VERMONT

State of Vermont
Department of Vermont Health Access
280 State Drive, NOB 1 South
Waterbury, VT 05671-1010

Agency of Human Services
[Phone] 802-879-5903
[Fax] 802-879-5963
[Email] AHS.DVHAClinicalUnit@vermont.gov
www.dvha.vermont.gov

The Department of Vermont Health Access Clinical Criteria

Subject: Genetic Testing for Hereditary Breast and Ovarian Cancer
Last Review: February 22, 2024*
Past Revisions: January 11, 2023, September 25, 2019, January 2, 2015, December 11, 2013, April 4, 2012, March 6, 2013, April 4, 2012, March 3, 2011, November 30, 2010

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

BRCA1, BRCA2, and Hereditary Breast and Ovarian Cancer (HBOC) Gene Testing

Genetic testing of an individual's genetic material or deoxyribonucleic acid (DNA) can aid to detect gene mutations also referred to as variants, in genes that are associated with hereditary cancers such as breast, ovarian, and pancreatic cancers. Pathogenic variants in BRCA 1 and BRCA 2 genes have been linked to some of the most common forms of hereditary breast cancers. Over time, variants in other genes beyond BRCA1 and BRCA2 have been identified as associated with other germline cancers including, though not exhaustive, genes PALB2, PTEN, and TP53.

From the National Comprehensive Cancer Network (2023):

> Prior to 2020, the NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian (Breast, Ovarian, and Pancreatic as of 2020) focused largely on testing criteria for BRCA1/2 and appropriate risk management for carriers of a BRCA1 or BRCA2 pathogenic/likely pathogenic variant…. Based on strong evidence that genes beyond BRCA1/2, TP53, and PTEN confer markedly increased risk of breast and/or ovarian cancers, these Guidelines have been expanded…

Also from the National Comprehensive Cancer Network guideline for genetic/familial high-risk assessment of breast, ovarian, and pancreatic cancers (2023):

> Because tumor genomic testing is designed to address treatment actionability, not germline status, a variant that may be considered as pathogenic or likely pathogenic (P/LP) in the germline may not be reported at all, or reported as normal in the tumor if it lacks clinical implications.

Genetic testing for high-penetrance genes linked to HBOCs aids identification of gene variants that have clinical implications to guide treatment. The USPSTF (2019) recommends against routine risk assessment, genetic counseling, or genetic testing for individuals with no personal or family history or ancestry associated with potential BRCA 1 or 2 gene mutations. Per the NCCN (2023), genetic testing for individuals with low probability of testing positive for a pathogenic variant of significance (measured by established cancer risk calculation models), is unlikely to provide results of clinical utility.

Genetic counseling should be completed in conjunction with BRCA and other HBOC genetic testing.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertain to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

7102.2 Prior Authorization Determination
7405 Laboratory and Radiology Services
4.101 Medical Necessity for Covered Services
4.104 Medicaid Non-Covered Services
4.106 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

Coverage Position

BRCA 1 and 2, and HBOC genetic testing may be covered for members:

- When the genetic testing for hereditary breast and ovarian cancer is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding the genetic test and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

Coverage Criteria

DVHA covers testing for breast and/or ovarian cancer susceptibility genes in alignment with NCCN testing criteria for high-penetrance breast and ovarian cancer susceptibility genes.

Considerations:

Providers requesting this test should provide pre- and post-test genetic counseling for the member and family, if applicable.
At this time, DVHA does not provide coverage of multigene panels for HBOC.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

One hereditary breast and ovarian cancer testing of the above referenced tests per lifetime.

Coding guidelines

Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements.

As above, DVHA does not currently cover multigene panels for HBOC.

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