

BRCA 1, BRCA 2 Genetic Testing

Origination: 09/09/10	Revised:	Annual Review: 12/15/11
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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to *BRCA 1, BRCA 2 Genetic Testing* in order to determine inclusion in the benefit plan.

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

Additional Information

- The USPSTF recommends against routine referral for genetic counseling or routine *breast cancer susceptibility genes (BRCA)* testing for women whose family history is not associated with an increased risk for deleterious mutations in *breast cancer susceptibility gene 1 (BRCA1)* or *breast cancer susceptibility gene 2 (BRCA2)*.
- The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.

Coverage Guidelines

Testing for genetic mutations in *BRCA1* and/or *BRCA2* genes is covered for the following specific family history patterns:

- 1.) Member of family with a known *BRCA1/2* sequence variant.
- 2.) Personal history of breast cancer, with one (1) or more of the following:
 - Diagnosed age ≤ 40 years, with or without family history;
 - Diagnosed age ≤ 50 years or two breast primaries, with ≥ 1 close blood relative with breast cancer ≤ 50 years and/or ≥ 1 close blood relative with epithelial ovarian cancer;
 - Diagnosed at any age, with ≥ 2 close blood relatives with breast and/or epithelial ovarian cancer at any age;
 - Close male blood relative with breast cancer;
 - Personal history of epithelial ovarian cancer.
 - For an individual of ethnicity associated with deleterious sequence variants (e.g., founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian, or other descent; testing for founder-specific sequence variants should be performed first if available).

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Recommendation, continued:

Coverage Guidelines, continued

Testing for genetic mutations in BRCA1 and/or BRCA2 genes is covered for the following specific family history patterns, continued:

- 3.) Personal history of epithelial ovarian cancer:
 - For an individual of ethnicity associated with deleterious sequence variants.
- 4.) Personal history of male breast cancer particularly if:
 - ≥ 1 close male blood relative with breast cancer;
 - ≥ 1 close female blood relative with breast or epithelial ovarian cancer;
 - For an individual of ethnicity associated with deleterious sequence variants.
- 5.) Family history only - close family member meeting any of the above criteria (e.g., mother, grandmother, daughter, sister, aunt)

Exclusions

- All other requests for testing will be considered investigational and therefore, not a covered benefit.

References:

1. U.S. Preventive Services Task Force (USPSTF). Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: recommendation statement. *Ann Intern Med* 2005 Sep 6;143(5):355-61.
2. Agency for Health care research and Quality (AHRQ). Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility.
3. National Comprehensive Cancer Network (NCCN). Genetic Counseling and testing service. Guidelines and clinical resources.

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Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plans service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.