**CMS Policy for Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia**

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

**Coverage Indications, Limitations, and/or Medical Necessity**

**Indications and Limitations of Coverage**

**Nationally Covered Indications**

This policy covers testing for the BRCA 1 and BRCA 2 genes for patients suspected of hereditary breast and/or ovarian cancer syndromes. To be eligible for Medicare coverage, the individual being tested must have signs or symptoms of breast (invasive or ductal carcinoma in situ (DCIS)), ovarian cancer (including fallopian tube and primary peritoneal cancer), pancreatic cancer, or prostate cancer and meet one of the criteria below. Genetic testing for a known mutation in a family is a covered service for individuals with signs and/or symptoms of cancer. Testing of an unaffected Medicare eligible individual or family member is not a covered Medicare benefit.

BRCA 1 and BRCA 2 testing consists of full sequence and duplication/deletion analysis. Genetic testing for a known mutation in a family may be limited to the known familial variant.

The following indications for BRCA 1 and BRCA 2 testing are covered by Medicare:

**Criteria for Testing**

- Individual with breast, ovarian\(^1\), pancreatic, or prostate cancer from a family with a known deleterious BRCA1 or BRCA2 gene mutation.

- Individual with a personal history of ovarian\(^1\)* cancer

- Individual with a breast cancer diagnosis meeting any of the following criteria:
  - Diagnosed ≤45 y
  - Triple negative breast cancer (estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative) breast cancer diagnosed ≤ 60 y
  - Diagnosed at 46-50 y with:
    - An additional breast cancer primary
    - ≥1 first, second, or third degree relative\(^5\) with breast cancer at any age, or
    - ≥1 first, second, or third degree relative\(^5\) with prostate cancer (Gleason score ≥7), or
    - An unknown or limited family history\(^3\)
  - Breast cancer diagnosed at any age, and
    - ≥1 first, second, or third degree relative\(^5\) with breast cancer ≤50 y, or
    - ≥1 first, second, or third degree relative\(^5\) with ovarian cancer at any age, or
    - ≥1 first, second, or third degree relative\(^5\) with metastatic prostate cancer or pancreatic cancer at any age, or
    - ≥2 additional diagnoses of breast cancer at any age in patient and/or in close blood relative\(^5\), or
    - A first, second, or third degree male relative with breast cancer
    - For an individual of ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish\(^4\)) no additional family history may be required.
    - Male breast cancer

Visit [QuestDiagnostics.com/MLCP](https://www.questdiagnostics.com/MLCP) to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference [www.cms.gov](https://www.cms.gov).
CMS Policy for Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia (continued)

- Personal history of prostate cancer (Gleason score ≥7) at any age with:
  - ≥1 first, second, or third degree relative\(^5\) with ovarian cancer at any age, or
  - ≥1 first, second, or third degree relative\(^5\) with breast cancer ≤50 y, or
  - ≥1 first, second, or third degree relative\(^5\) pancreatic cancer at any age, or
  - ≥1 first, second, or third degree relative\(^5\) with metastatic prostate cancer at any age, or
  - ≥2 first, second, or third degree relatives\(^5\) with breast cancer and/or pancreatic cancer and/or prostate cancer (any grade) at any age, or
  - Ashkenazi Jewish ancestry
  - Personal history of pancreatic cancer at any age
  - Personal history of metastatic prostate cancer (radiographic evidence of or biopsy-proven disease)
  - \(\text{BRCA1/2}\) pathogenic mutation detected by tumor profiling on any tumor type in the absence of germline mutation analysis

\(^1\)Includes fallopian tube and primary peritoneal cancers. \(\text{BRCA}\)–related ovarian cancers are associated with epithelial, non-mucinous histology.

\(^2\)Two breast cancer primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors either synchronously or asynchronously).

\(^3\)Medicare will cover \(\text{BRCA}\)-testing for an adopted individual with breast cancer diagnosed ≤50 y that is suspicious of being a \(\text{BRCA}\)-related cancer. Individuals with limited family history/structure, defined as fewer than 2 female first- or second-degree relatives having lived beyond age 45 in either lineage may also be eligible for \(\text{BRCA}\) gene testing. Similar to all testing, these situations require explanation of medical necessity for \(\text{BRCA}\) testing in the patient's medical record, and documentation of genetic counseling prior to \(\text{BRCA}\) testing.

\(^4\)Testing for Ashkenazi Jewish founder-specific mutations should be performed first. Comprehensive \(\text{BRCA1/2}\) testing may be considered if ancestry also includes non-Ashkenazi Jewish relatives or if any of the other \(\text{BRCA}\)-related criteria are met.

\(^5\)NCCN defines blood relative as first- (parents, siblings and children), second- (grandparents, aunts, uncles, nieces and nephews, grandchildren and half-siblings), and third degree-relatives (great-grandparents, great-aunts, great uncles, great grandchildren and first cousins) on same side of family.
Multigene Panels***

The indications and limitations of coverage listed in National Coverage Determination (NCD) 90.2 (Next Generation Sequencing - NGS) apply to genetic testing for susceptibility to breast or ovarian cancer. While the NGS NCD Section 90.2 B describes specific coverage criteria for nationally covered tests, Section 90.2 D permits coverage of other NGS as a diagnostic laboratory test for patients with cancer when performed and ordered according to the requirements described by the NCD. According to Section D of the NGS NCD AB Medicare Administrative Contractors (AB MACs) may cover next generation sequencing tests in patients with cancer. As such, genetic testing for susceptibility to breast or ovarian cancer with multi-gene NGS panels (not otherwise covered under NCD 90.2 Section B) may be covered by this AB MAC as reasonable and necessary when ALL of the NCD criteria are met in addition to the following:

- Pretest genetic counseling by a cancer genetics professional has been performed and posttest genetic counseling by a cancer genetics professional meeting NCCN accreditation criteria is planned;
- All genes in the panel are relevant to the personal and family history for the individual being tested (panels with genes that are not relevant to the individual's personal and family history are not reasonable and necessary);
- Criteria listed under "Personal History of Female Breast Cancer" and/or "Personal History of Other Cancer" are met.
- Individual also meets criteria for at least ONE hereditary cancer syndrome for which NCCN guidelines provide clear testing criteria and management recommendations, including but not limited to HBOC, LiFraumeni Syndrome, Cowden Syndrome, or Lynch Syndrome.

*** While not required for payment, NCCN Guidelines recommend referral to a cancer genetics professional with expertise and experience in cancer genetics prior to genetic testing and after genetic testing. Examples of cancer genetics professionals with expertise and experience in cancer genetics include: an American Board of Medical Genetics or American Board of Genetic Counseling certified or board eligible Clinical Geneticist, Medical Geneticist or Genetic Counselor not employed by a commercial genetic testing laboratory (excludes individuals employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself as these individuals are also considered independent); medical oncologist, obstetrician-gynecologist or other physician trained in medical cancer genetics, a genetic nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APGN) by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who is not employed by a commercial genetic testing laboratory (excludes individuals employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself as these individuals are also considered independent).

Limitations

BRCA testing is limited to once-in-a-lifetime. If a patient has been previously tested for BRCA1 and BRCA2, repeat testing prior to Lynparza therapy is not reasonable and necessary and will not be covered by Medicare.

Nationally Non-Covered Indications

BRCA1/BRCA2 genetic testing is not reasonable and necessary, thus it is non-covered, for the following indications:

- Genetic screening in the general population. Such testing is considered screening and is excluded by Medicare statute. An ABN must be obtained for BRCA 1 and BRCA 2 testing for individuals without signs and symptoms of breast, ovarian or other hereditary cancer syndromes as indicated in this policy.
- Testing of individuals with no personal history of breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer. Such testing is considered screening and is excluded by Medicare statute. An ABN must be obtained for BRCA 1 and BRCA 2 testing for individuals without signs and symptoms of breast, ovarian or other hereditary cancer syndromes as indicated in this policy.
- Testing of individuals under 18 years of age.

Associated Information

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Coverage Indications, Limitations, and/or Medical Necessity") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the MAC upon request.

Visit QuestDiagnostics.com/MLCP to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference.
The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare’s limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

*Note—Bolded diagnoses below have the highest utilization

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z85.3</td>
<td>Personal history of malignant neoplasm of breast</td>
</tr>
</tbody>
</table>

There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).