

05-82000-30

Original Effective Date: 10/15/01

Reviewed: 01/24/19

Revised: 02/15/19

Subject: Genetic Testing for BRCA1 or BRCA2 for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

Several genetic syndromes with an autosomal dominant pattern of inheritance that feature breast cancer have been identified. Of these, hereditary breast and ovarian cancer (HBOC) and some cases of hereditary site-specific breast cancer have in common causative mutations in BRCA (breast cancer susceptibility) genes. Families suspected of having HBOC syndrome are characterized by an increased susceptibility to breast cancer occurring at a young age, bilateral breast cancer, male breast cancer, and ovarian cancer at any age as well as cancer of the fallopian tube and primary peritoneal cancer. Other cancers, such as prostate cancer, pancreatic cancer, gastrointestinal cancers, melanoma, and laryngeal cancer, occur more frequently in HBOC families. Hereditary site-specific breast cancer families are characterized by early-onset breast cancer with or without male cases, but without ovarian cancer.

Germline variants in the BRCA1 and BRCA2 genes are responsible for the cancer susceptibility in most HBOC families, especially if ovarian cancer or male breast cancer are features. However, in site-specific breast cancer, BRCA variants are responsible for only a proportion of affected families. BRCA gene variants are inherited in an autosomal dominant fashion through either the maternal or paternal lineage. It is possible to test for abnormalities in BRCA1 and BRCA2 genes to identify the specific variant in cancer cases, and to identify family members at increased cancer risk. Family members without existing cancer who are found to have BRCA variants can consider preventive interventions for reducing risk and mortality.

POSITION STATEMENT:

NOTE: Coverage for genetic testing, screening, and counseling are applicable only under those contracts that include benefits for genetic testing, preventive health services, screening services, and medical counseling.

Genetic testing for BRCA1 and BRCA2 variants **meets the definition of medical necessity** for cancer-affected women or men who meet **ONE** or more of the following criteria:

1. Member from a family with a known BRCA 1 or BRCA2 variant.
2. Personal history of breast cancer and **ONE** or more of the following:
 - Diagnosed at age ≤ 45 years;
 - Diagnosed age 46-50 years with:
 - An additional breast cancer primary (bilateral disease or two or more clearly separate ipsilateral primary tumors diagnosed either synchronously or asynchronously) at any age
 - ≥ 1 close blood relative* with breast cancer at any age
 - ≥ 1 close blood relative* with high grade (Gleason score ≥ 7) prostate cancer
 - An unknown or limited family history.
 - Diagnosed age ≤ 60 years with a [triple negative breast cancer](#);
 - Diagnosed at any age with:
 - ≥ 1 close blood relative* with:
 - Breast cancer diagnosed ≤ 50 years; or
 - Ovarian carcinoma (includes fallopian tube & primary peritoneal cancers); or
 - Male breast cancer; or
 - Metastatic prostate cancer; or
 - Pancreatic cancer.
 - ≥ 2 additional diagnoses of breast cancer at any age in member and/or close blood relative*.
 - Ashkenazi Jewish ancestry.
3. Personal history of ovarian carcinoma (includes fallopian tube & primary peritoneal cancers).
4. Personal history of male breast cancer.
5. Personal history of pancreatic cancer.
6. Personal history of metastatic prostate cancer.
7. Personal history of high-grade prostate cancer (Gleason score ≥ 7) at any age with:
 - ≥ 1 close blood relative* with ovarian carcinoma, pancreatic cancer, or metastatic prostate cancer at any age or breast cancer < 50 years; or
 - ≥ 2 close blood relatives* with breast or prostate cancer (any grade) at any age; or
 - Ashkenazi Jewish ancestry.
8. BRCA1 or BRCA2 pathogenic or likely pathogenic variant detected by tumor profiling on any tumor type in the absence of germline pathogenic or likely pathogenic variant analysis.

9. Regardless of family history, a member with a BRCA-related cancer that would benefit from genetic testing to determine eligibility for targeted treatment.
10. A member who does not meet the other criteria but with ≥ 1 first- or second-degree blood relatives* meeting any of the above criteria.

Genetic testing for BRCA1 and BRCA2 variants of cancer-unaffected women or men **meets the definition of medical necessity** under any ONE of the following circumstances:

- Member from a family with a known BRCA1 or BRCA2 variant;
- first- or second-degree blood relative* meeting any criterion listed above for Members With Cancer; or
- Third-degree blood relative* with breast cancer and/or ovarian, fallopian tube, or primary peritoneal cancer AND 2 or more first-, second-, or third-degree relatives* with breast cancer (≥ 1 at age ≤ 50 years) and/or ovarian, fallopian tube, or primary peritoneal cancer.

*Close blood relatives include first-, second-, and third-degree relatives on each side of the family (maternal or paternal): **First-degree** relatives: parents, siblings, and children; **Second-degree** relatives: grandparents, aunts, uncles, nieces, nephews, grandchildren, and half-siblings; **Third-degree** relatives: great-grandparents, great-aunts, great-uncles, great-grandchildren, first cousins, half aunts and uncles.

BRCAAnalysis® Rearrangement Test (BART™) **meets the definition of medical necessity** for individuals that meet the BRCA testing criteria listed above.

BRCAAnalysis Rearrangement Test (BART) is considered **experimental or investigational** for all other indications including screening in the general population. There is a lack of clinical data to permit conclusions on the clinical management of the patient and net health outcomes.

Genetic testing for BRCA1 and BRCA2 variants in cancer-affected members or of cancer-unaffected members with a family history of cancer when criteria above are not met is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

Genetic testing in minors for BRCA1 or BRCA variants is considered **experimental or investigational**. There is no change in management for minors as a result of knowledge of the presence or absence of a deleterious variant. In addition, there are potential harms related to stigmatization and discrimination.

Testing for BARD1 variants is considered **experimental or investigational** for all indications. The evidence is insufficient to determine the effects of this testing on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (ie, detection of large gene rearrangements)
81163	BRCA1 (BRCA1, dna repair associated), BRCA2 (BRCA2, dna repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)

81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81212	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81215	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant

Genetic Counseling: Genetic counseling is covered in accordance to the member's contract benefits for medical counseling. Pre and post genetic counseling may be considered medically necessary as an adjunct to the genetic tests. The following codes may be reported:

CPT Coding:

96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family
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HCPCS Coding:

S0265	Genetic counseling, under physician supervision, each 15 minutes
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REIMBURSEMENT INFORMATION:

None applicable

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: BRCA1 and BRCA2 Genetic Testing (L36499) located at fcsso.com.

DEFINITIONS:

Triple-negative breast cancer: describes breast cancer cells that do not have estrogen receptors, progesterone receptors, or large amounts of HER2/neu protein. Also called ER-negative PR-negative HER2/neu-negative and ER-PR-HER2/neu-.

RELATED GUIDELINES:

[Genetic Testing, 05-82000-28](#)

[Magnetic Resonance Imaging of the Breast, 04-70540-09](#)

[Preventive Services, 01-99385-03](#)

[Prophylactic Mastectomy, 02-12000-15](#)

OTHER:

None applicable

REFERENCES:

1. American College of Obstetricians and Gynecologists (ACOG), Clinical Management Guidelines for Obstetrician-Gynecologists: Hereditary Breast and Ovarian Cancer Syndrome, Number 103, April 2009.
2. American College of Obstetricians and Gynecologists (ACOG), Routine Screening for Hereditary Breast and Ovarian Cancer Recommended, 03/09, accessed at acog.org on 08/14/09.
3. The American Society of Breast Surgeons, Position Statement on BRCA Genetic Testing for Patients With and Without Breast Cancer, 09/2012, accessed at breastsurgeons.org 05/21/15.
4. American Society of Clinical Oncology (ASCO) Policy Statement Update: Genetic Testing for Cancer Susceptibility, 2010, accessed at asco.org 05/21/15.
5. Berliner JL, Fay AM, et al, Risk Assessment and Genetic Counseling for Hereditary Breast and Ovarian Cancer: Recommendations of the National Society of Genetic Counselors, accessed at guideline.gov on 08/14/09.
6. Blue Cross Blue Shield Association Medical Policy Reference Manual 2.04.02 Genetic Testing for BRCA1 or BRCA2 for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers, 11/18.
7. Blue Cross Blue Shield Association Technology Evaluation Center (TEC) "Genetic Testing for Inherited BRCA1 or BRCA2 Mutations" (06/97).
8. First Coast Service Options, Inc. (FCSO) Local Coverage Determination (LCD): BRCA1 and BRCA2 Genetic Testing (L36499) located at fcso.com.
9. Hirst JE, Gard GB, McIlroy K, et al, High Rates of Occult Fallopian Tube Cancer Diagnosed at Prophylactic Bilateral Salpingo-Oophorectomy, *Int J Gynecol Cancer* 2009; 19(5): 826-9.
10. Irminger-Finger, Ratajska M, Pilyugin M, New Concepts on BARD1: Regulator of BRCA Pathways and Beyond. *Int J Biochem Cell Biol.* 2016 Mar;72:1-17.
11. Judkins T, et al. Clinical significance of large rearrangements in BRCA1 and BRCA2. *Cancer.* doi: 10.1002/cncr.27556, 2012.
12. National Cancer Institute (NCI), NCI Fact Sheet- BRCA1 and BRCA2: Cancer Risk and Genetic Testing, last reviewed: 01/22/14. Accessed at cancer.gov 09/09/14.
13. National Comprehensive Cancer Network, (NCCN) Clinical Practice Guidelines in Oncology, Genetic/Familial High-Risk Assessment: Breast and Ovarian, Version 2.2019; accessed at nccn.org.
14. U.S. Preventive Services Task Force (USPSTF). BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing. Release date: December 2013. Accessed at uspreventiveservicestaskforce.gov 12/19/18.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 01/24/19.

GUIDELINE UPDATE INFORMATION:

11/15/03	Annual review. Developed separate policy for Genetic Testing for Inherited BRCA1 and BRCA2 Mutations. Added coverage and non-coverage statement for BRCA testing of men.
07/01/05	HCPCS update. Added S0265.
12/15/05	Biennial review. Coverage statement changed to reflect BCA policy. Non-coverage section reworded. Information added to Description section.
01/01/06	Annual HCPCS coding update: added 83900, 83907, 83908, 83909, and 83914; revised 83898 & 83901.
06/15/06	Revision to include new codes into limitation section.
10/15/06	Revision to coverage statement; definitions added.
01/01/07	Annual HCPCS coding update: added 96040, deleted 99401, 99402, 99403, 99404.
07/15/07	Annual review, coverage statements maintained, guideline reformatted, references updated.
01/01/08	Annual HCPCS coding update: revised 83898, 83900, 83901, and 83908.
01/01/09	Annual HCPCS coding update: descriptor revised for codes 83890, 83891, 83892, 83893, 83894, 83897, 83900, 83903, 83907, 83909, and 83914.
09/15/09	Annual review: position statements updated, description section, guideline title, and references updated.
10/15/09	Reimbursement Information section updated.
08/15/10	Annual review: position statements updated to include "cancer of fallopian tube or primary peritoneal cancer" to be considered along with breast and ovarian cancer in assessing family history; additional position statements added regarding CHEK2 testing and testing for minors; description section and references updated.
04/01/11	Revision; Certificate of Medical Necessity added.
08/15/11	Scheduled review; position statements and references updated; formatting changes.
01/01/12	Annual HCPCS update. Added CPT codes 81211-81217; revised Billing/Coding and Reimbursement Information sections.
04/01/12	Quarterly HCPCS update. Deleted codes S3818-S3823.
08/15/12	Annual review; position statements, description section, and references updated.
11/15/13	Annual review; position statements, program exception, and references updated.
11/15/14	Annual review; position statements and references updated.
07/15/15	Annual Review; position statements, program exception, and references updated.
01/01/16	Annual HCPCS/CPT update; code 81162 added.
08/15/16	Revision; position statement section and references updated.
02/15/17	Revision; position statements and references updated.
02/15/18	Revision; position statements and references updated.
01/01/19	Annual CPT/HCPCS coding update. Added codes 81163, 81167; revised codes 81162, 81212, 81215-81217; deleted codes 81211, 81213, 81214.
02/15/19	Revision; position statements updated and reorganized; policy title, description, and references updated.