCA1/BRCA2 mutation;
- 1st- or 2nd-degree blood relative meeting any criterion listed above for patients with cancer; or
- 3rd-degree blood relative with breast cancer and/or ovarian/fallopian tube/primary peritoneal cancer AND ≥2 1st-, 2nd-, or 3rd-degree relatives with breast cancer.

For the purpose of familial assessment, 1st-, 2nd-, and 3rd-degree relatives are blood relatives on the same side of the family (maternal or paternal):

- 1st-degree relatives are parents, siblings, and children;
- 2nd-degree relatives are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings; or
- 3rd-degree relatives are great-grandparents, great-aunts, great-uncles, great grandchildren and first cousins.

For the purpose of familial assessment, prostate cancer is defined as Gleason score ≥7. Testing for Ashkenazi Jewish or other founder mutation(s) should be performed first (see guidelines: High risk ethic groups).

NOTE: Generally, genetic testing for a particular disease should be performed once per lifetime; however, there are rare instances in which testing may be performed more than once in a lifetime (e.g., previous testing methodology is inaccurate or a new discovery has added significant relevant mutations for a disease).

When Genetic Testing for Breast and Ovarian Cancer is not covered

Unless the above criteria is met, genetic testing either for those affected by breast, ovarian, fallopian tube, or primary peritoneal cancer or for unaffected individuals, including those with a family history of pancreatic cancer, is considered 'investigational'.

Genetic testing in minors for BRCA1 and BRCA2 mutations is considered investigational.

High-risk ethnic groups

Testing in eligible individuals who belong to ethnic populations in which there are well-characterized founder mutations should begin with tests specifically for these mutations. For example, founder mutations account for approximately three quarters of the BRCA mutations found in Ashkenazi Jewish populations. When the testing for founder mutations is negative, comprehensive mutation analysis should then be performed.

Testing unaffected individuals

In unaffected family members of potential BRCA mutation families, most test results will be negative and uninformative. Therefore, it is strongly recommended that an affected family member be tested first whenever possible to adequately interpret the test. Should a BRCA mutation be found in an affected family member(s), DNA from the unaffected family member can be tested specifically for the same mutation of the affected family member without having to sequence the entire gene. Interpreting the test results for an unaffected family member without knowing the genetic status of the family may be possible in the case of a positive result for an established disease-associated mutation, but leads to difficulties in interpreting negative test results (uninformative negative) or mutations of uncertain significance because the possibility of a causative BRCA mutation is not ruled out.

Prostate cancer

Recipients with BRCA mutations have an increased risk of prostate cancer, and patients with known BRCA mutations may therefore consider more aggressive screening approaches for prostate cancer. However, the presence of prostate cancer in an individual, or in a family, is not itself felt to be sufficient justification for BRCA testing.

Prior Authorization

BRAC1 and BRCA2 testing must be prior approved by the fiscal intermediary's PAU or the managed care organization (MCO). Prior authorization (PA) requests should include the following:

- PA request form;
- Documentation of medical necessity; and
- Other pertinent clinical information that may be requested.

Clinical information must be submitted by the provider involved in the recipient's care.

The documentation required for PA requests to the MCO shall be determined by the MCO. Managed care organizations will utilize the criteria they deem appropriate for BRCA1 and BRCA2 testing based upon the clinical information submitted by the provider involved in the recipient's care.

Reimbursement

BRAC1 and BRCA2 testing are reimbursed for *Current Procedural Terminology* (CPT) codes currently approved for cancer-affected individuals and cancer- unaffected individuals. Information regarding the fee Schedule to be used for BRCA1 and BRCA2 testing can be obtained on the Louisiana Medicaid website following the links under "Fee Schedule," "Professional Services Fee Schedule," "Laboratory and Radiology".