

The Department of Vermont Health Access Clinical Criteria

Subject: Genetic Testing for Hereditary Breast and Ovarian Cancer

Last Review: January 11, 2023*

Past Revisions: 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 HBOC Gene Testing

BRCA genetic testing uses blood for DNA analysis to identify changes (mutations) in either one of two breast cancer susceptibility genes — known as BRCA1 and BRCA2. The terms hereditary breast and ovarian cancer syndrome (HBOC) or BRCA 1-2 syndrome are often utilized to describe cancers related to these gene mutations. BRCA genetic testing identifies individuals that carry an inherited BRCA gene mutation and may provide an estimate of the individual and/or familial risk of breast and ovarian cancer. Genetic counseling should be performed in conjunction with BRCA genetic testing.

Per the United States Preventative Services Task Force (USPSTF) recommendation statement related to genetic testing for BRCA-related cancers (2019), the occurrence rate of BRCA1 or BRCA 2 mutations is about one in 300-500 women and cancers related to mutations in these gene comprise approximately 5% - 10% of all breast cancers and ~ 15% of ovarian cancers. Also per the USPSTF (2019), clinically significant mutations in the BRCA1 and BRCA2 genes dramatically increase risk of cancer development by 45% - 65% by age 70 for breast cancers and 10% - 39% for ovarian, fallopian tube, or peritoneal cancers.

BRCA genetic testing is not recommended for women at average or low increased risk of these gene mutations. BRCA gene testing is indicated for women with a personal or family history of ovarian cancer. The selection of candidates for BRCA1 and BRCA2 testing is based on the probability of the presence of a BRCA mutation. Risk model tools aid in estimating BRCA mutation likelihood. The American Society of Clinical Oncology (1996) has recommended a probability threshold of 10% for likelihood of identifying a BRCA1 or BRCA2 mutation when considering BRCA genetic testing. The National Comprehensive Cancer Network Clinical (NCCN) Practice Guidelines in Oncology for Genetic/Familial High-Risk Assessment of Breast, Ovarian, and Pancreatic Cancers (2022) recommend that individuals assigned female at birth with BRCA1 or BRCA2 mutations receive yearly breast MRI (or mammogram if MRI is unavailable) beginning at age 25 to 29 and monthly breast self-examinations beginning at age 18. The NCCN guidelines panel “supports discussion of the option of risk-reduction mastectomy for individuals assigned female at birth on a case-by-case basis” (NCCN, 2022, MS-16).



Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains 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

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 gene 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.

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.

References

American College of Obstetricians and Gynecologists. (2019). Hereditary cancer syndromes and risk assessment. ACOG committee opinion no. 793. *Obstetrics and Gynecology*, 134, e143-149.

American Society of Clinical Oncology. (2015). American Society of Clinical Oncology policy statement update: Genetic and genomic testing for cancer susceptibility. *Journal of Clinical Oncology*, 33(31), 3660-3667. doi: 10.1200/JCO.2015.63.0996

Centers for Medicare and Medicaid Services. (n.d). *Early and periodic screening, diagnostic, and treatment*. <https://www.medicaid.gov/medicaid/benefits/epsdt/index.html>

Centers for Medicare and Medicaid Services. (2020, December 10). *Local coverage determination (LCD) BRCA1 and BRCA 2 genetic testing L36499*. Medicare Coverage Database. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=36499&ver=24>

Forbes, C. Fayter, D., de Kock, S., & Quek, R. (2019). A systematic review of international guidelines and recommendations for the genetic screening, diagnosis, genetic counseling, and treatment of BRCA-mutated breast cancer. *Cancer Management and Research*, 11, 2321-2337. <https://doi.org/10.2147/CMAR.S1896277>

Hayes, Inc. Clinical Utility Evaluation. *Screening All Women with New Diagnoses of Breast Cancer for Hereditary Cancer Risk Variants*. Lansdale, PA: Hayes, Inc.; July 2022. <https://evidence.hayesinc.com/report/gtu.screen5077>

Judkins, T., Rosenthal, E., Arnell, C., Burbidge, L.A., Geary, W., Barrus, T., & Roa, B. (2012). Clinical significance of large rearrangements in BRCA 1 and BRCA2. *Cancer*, 118(21), 5210-5216. doi: 10.1002/cncr.27556

Konstantinopoulos, K.A., Norquist, B., Lacchetti, C., Armstrong, D., Grisham, R.N., Goodfellow, P.J., Kohn, E.C., Levine, D.A., Liu, J.F., Lu, K.H., Sparacio, D., & Annunziata, C.M. (2020). *Journal of Clinical Oncology*, 38, 1222-1245. <https://doi.org/10.1200/JCO.19.02960>

Myriad - BRCAAnalysis® Technical Specifications. (2020, September 3). Myriad Genetics. Retrieved December 20, 2022 from https://s3.amazonaws.com/myriad-library/technical-specifications/BRCA+Tech+Specs_Integrated.pdf

National Cancer Institute. (2020, November 19). *BRCA mutations: Cancer risk and genetic testing*. About Cancer. <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA>

National Comprehensive Cancer Network. (2022, September 7). *NCCN clinical practice guidelines in oncology (NCCN Guidelines®). (2022). Genetic/familial high-risk assessment: Breast, ovarian, and pancreatic*. NCCN Guidelines. <https://www.nccn.org/guidelines/guidelines-detail?category=2&id=1503>

Peshkin, Beth N. & Isaacs, Claudine. (2022, August 18). Genetic testing and management of individual at risk of hereditary breast and ovarian cancer syndromes. *UpToDate*. Retrieved from: <https://www.uptodate.com/contents/genetic-testing-and-management-of-individuals-at-risk-of-hereditary-breast-and-ovarian-cancer->

[syndromes?search=genetic%20testing%20hereditary%20breast%20and%20ovarian%20cancer&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1](https://pubmed.ncbi.nlm.nih.gov/search_result/?search=genetic%20testing%20hereditary%20breast%20and%20ovarian%20cancer&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1)

United States Preventative Services Task Force (2019). Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer: U.S. Preventive Services Task Force recommendation statement. *JAMA*, 322(7), 652-665. doi: 10.1001/jama.2019.10987

This document has been classified as public information.