

The Department of Vermont Health Access Medical Policy

Subject: BRCA1/2, HBOC, and BART Gene Tests

Last Review: July 7, 2016

Revision 6: January 2, 2015

Revision 5: December 11, 2013

Revision 4: April 4, 2012

Revision 3: March 6, 2013 Technical Revision

Revision 2: April 4, 2012

Revision 1: March 3, 2011

Original Effective: November 30, 2010

Description of Service or Procedure

The BRCA gene test uses blood for DNA analysis to identify changes (mutations) in either one of two breast cancer susceptibility genes — known as BRCA1, BRCA2 (breast cancer) or Hereditary breast-ovarian cancer (HBOC) or BRCA 1/2 syndrome. Genetic counseling should be included as part of BRCA gene testing. The BRCA gene test identifies individuals that carry an inherited BRCA gene mutation and may provide an estimate of the individual and/or family risk of breast and ovarian cancer.

The BRCA gene test identifies only 5-7% of breast cancers and is indicated only for women and men who demonstrate a moderate to high risk for breast cancer estimated between 10 to 25% based on personal or family history. The BRCA gene test is not recommended for women at average risk or low increased risk of these gene mutations. The BRCA gene test is also indicated for women with a personal or family history of ovarian cancer.

A BRCA gene mutation is rare, occurring only in about one in 300 to 800 people. Inherited BRCA gene mutations may be responsible for only 5 to 10% of breast cancers and about 10 to 15% of ovarian cancers. Women from a high risk family with a positive BRCA1 mutation have a greater than 80% lifetime risk of inheriting breast cancer and a 45 % risk of developing ovarian cancer by age 70. The majority of breast and ovarian cancers that occur are not related to BRCA gene mutations but are based on relative family and personal risk factors.

The selection of candidates for BRCA1 and BRCA2 testing is based on the probability of the presence of a BRCA mutation; less than a 10% probability is considered low risk, a 10 to 25% probability is considered a moderate risk, and a probability of 25% or greater is considered a high risk. The American Society of Clinical Oncology (ASCO) guidelines recommend that women with a greater than 10% likelihood of carrying a BRCA mutation, based on family and genetic background, should be offered genetic testing. Current recommendations call for follow-up of individuals with BRCA1 and BRCA2 mutations with counseling and yearly breast cancer screening, which may include yearly mammograms



beginning at age 25 to 35 years and monthly breast self-examinations beginning at age 18 to 21 years. Prophylactic mastectomies at a young age substantially improve survival in patients with strong risk factors and positive BRCA gene mutations.

Disclaimer

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

Medicaid Rule

[7102.2](#) Prior Authorization Determination

[7103](#) Medical Necessity

Medicaid Rules can be found at <http://humanservices.vermont.gov/on-line-rules>

Coverage Position

A BRCA gene test may be covered for those beneficiaries:

- When the BRCA gene test is prescribed by a licensed medical provider enrolled in the Vermont Medicaid program who is knowledgeable in the use of the BRCA gene test and who provides medical care to the beneficiary AND
- When the clinical guidelines below are met.

Coverage Guidelines

The Department of Vermont Health Access (DVHA) may cover BRCA1/2, HBOC, and BART, including the BRCA1 and BRCA2 full sequence analysis and full duplication/deletion analysis for beneficiaries when the following criteria are met:

1. Women with a personal history of breast cancer and one of the following:
 - a. Breast cancer diagnosed at age 45 years or younger
 - b. Breast cancer diagnosed at 50 years or younger and one of the following:
 - at least one first or second degree blood relative with breast cancer at age 50 years or younger
 - at least one first or second degree blood relative with epithelial ovarian cancer
 - has bilateral breast cancers
 - limited family history or no family history because adopted
 - c. Breast cancer diagnosed at any age and one of the following:
 - at least 2 first or second degree blood relatives with breast cancer or epithelial ovarian cancer
 - the member has two breast primaries and one first or second degree blood relative with breast cancer diagnosed age 50 years or younger
 - at least one first, second, or third degree blood relative with known BRCA1 or BRCA2 mutation.

- a member ethnically associated with a higher mutation frequency (Ashkenazi Jewish, Icelandic, Swedish, Hungarian, or Dutch)
- two close relatives, on the same side of the family with pancreatic adenocarcinoma at any age.

OR

2. Women without personal history of breast cancer or epithelial ovarian cancer
 - a. at least three first or second blood relatives with breast cancer or epithelial ovarian cancer
 - b. at least two first or second degree blood relatives with one of the following:
 - epithelial ovarian cancer
 - breast cancer age 50 years or younger
 - one relative diagnosed with multiple primaries or bilateral breast cancer
 - one first or second degree blood relative with breast cancer age 50 year or younger and another first or second degree blood relative with epithelial ovarian cancer
 - one first or second degree blood relative with multiple primary breast cancer and another with epithelial ovarian cancer
 - c. Women with one or more first or second degree blood relatives with one of the following:
 - male with at least one first or second degree blood relative with breast cancer
 - breast cancer or epithelial ovarian cancer and member with increased risk due to ethnic background
 - d. Women with one first degree blood relative with both breast cancer and epithelial ovarian cancer
 - e. Women with first, second or third degree blood relatives with BRCA1 or BRCA2.

OR

3. Women with a history of epithelial ovarian cancer

OR

4. Men with any of the following:
 - a. A first, second, or third degree blood relative with a BRCA1 or BRCA2 mutation.
 - b. Personal history of breast cancer

OR

5. Women with a personal history of pancreatic adenocarcinoma at any age with two close relatives (on the same side of the family) with pancreatic adenocarcinoma, breast cancer and/or epithelial ovarian cancer.

OR

6. Breast cancer is diagnosed at age 60 years or younger and is triple negative.

OR

7. Women or men with a personal history of pancreatic cancer and Ashkenazi Jewish ancestry.

OR

8. Men with a personal history of prostate cancer (Gleason score ≥ 7) and a first, second or third degree blood relative (*on the same side of the family*) with at least one of the following:
 - Breast cancer, ≤ 50 years of age)
 - ovarian cancer
 - pancreatic cancer
 - prostate cancer (Gleason score ≥ 7)

Definitions:

1. A first degree blood relative shares 50 % DNA (mother, sister, daughter)
2. A second degree blood relative shares 25 % DNA (grandmother, aunt, niece)
3. A third degree blood relative shares less than 25% DNA (cousin, great grandmother, great aunt)

BRCA Testing Documentation Requirements:

1. The member's PCP, internist, family practitioner, or gynecologist must provide at a minimum a three generation pedigree of breast and ovarian cancer to confirm the family history.
2. A supporting statement how this genetic test will be used in the immediate care of the member.
3. A statement who will provide genetic counseling as to the appropriateness of the test and interpretation of the results.
4. Informed consent has been given.

BRAC Analysis Rearrangement Test (BART™) requests: In the event the BRCA Analysis is negative, the lab will automatically run the BART™ on all samples of patients that they determine have a significant cancer history based on the medical documentation supplied to them by the requesting provider.

The BART may be requested without the BRCA in the following:

History of BRCA testing with negative results and the meet the following criteria:

1. Breast cancer before the age of 50: Two or more first or second degree relatives with breast cancer before the age 50 and/or ovarian cancer at any.
2. Ovarian cancer at any age: Two or more first or second degree relatives with breast cancer before the age 50 and/or ovarian cancer at any.
3. Male breast cancer at any age: Two or more first or second degree relatives with breast cancer before the age 50 and/or ovarian cancer at any.
4. Breast cancer at or after age 50 and ovarian cancer at any age: One or more first or second degree relatives with breast cancer before the age 50 and/or ovarian cancer at any.
5. Breast cancer before age 50 and ovarian cancer at any age: No additional relatives required.
6. Patients with a known large rearrangement in their family.

Clinical guidelines for repeat service or procedure

The same criteria apply as for the initial use.

Type of service or procedure not covered (this list may not be all inclusive)

BRCAVantage Plus (BRCA1, BRCA2, TP53, STK11, PTEN, CDH1, PALB2) is considered experimental and investigational.

References

Ambry Genetics. (2015). BRCA1 and BRCA2. Retrieved December 22, 2015, from: <http://www.ambrygen.com/print/tests/brca1-and-brca2>

American Society of Clinical Oncology Policy Statement Update: Genetic and Genomic Testing for Cancer Susceptibility. (February 10, 2010). *Journal of Clinical Oncology*, 28(5). Retrieved June 24, 2016, from: <http://jco.ascopubs.org/content/28/5/893.full.pdf+html>

Beattie, M. (2008). Updated test improves detection for breast and ovarian cancer gene. Retrieved June 24, 2016, from: http://www.ucsfhealth.org/newsletters/primary_care_connections/june_2008/cancer_genes/

BRCAAnalysis® Technical Specifications Myriad Genetic Laboratories. (2012). Retrieved December 22, 2015, from: <https://www.myriad.com/lib/technical-specifications/BRCAAnalysis-Technical-Specifications.pdf>

BRCA gene test for breast cancer. (2013). Mayo Clinic. Retrieved June 24, 2016, from: <http://www.mayoclinic.com/health/brca-gene-test/MY00322>

Dent, R., Trudeau, M., Pritchard, K., Hanna, W., Kahn, H., Sawka, C., et al. (2007). Triple-negative breast cancer: Clinical features and patterns of recurrence. *American Association for Cancer*, 13(15). Retrieved June 24, 2016, from: <http://clincancerres.aacrjournals.org/content/13/15/4429.full.pdf+html>

Emory University. Emory Genetic Laboratory. (2015). Hereditary Breast and Ovarian Cancer Syndrome: *BRCA1/BRCA2* Gene Sequencing and Deletion/Duplication Panel. Retrieved December 22, 2015, from: <http://geneticslab.emory.edu/tests/MM070>

Hayes, Inc. Hayes GTE Algorithm. *BRCA1 and BRCA2 Testing in Hereditary Breast and Ovarian Cancer*. Lansdale, PA: Hayes, Inc.; December 20, 2012.

Hayes, Inc. Hayes GTE Overview. *Breast Cancer Susceptibility 1 and 2 (BRCA1/2) Gene Testing for Hereditary Breast and Ovarian Cancer (HBOC) for Familial Breast and Ovarian Cancer (Various Manufacturers)*. Lansdale, PA: Hayes, Inc.; December 20, 2012.

Hayes, Inc. Hayes GTE Report. *Breast Cancer Susceptibility 1 and 2 (BRCA1/2) Gene Testing for Hereditary Breast and Ovarian Cancer (HBOC) for Familial Breast and Ovarian Cancer (Various Manufacturers)*. Lansdale, PA: Hayes, Inc.; August 6, 2013.

Hayes, Inc. Hayes GTE Synopsis. *BRCAAnalysis Large Rearrangement Test BART*. Lansdale, PA: Hayes, Inc.; March 15, 2015.

Hayes, Inc. Hayes GTE Synopsis. *BRCAVantage Plus (BRCA1, BRCA2, TP53, STK11, PTEN, CDH1, PALB2)*. Lansdale, PA: Hayes, Inc.; December 17, 2015.

Hayes, Inc. Hayes News – Clinical Study. *Breast Cancer Outcomes in Carriers of BRCA1 and BRCA2 Mutations*. Lansdale, PA: Hayes, Inc.; July 26, 2007.

Hayes, Inc. Hayes News – Clinical Study. *Broad Variations in Risk Exist Among Carriers of BRCA Mutation*. Lansdale, PA: Hayes, Inc.; January 2008.

Hayes, Inc. Hayes News – Medical Association/Organization. *New Draft Recommendations: Screening Women with History of Breast or Ovarian Cancer*. Lansdale, PA: Hayes, Inc.; April 4, 2013.

Hayes, Inc. Hayes GTE Custom Report: *Comparison of Commercially Available Tests for Hereditary Breast and Ovarian Cancer (BRCA1 and BRCA2)*. Lansdale, PA: Hayes, Inc.; August 3, 2014.

Hayes, Inc. Hayes GTE Overview: *Breast Cancer Susceptibility 1 and 2 (BRCA 1/2) Gene Testing for Hereditary Breast and Ovarian Cancer (HBOC) for Familial Breast and Ovarian Cancer (Various Manufacturers)*. Lansdale, PA: Hayes, Inc.; August 6, 2014.

Hayes, Inc. Hayes News – Medical Association/Organization. *New Draft Recommendations: Screening Women with History of Breast of Ovarian Cancer*. Lansdale, PA: Hayes, Inc.; April 4, 2013.

Hilgart, J.S., Coles, B., Iredale, R. Cancer genetic risk assessment for individuals at risk of familial breast cancer (review). In: *The Cochrane Library*, Issue 2, 2012. Chichester: Wiley. Updated Quarterly.

Kwon, J., Gutierrez-Barrera, A., Young, D., Sun, C., Daniels, M., Lu, K. et al. (2010). Expanding the criteria for BRCA mutation testing in breast cancer survivors. *Journal of Clinical Oncology*, 28(27). Retrieved June 24, 2016, from: <http://jco.ascopubs.org/content/28/27/4214.full.pdf+html>

Lostumbo, L., Carbine, N.E., & Wallace, J. Cancer genetic risk assessment for individuals at risk of familial breast cancer (Review). In: *The Cochrane Library*, Issue 2, 2012. Chichester: Wiley. Updated Quarterly.

Lostumbo, L., Carbine, N.E., Wallace, J., Ezzo, J., & Dickersin, K. Prophylactic mastectomy for the prevention of breast cancer (Review). In: *The Cochrane Library*, Issue 11, 2010. Chichester: Wiley. Updated Quarterly.

Medicare Coverage Updated to Include the BRCAAnalysis® Large Rearrangement Test! (2012). Myriad Genetics, Inc. Retrieved June 24, 2016, from: https://d1izdzz43r5o67.cloudfront.net/insurance/BART_Medicare+092412.pdf

Myriad introduces Enhanced BRCAAnalysis® Test for exceptionally high-risk breast cancer patients. New BART™ technology detects rare DNA rearrangements in BRCA1 and BRCA2 genes. (2006). Myriad Genetics, Inc. Retrieved June 24, 2016, from: <http://investor.myriad.com/releasedetail.cfm?ReleaseID=325803>

Myriad - BRCA1 and BRCA2 Prevalence Tables for Mutations Detected by Sequencing, the 5-site Rearrangement Panel (LRP) and the BRCAAnalysis® Large Rearrangement Test (BART™) in High Risk Patients. Myriad Genetics, Inc. Retrieved June 24, 2016, from: <http://d1izdzz43r5o67.cloudfront.net/brac/BART-table-faq.pdf>

Myriad - BRCAAnalysis® Large Rearrangement Test (BART™). Myriad Genetics, Inc. Retrieved June 24, 2016, from: <https://www.myriad.com/lib/brac/BART-faq.pdf>

Myriad -Integrated BRACAnalysis ®to Include BART™. Myriad Genetics, Inc. Retrieved June 24, 2016, from: <http://d1izdzz43r5o67.cloudfront.net/sales-aids/Integrated+BRACAnalysis+to+Include+BART.pdf>

National Cancer Institute. (2009). *BRCA1 and BRCA2: Cancer risk and genetic testing*. (NCI Publication). Retrieved June 24, 2016, from: <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA>

National Comprehensive Cancer Network. NCCN guidelines Version 2.2013 Hereditary breast and/or ovarian cancer syndrome.

New ACOG Guidelines Recommend Routine Genetic Risk Assessment. (2009). *Cancer Connect.com*. Retrieved June 24, 2016, from: <http://news.cancerconnect.com/new-acog-guidelines-recommend-routine-genetic-risk-assessment/>

Stacey, D., Bennett, C.L., Barry, M.J., Col, N.F., Eden, K.B., Holmes-Rovner, M., Llewellyn-Thomas, H., Lyddiatt, A., Légaré, F., & Thomson, R. Decision aids or people facing health treatment of screening decisions (review). In: *The Cochrane Library*, Issue 10, 2011. Chichester: Wiley. Updated Quarterly.

This document has been classified as public information.