Clinical Review Criteria for BRCA Genetic Testing for Medicare Advantage:
This policy applies to all HS staff that makes decisions regarding BRCA 1 or BRCA 2 genetic testing for the Health New England (HNE) Medicare Advantage membership.

Coverage Guidelines

1. Genetic tests for cancer are only a covered benefit for a **beneficiary with a personal history** of an illness, injury, or signs/symptoms thereof (i.e. clinically affected). A person with a personal history of a relevant cancer is a clinically affected person, even if the cancer is considered cured. Genetic testing is considered a non-covered screening test for patients unaffected by a relevant illness, injury, or signs/symptoms thereof.

2. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary, are not covered under national Medicare rules. For example, Medicare does not cover genetic tests based on family history alone.

3. A covered genetic test must be used to manage a patient. Medicare does not cover a genetic test for a clinically affected individual for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician in accordance with accepted standards of medical care (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy).

5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.

6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agree to post-test counseling is required. This consent form must be available on request by Medicare.

7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:
   - The lab must meet appropriate Clinical Laboratory Improvement Amendment (CLIA) 1988 regulations;
   - Successful participation in the American College of Medical Genetics (ACMG)/College of American Pathologists (CAP) inspection and survey program;
   - appropriate state licensing; and
   - credentialing of laboratory directors and staff by the American Board of Medical Genetics (ABMG).
Hereditary Breast and Ovarian Cancer Syndromes Criteria

BRCA1 and BRCA2 genetic testing is covered only for the following individuals: For the purpose of this policy, only genetic relations are relevant (i.e. "blood relatives"). Non-genetic relations, such as through marriage or adoption are not relevant to coverage. A close relative means a first degree (parents, full siblings, offspring), second degree (grandparents, grandchildren, aunts, uncles, nephews, nieces, half-siblings), or third degree (great-grandparents, great-aunts, great-uncles, first cousins) relatives. Also, for this policy, invasive and ductal carcinoma in situ (DCIS) breast cancers should be included. If the individual is of Ashkenazi Jewish descent, test the three common mutations first. Then if negative, consider full sequence ("Reflex") testing based on assessment of individual and family history as if the individual is of non-Ashkenazi Jewish descent.

1. **Personal history of breast cancer + one or more of the following:**

   - Diagnosed age ≤40 y, with or without family history
   - Diagnosed age ≤50 y or two breast primaries, with ≥1 close blood relative(s) with breast cancer ≤50 y or ≥1 close blood relative(s) with ovarian cancer
   - Diagnosed at any age, with ≥2 close blood relatives with ovarian cancer at any age
   - Diagnosed at any age, with ≥2 close blood relatives with breast cancer, especially if ≥1 woman is diagnosed before age 50 y or has two breast primaries
   - Close male blood relative with breast cancer
   - Personal history of ovarian cancer
   - If of certain ethnic descent associated with deleterious mutations (eg, founder populations of Ashkenazi Jewish) no additional family history required
   - a first or second-degree relative with a known BRCA1 or BRCA2 gene mutation

2. **Personal history of ovarian cancer + one or more of the following:**

   - ≥1 close blood relative(s) with ovarian cancer
   - ≥1 close female blood relative(s) with breast cancer at age ≤50 y or two breast primary cancers
   - ≥2 close blood relatives with breast cancer
   - ≥1 close male blood relative(s) with breast cancer
   - If of Ashkenazi Jewish descent, no additional family history is required
   - a first or second-degree relative with a known BRCA1 or BRCA2 gene mutation

3. **Personal history of male breast cancer if one or more of the following is present:**

   - ≥1 close male blood relative(s) with breast cancer
   - ≥1 close female blood relative(s) with breast or ovarian cancer
   - a first or second-degree relative with a known BRCA1 or BRCA2 gene mutation

EXCLUSIONS:

1. Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury...". Furthermore, it has been longstanding CMS policy that "tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute". Screening services, such as predictive and pre-symptomatic
genetic tests and services, are those used to detect an undiagnosed disease or disease predisposition, and as such are not a Medicare benefit and not covered by Medicare. However, Medicare does cover a broad range of legislatively mandated **preventive services** to prevent disease, detect disease early when it is most treatable and curable, and manage disease so that complications can be avoided. These services can be found on the CMS website at [http://new.cms.hhs.gov/PrevntionGenInfo/](http://new.cms.hhs.gov/PrevntionGenInfo/). Any preventive services and tests not listed on the CMS Preventive Services webpage are considered non-covered screening (preventive) tests or services which are not a benefit of the Medicare program.

2. The clinical information preceding this statement notwithstanding, testing of unaffected family members or other individuals is considered by Medicare to be screening and is not payable under the Medicare program.

3. Members who seek coverage for BRCA1 and BRCA2 genetic testing for the benefit of OTHER family members must seek reimbursement of payment from the OTHER family member’s insurance carrier. BRCA analysis for the medical management of OTHER family members is not a covered benefit for HNE Medicare Advantage members.

**Reference:**

LDC: Centers for Medicare & Medicare Services

