Guidelines for Medical Necessity Determination for Genetic Testing for BRCA-related Breast and/or Ovarian Cancer

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for genetic testing for hereditary breast and/or ovarian cancer, hereinafter referred to as "BRCA-related cancer." These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 401.000: *Independent Clinical Laboratory Services*, 130 CMR 433.000: *Physician Services*, 130 CMR 450.000: *Administrative and Billing Regulations*, Subchapter 6 of the *Independent Clinical Laboratory Manual* and Subchapter 6 of the *Physician Manual* for information about coverage, limitations, service conditions, and other prior authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Options (SCO) plan, or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care organization's, SCO's, or PACE's medical policies, respectively, for covered services.

MassHealth requires PA for genetic testing for BRCA-related cancer. MassHealth reviews requests for PA based on medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

1 SECTION I. GENERAL INFORMATION

The genetic basis for BRCA-related cancer is a germline (inherited) pathogenic/likely pathogenic variant in either BRCA1 or BRCA2, which is inherited in an autosomal dominant pattern. PALB2 (Partner and Localizer of BRCA2) is another gene implicated in hereditary breast cancer.

Approximately 3% of breast cancers and 10% of ovarian cancers diagnosed annually in the United States are thought to be BRCA-related. Clinically significant or deleterious pathogenic/likely pathogenic variants in these genes have been linked to an increased risk of breast, ovarian, fallopian tube, and peritoneal cancer in women. BRCA pathogenic/likely pathogenic variants are also associated with male breast cancer and, to a lesser degree, pancreatic, testicular, and early-onset prostate cancer.

Published estimates of the lifetime risk of developing BRCA-related cancer are age dependent and vary widely. Genetic testing for BRCA-related cancer is not recommended for children because no risk-reduction strategies for children exist, and because their risk of developing a cancer associated with a BRCA1, BRCA2, or PALB2 pathogenic/likely pathogenic variant during childhood is extremely low.

Several tests are currently available to identify inherited pathogenic/likely pathogenic variants in BRCA1, BRCA2, and PALB2. Test selection is based on a combination of factors, including personal and family history of BRCA-related cancer(s), ancestry, and whether a pathogenic/likely pathogenic

variant has been previously identified in a family member. MassHealth considers approval for coverage of genetic testing for BRCA-related cancer on an individual, case-by-case basis, in accordance with 130 CMR 401.000, 130 CMR 433.000, and 130 CMR 450.204.

For the purposes of these Guidelines, the following terms are defined:

1. **Close blood relatives**—includes first-, second-, and third-degree relatives on same side of family.
   - First-degree relatives include parents, siblings, and children.
   - Second-degree relatives include half-brothers/sisters, aunts/uncles, grandparents, grandchildren, and nieces/nephews affected on the same side of the family.
   - Third-degree relatives include first cousins, great-aunts/uncles, great-grandchildren, and great-grandparents affected on same side of family.
2. **High-grade prostate cancer**—Gleason score ≥ 7.
3. **Breast cancer**—includes both invasive and ductal carcinoma in situ (DCIS).
4. **Ovarian carcinoma**—includes fallopian tube and primary peritoneal cancers. Ovarian cancers with epithelial, non-mucinous histology are associated with the BRCA gene.

2 SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth considers genetic testing for BRCA-related cancer medically necessary once per lifetime. MassHealth bases its determination of medical necessity for genetic testing for BRCA-related cancer on clinical data, including indicators that would affect the relative risks and benefits of genetic testing for BRCA-related cancer. The criteria for adults at high risk include the following.

1. The member is 18 years of age or older; AND
2. The results of genetic testing will be clinically useful (i.e., will provide added value compared with not using the test) in the clinical management of the member; AND
3. The member has given prior written consent for genetic testing in accordance with Massachusetts General Laws Chapter 111, Section 70G; AND
4. The member's personal and/or family cancer history suggests that an inherited pathogenic/likely pathogenic variant in BRCA1, BRCA2, or PALB2 may exist by meeting criteria for one of the following categories of genetic test (I, II, III, or IV) for BRCA-related cancer.

   Category I. Family with a Known BRCA1/BRCA2/PALB2 Variant

   MassHealth covers BRCA1, BRCA2, and PALB2 genetic testing for susceptibility to breast or ovarian cancer in unaffected adults as medically necessary with single-site analysis for the known familial variant for an individual with a first- or second-degree biological relative with a known BRCA1, BRCA2, or PALB2 pathogenic/ likely pathogenic variant when a recommendation for testing is confirmed and there has been appropriate genetic counseling. Documents of the known familial variant and relationship of the carrier(s) to the member is required.

Category II. Individuals with Active Cancer or a Personal History of Cancer

Genetic testing for BRCA1, BRCA2, and PALB2 variants (including large genomic rearrangement testing (i.e., BART)) in cancer-affected individuals may be considered medically necessary when the BRCA variant status is unknown, there has been appropriate genetic counseling, and any of the following criteria (A.-G.) are met.

A. The member has a personal history of breast cancer AND one or more of the following.
    1. Diagnosed at age ≤ 50 years; OR
    2. Diagnosed at any age with
        a. Multiple primary breast cancers (at any age); OR
        b. Lobular breast cancer with personal or family history of diffuse gastric cancer; OR
        c. Triple negative breast cancer (ER-, PR-, HER2-); OR
        d. Requirement for testing to aid in the following systemic treatment decisions:
            - PARP inhibitors for metastatic breast cancer; OR
            - Adjuvant treatment with Olaparib for high-risk, HER2-negative breast cancer; OR
        e. An unknown or limited family history, defined as having fewer than two known first-degree or second-degree female relatives or female relatives surviving beyond 45 years of age on either or both sides of the family (e.g., member who is adopted); OR
        f. Ashkenazi Jewish ancestry.
    3. Diagnosed at any age with a family history of
        a. One or more close blood relatives- on the same side of the family with any of the following:
            - female breast cancer (age ≤50 years)
            - ovarian cancer
            - pancreatic cancer
            - prostate cancer with metastatic or high- or very-high-risk prostate
            - male breast cancer; OR
        b. Three or more diagnoses of breast and/or prostate cancer (any grade) on the same side of the family including the patient with breast cancer; OR
        c. Ashkenazi Jewish ancestry.
B. Personal history of any-grade prostate cancer diagnosed at any age with
    1. Ashkenazi Jewish ancestry; OR
    2. One or more close blood relatives with any of the following:
        a. ovarian cancer
        b. pancreatic cancer
        c. breast cancer (age <50 years) high-grade prostate cancer

3. Three or more close blood relatives with breast and/or prostate cancer (any grade) at any age on the same side of the family

C. Personal history of male breast cancer; OR

D. Personal history of ovarian cancer; OR

E. Personal history of exocrine pancreatic cancer; OR

F. Personal history of metastatic (Stage IVB) or node-positive prostate cancer; OR

G. BRCA1 or 2, PALB2, or pathogenic/likely pathogenic variant detected by tumor-profiling on any tumor type in the absence of germline pathogenic/likely pathogenic variant analysis

Category III. Individuals with No Personal History of the Following BRCA-Related Cancers: Breast, Ovarian, Pancreatic, or Prostate

Testing of an individual without a cancer diagnosis should be considered only when an appropriate family member is unavailable for testing. Genetic testing for BRCA1, BRCA2, and PALB2 variants (including large genomic rearrangement testing (i.e., BART) of cancer-unaffected individuals with unknown variant status) may be considered medically necessary when the treating provider has documented genetic counseling and a determination that the patient is high-risk for a BRCA/PALB2 variant through use of a prior probability model, such as a validated quantitative risk assessment tool endorsed by the U.S. Preventive Services Task Force (USPSTF).

Category IV: Adults Considering Treatment with a PARP-Inhibitor

Please refer to the MassHealth Drug List website for PA criteria for PARP-inhibitors. Criteria is available for Lynparza (Olaparib), Rubraca (rucaparib), and Talzenna (talazoparib).

B. NONCOVERAGE

MassHealth considers BRCA and PALB2 testing experimental and investigational for all other indications, including testing in men for surveillance; screening for breast or epithelial ovarian cancers; and assessment of risk of other cancers, such as colon cancer, as effectiveness for these indications has not been established.

MassHealth does not consider genetic testing for BRCA-related cancer to be medically necessary under certain circumstances. Examples of such circumstances include the following.

1. Genetic testing is being performed primarily for the medical management of a family member;
2. The only indication for testing is family history, and clinical judgment indicates that the member does not have a reasonable likelihood of having a BRCA/PALB2-pathogenic/likely pathogenic variant, considering the member's current age and the age of female unaffected relatives who link the member with the affected relatives. who link the member with the affected relatives.
3. The member has been previously tested.

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SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for genetic testing for BRCA-related cancer must be accompanied by clinical documentation that supports the medical necessity of this procedure.

A. Documentation of medical necessity must include the following

1. Clinical documentation by the provider (e.g., primary care provider, gynecologist, oncologist) of personal or family history, risk factors, and supporting rationale for the requested test(s); OR a copy of the completed BRCA or PALB2 test request form, with the exact gene(s) and/or variants being tested, which has been signed and dated by the ordering physician. MassHealth does not have its own BRCA/PALB2 test request form.

    a. If a member qualifies for coverage under Category III, the following items must be included: the validated quantitative risk assessment tool used and the responses to the tool that compose the positive scoring and/or guidelines and risk factors used to determine member risk. In addition, a three-generation pedigree with documentation of affected family members must be provided to MassHealth.

    b. If member qualifies for coverage under Category IV, the diagnosis and hormone receptor status, prior and current treatment, and rationale for testing to impact treatment must be included.

2. A description of how the genetic test results will guide clinical decisions that would not otherwise be made in the absence of testing.

Clinical information must be submitted by the clinical laboratory performing the genetic testing.

Providers must electronically submit PA requests and all supporting documentation using the Provider Online Service Center (POSC), unless the provider has a currently approved electronic claims waiver (hereinafter, "waiver"). Please see All Provider Bulletin 369 for further waiver information. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900, TDD/TTY: 711.

For PA requests that are not submitted using the POSC, providers with currently approved waivers must include the MassHealth Prior Authorization Request (PA-1 Form) and all supporting documentation. The PA-1 Form can be found at mass.gov/prior-authorization-for-masshealth-providers.

Appendix

CPT Codes for BRCA testing

CPT Code	Description
81162	BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements
81165	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements
81212	BRCA1, BRCA2 (breast cancer 1 and 2) (Ashkenazi Jewish descent, founder mutations) gene analysis; 185delAG, 5385insC, 6174delT variants
81215	BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81307	PALB2 (partner and localizer of BRCA2) (e.g., breast and pancreatic cancer) gene analysis; full gene sequence
81308	PALB2 (partner and localizer of BRCA2) (e.g., breast and pancreatic cancer) gene analysis; known familial variant
81479	Unlisted Molecular Pathology

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These Guidelines are based on review of the medical literature and current practice in genetic testing for BRCA-related cancer. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, such readers should contact their health care provider for guidance or explanation.

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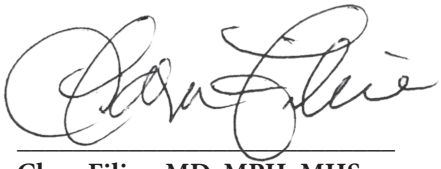
Approved by:



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