MEDICAL POLICY

POLICY TITLE	GENETIC TESTING FOR BRCA1 OR BRCA2 FOR HEREDITARY BREAST/OVARIAN CANCER SYNDROME AND OTHER HIGH-RISK CANCERS
POLICY NUMBER	MP-2.211

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**3/6/2020**
Effective Date:	**7/1/2020**

I. POLICY

Genetic testing should be performed in a setting that has suitably trained healthcare providers who can give appropriate pre- and post-test counseling and that has access to a Clinical Laboratory Improvement Amendments (CLIA)-licensed laboratory that offers comprehensive variant analysis (see Policy Guidelines: Comprehensive Variant analysis).

Patients with Cancer or with Personal History of Cancer

Genetic testing for *BRCA1* and *BRCA2* variants in cancer-affected individuals may be considered **medically necessary** under any of the following circumstances:

- from a family with a known *BRCA1/BRCA2* variant; **or**
- *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; **or**
- unknown or limited family history. For example, fewer than 2 first- or second-degree female relatives having lived beyond age 45 in either lineage; **or**
- Ashkenazi Jewish ancestry; **or**
- Personal history of any one of the following:
  - BRCA related cancers (breast, fallopian tube, epithelial ovarian, pancreatic, primary peritoneal or prostate cancer); **or**
  - one or more close relatives* with ovarian carcinoma, pancreatic cancer, or metastatic prostate cancer; **or**
  - one or more close relatives* with high grade prostate cancer Gleason score greater than or equal to 7); **or**
- Individual does not meet the criteria above but has at least one first- or second-degree blood relatives with any one of the above.

Note*-Close blood relatives include first-, second-, and third-degree relatives.

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Patients Without Cancer or Without History of Cancer

(See Policy Guidelines: Testing unaffected individuals)

Genetic testing for *BRCA1* and *BRCA2* variants of cancer-unaffected individuals may be considered **medically necessary** under any of the following circumstances:

- From a family with a known *BRCA1/BRCA2* variant; **or**
- *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; **or**
- Unknown or limited family history. For example, fewer than 2 first- or second-degree female relatives having lived beyond age 45 in either lineage; **or**
- Ashkenazi Jewish ancestry; **or**
- Personal history of any one of the following:
  - BRCA related cancers (breast, fallopian tube, epithelial ovarian, pancreatic, primary peritoneal or prostate cancer); **or**
  - one or more close relatives* with ovarian carcinoma, pancreatic cancer, or metastatic prostate cancer; **or**
  - one or more close relatives* with high grade (Gleason score ≥ 7) prostate cancer; **or**
- Individual has a 3rd-degree blood relative with breast cancer and/or ovarian, fallopian tube, or primary peritoneal cancer AND 2 or more 1st-, 2nd-, or 3rd-degree relatives* with breast cancer (at least one at age 50 years or more) and/or ovarian, fallopian tube, or primary peritoneal cancer; **or**
- Individual does not meet the criteria above but has at least one first- or second-degree blood relatives with any one of the above.

Note*-Close blood relatives include first-, second-, and third-degree relatives

For the purpose of familial assessment, 1st-, 2nd-, and 3rd- degree relatives are blood relatives on the same side of the family (maternal or paternal).

- 1st-degree relatives are parents, siblings, and children; **and**
- 2nd-degree relatives are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half-siblings; **and**
- 3rd-degree relatives are great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.

Genetic testing for *BRCA*1 and *BRCA2* variants in cancer-affected individuals or of cancer-unaffected individuals with a family history of cancer when criteria above are not met is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Genetic testing in minors for *BRCA1* and *BRCA2* variants is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY TITLE	GENETIC TESTING FOR BRCA1 OR BRCA2 FOR HEREDITARY BREAST/OVARIAN CANCER SYNDROME AND OTHER HIGH-RISK CANCERS
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Policy Guidelines

Current U.S. Preventive Services Task Force guidelines recommend screening women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or who have an ancestry associated with BRCA1/2 gene mutation. Women with a positive result on the risk assessment tool should receive genetic counseling and, if indicated after counseling, genetic testing (B recommendation.)

Recommended screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful variants in *BRCA1* or *BRCA2* are:

- Ontario Family History Assessment Tool (FHAT); **or**
- Manchester Scoring System; **or**
- Referral Screening Tool (RST) ; **or**
- Pedigree Assessment Tool (PAT) ; **or**
- Family History Screen (FHS-7) ; **or**
- International Breast Cancer Intervention Study instrument (Tyrer-Cuziak); **or**
- Brief versions of the BRCAPRO.

Recommended Testing Strategies

Patients who meet criteria for genetic testing as outlined in the policy statements above should be tested for variants in *BRCA1* and *BRCA2*. Recommended strategies are listed below.

- In patients with a known familial *BRCA* variant, targeted testing for the specific variant is recommended.
- In patients with unknown familial *BRCA* variant:
  - Non-Ashkenazi Jewish descent:
    - To identify clinically significant variants, National Comprehensive Cancer Network (NCCN) advises testing a relative who has breast or ovarian cancer-especially with early-onset disease, bilateral disease, multiple primaries, or ovarian cancer-because that individual has the highest likelihood of obtaining a positive test result.
    - If no living family member with breast or ovarian cancer exists, NCCN suggests testing first- or second-degree family members affected with cancer thought to be related to deleterious *BRCA1* or *BRCA2* variants (e.g., prostate cancer, pancreatic cancer, melanoma).
    - If no familial variant can be identified, 2 possible testing strategies are:
      - Full sequencing followed by testing for *common* large genomic rearrangements (deletions, duplications) only if sequencing detects no variant (negative result).
      - More than 90% of *BRCA* variants will be detected by full sequencing. Alternatively, simultaneous full sequencing and testing for *common* large genomic rearrangements (also known as comprehensive *BRCA* testing; see

Comprehensive Variant Analysis below) may be performed as is recommended by NCCN.

- Comprehensive testing can detect 92.5% of *BRCA*1 or *BRCA2* variants.
  - If comprehensive *BRCA* testing is negative, testing for *uncommon* large genomic rearrangements (e.g., BART) may be done.

- Testing for *uncommon* large rearrangements should not be done unless both sequencing and testing for *common* large rearrangements have been performed and are negative.
  - Among patients with negative comprehensive testing, BART identified a deleterious variant (positive result) in less than 1%.
  - Ashkenazi Jewish descent
    - If patient is of known Ashkenazi Jewish descent, NCCN recommends testing for the 3 known founder mutations (185delAG and 5182insC in *BRCA1*; 6174delT in *BRCA2*) first.
    - If testing is negative for founder mutations, comprehensive genetic testing may be considered (see Comprehensive Variant Analysis).

Comprehensive Variant Analysis

Comprehensive variant analysis currently includes sequencing the coding regions and intron and exon splice sites, as well as testing to detect common large deletions and rearrangements that can be missed with sequence analysis alone. In addition, before August 2006, testing for large deletions and rearrangements was not performed, thus some patients with familial breast cancer who had negative *BRCA* testing before this time may consider repeat testing for the rearrangements (see Policy section for criteria).

High-Risk Ethnic Groups

Testing of eligible individuals who belong to ethnic populations in which there are well-characterized founder mutations should begin with tests specifically for these variants. For example, founder mutations account for approximately three-quarters of the *BRCA* variants found in Ashkenazi Jewish populations (see Rationale section). When testing for founder mutations is negative, comprehensive variant analysis should then be performed.

Testing Unaffected Individuals

In unaffected family members of potential *BRCA* variant families, most test results will be negative and uninformative. Therefore, it is strongly recommended that an *affected* family member be tested first whenever possible to adequately interpret the test. Should a *BRCA* variant be found in an affected family member(s), DNA from an *unaffected* family member can be tested specifically for the same variant of the affected family member without having to sequence the entire gene. Interpreting test results for an unaffected family member without knowing the genetic status of the family may be possible in the case of a positive result for an established disease-associated variant but leads to difficulties in interpreting negative test

results (uninformative negative) or variants of uncertain significance because the possibility of a causative *BRCA* variant is not ruled out.

Testing Minors

The use of genetic testing for *BRCA* variants has limited or no clinical utility in minors, because 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.

Prostate Cancer

Patients with *BRCA* variants have an increased risk of prostate cancer, and patients with known *BRCA* variants may, therefore, consider more aggressive screening approaches for prostate cancer. However, the presence of prostate cancer in an individual, or in a family, is not itself considered sufficient justification for *BRCA* testing.

Genetic Counseling

Genetic counseling is primarily aimed at patients who are at risk for inherited disorders, and experts recommend formal genetic counseling in most cases when genetic testing for an inherited condition is considered. The interpretation of the results of genetic tests and the understanding of risk factors can be very difficult and complex. Therefore, genetic counseling will assist individuals in understanding the possible benefits and harms of genetic testing, including the possible impact of the information on the individual's family. Genetic counseling may alter the utilization of genetic testing substantially and may reduce inappropriate testing. Genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

Cross-references:

MP 2.279 Moderate Penetrance Variants Associated with Breast Cancer in Individuals at High Breast Cancer Risk

MP 2.325 Genetic Cancer Susceptibility Panels Using Next Generation Sequencing

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Benefit Brochure for information on BRCA Testing: https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms

Note* - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND

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Hereditary Breast and Ovarian Cancer Syndrome

POLICY TITLE	GENETIC TESTING FOR BRCA1 OR BRCA2 FOR HEREDITARY BREAST/OVARIAN CANCER SYNDROME AND OTHER HIGH-RISK CANCERS
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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 variants 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, 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. For this evidence review, BCBSA refers collectively to both as *hereditary breast and/or 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 cancer, *BRCA* variants are responsible only for a proportion of affected families. *BRCA* gene variants are inherited in an autosomal dominant fashion through 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.

Clinical Features Suggestive of BRCA Variant

Young age of onset of breast cancer, even in the absence of family history, is a risk factor for *BRCA1* variants. Winchester (1996) estimated that hereditary breast cancers account for 36% to 85% of patients diagnosed before age 30. In several studies, *BRCA* variants were independently predicted by early age at onset, being present in 6% to 10% of breast cancer cases diagnosed at ages younger than various premenopausal age cutoffs (age range, 35-50 years). In cancer-prone families, the mean age of breast cancer diagnosis among women carrying *BRCA1* or *BRCA2* variants is in the 40s. In the Ashkenazi Jewish population, Frank et al (2002) reported that 13% of 248 cases with no known family history and diagnosed before 50 years of age had *BRCA* variants.[1] In a similar study by Gershoni-Baruch et al (2000), 31% of Ashkenazi Jewish women, unselected for family history, diagnosed with breast cancer at younger than 42 years of age had *BRCA* variants. Other studies have indicated that early age of breast cancer diagnosis is a significant predictor of *BRCA* variants in the absence of family history in this population.

As in the general population, family history of breast or ovarian cancer, particularly of early age onset, is a significant risk factor for a *BRCA* variant in ethnic populations characterized by founder mutations. For example, in unaffected individuals of Ashkenazi Jewish descent, 12% to 31% will have a *BRCA* variant depending on the extent and nature of the family history. Several other studies have documented the significant influence of family history.

In patients with “triple-negative” breast cancer (i.e., negative for expression of estrogen, progesterone, and overexpression of human epidermal growth factor receptor 2 receptors), there

is an increased prevalence of *BRCA* variants. Pathophysiologic research has suggested that the physiologic pathway for development of triple-negative breast cancer is similar to that for *BRCA*-associated breast cancer. In 200 randomly selected patients with triple-negative breast cancer from a tertiary care center, Kandel et al (2006) reported there was a greater than 3-fold increase in the expected rate of *BRCA* variants. *BRCA1*variants were found in 39.1% of patients and *BRCA2* variants in 8.7%. Young et al (2009) studied 54 women with high-grade, triple-negative breast cancer with no family history of breast or ovarian cancer, representing a group that previously was not recommended for *BRCA* testing. Six *BRCA* variants (5 *BRCA1*, 1 *BRCA2*) were found, for a variant rate of 11%. Finally, Gonzalez-Angulo et al (2011) in a study of 77 patients with triple-negative breast cancer, reported that 15 patients (19.5%) had *BRCA* variants (12 in *BRCA1*, 3 in *BRCA2*).

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

Myriad Genetic Laboratories offers the following tests:

- Comprehensive BRACAnalysis® test includes complete sequencing of *BRCA1* and *BRCA2* and gap polymerase chain reaction for 5 common rearrangements (deletions, duplications) in *BRCA1*
- BRACAnalysis® Large Rearrangement Test (BART™) is a reflex test for patients who test negative on the Comprehensive BRACAnalysis® test to detect uncommon large rearrangements in *BRCA1* and *BRCA2*
- Integrated BRACAnalysis® test includes BART™ as part of *BRCA1* or *BRCA2* analysis
- BRACAnalysis CDxs® is intended to detect germline *BRCA1* and *BRCA2* variants to identify patients with breast or ovarian cancer who may be considered treatment with olaparib, niraparib, or talazoparib.

Quest Diagnostics offers BRCAvantage™, which includes sequencing of *BRCA* and *BRCA2* and a multiplex ligation-dependent probe amplification assay to detect both common and uncommon gene rearrangements.

LabCorp offers the BRCAssure^{SM} suite of tests, which includes: targeted *BRCA1* and *BRCA2* variant analysis; a founder mutation panel for Ashkenazi Jewish patients (3 variants); comprehensive *BRCA1* and *BRCA2* analysis (full gene sequencing plus analysis of common and uncommon large rearrangements); and deletion and duplication analysis of uncommon large rearrangements only (without sequencing) when comprehensive analysis is negative.

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In addition to the various individual variant tests which are the focus of this policy, numerous other multigene panel tests exist that include BRCA1/2 among other genes. Although these multigene panel tests are outside of the scope of this review, among them, it is worth noting that FoundationOne CDx™ (F1CDx) is an FDA-approved companion diagnostic for use of Lynparza® (olaparib) and Rubraca® (rucaparib) in accordance with their respective FDA labels in women with ovarian cancer. F1CDx is FDAapproved to assess BRCA1/2 and other homologous recombination pathway genes (e.g. ATM, BRIP1, CHEK2, FANCA, FANCL, FANCM, NBN, RAD51C, RAD51D, and RAD54L as well as MSI and DNA mismatch repair genes (MLH1, MSH2, MSH6, PMS2). FoundationOne CDx is also FDA-approved for determining homologous recombination deficiency based on genomic loss of heterozygosity (LOH) and BRCA mutant status

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have cancer or a personal or family cancer history and meet criteria suggesting a risk of HBOC syndrome who receive genetic testing for a *BRCA1* or *BRCA2* variant, the evidence includes a TEC Assessment and studies of variant prevalence and cancer risk. Relevant outcomes are overall survival, disease-specific survival, test validity, and quality of life. The accuracy of variant testing has been shown to be high. Studies of lifetime risk of cancer for carriers of a *BRCA* variant have shown a risk as high as 85%. Knowledge of *BRCA* variant status in individuals at risk of a *BRCA* variant may impact health care decisions to reduce risk, including intensive surveillance, chemoprevention, and/or prophylactic intervention. In individuals with *BRCA1* or *BRCA2* variants, prophylactic mastectomy and oophorectomy have been found to significantly increase disease-specific survival and overall survival. Knowledge of *BRCA* variant status in individuals diagnosed with breast cancer may impact treatment decisions. A randomized controlled trial has reported that patients with human epidermal growth factor receptor 2-negative metastatic breast cancer and a *BRCA* variant experienced significantly longer progression-free survival with a targeted therapy vs standard therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have other high-risk cancers (e.g., cancers of the fallopian tube, pancreas, prostate) who receive genetic testing for a *BRCA1* or *BRCA2* variant, the evidence includes studies of variant prevalence and cancer risk. Relevant outcomes are overall survival, disease-specific survival, test validity, and quality of life. The accuracy of variant testing has been shown to be high. Knowledge of *BRCA* variant status in individuals with other high-risk cancers can inform decisions regarding genetic counseling, chemotherapy, and enrollment in clinical trials. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

POLICY TITLE	GENETIC TESTING FOR BRCA1 OR BRCA2 FOR HEREDITARY BREAST/OVARIAN CANCER SYNDROME AND OTHER HIGH-RISK CANCERS
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V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
81162	81163	81164	81165	81166	81167	81212	81215	81216
81217	81432	81433	0138U	0172U				

ICD-10-CM Diagnosis Code	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast

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C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast

POLICY TITLE	GENETIC TESTING FOR BRCA1 OR BRCA2 FOR HEREDITARY BREAST/OVARIAN CANCER SYNDROME AND OTHER HIGH-RISK CANCERS
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C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C61	Malignant neoplasm prostate
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.81	Secondary malignant neoplasm of breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
Z15.01	Genetic susceptibility to malignant neoplasm of breast
Z15.02	Genetic susceptibility to malignant neoplasm of ovary
Z80.0	Family history of malignant neoplasm of digestive organs
Z80.3	Family history of malignant neoplasm of breast
Z80.41	Family history of malignant neoplasm of ovary
Z80.42	Family history of malignant neoplasm of prostate
Z80.8	Family history of malignant neoplasm of other organs or systems
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate

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X. POLICY HISTORY

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MP 2.211	**CAC 4/29/03**
	CAC 9/28/04
	CAC 9/27/05
	CAC 7/25/06
	CAC 9/25/07
	CAC 7/29/08
	12/12/08 Definition Change
	CAC 7/28/09

POLICY TITLE	GENETIC TESTING FOR BRCA1 OR BRCA2 FOR HEREDITARY BREAST/OVARIAN CANCER SYNDROME AND OTHER HIGH-RISK CANCERS
POLICY NUMBER	MP-2.211

	CAC 5/25/10 The following indications were added to medical policy to reflect BCBSA recent revision: fallopian tube and peritoneal cancer. BART was added as an example test for genomic rearrangements. Testing for genomic rearrangements added to description/background. DeCode BreastCancer™ Test added as investigational.
	10/1/10. Note added to policy to address the US Preventive Services Task Forces (USPSTF) recommendations for genetic counseling.
	CAC 10/25/11 Consensus Review
	CAC 4/24/12 Policy criteria for BRCA mutation testing in cancer affected women who do not have a known family history of breast, epithelial ovarian, fallopian tube, or primary peritoneal cancer revised to match BCBSA policy criteria. NCCN definition of high risk BRCA mutation added to policy criteria section. Removed information regarding Non-BRCA Breast Cancer Risk Assessment (OncoVue®) and testing for one or more single nucleotide polymorphisms (SNPs) (e.g. deCode) and created separate medical policies. Testing for one or more single nucleotide polymorphisms (SNPs) remains investigational and non-BRCA breast cancer risk assessment (OncoVue®) remains investigational per BCBSA medical policy.
	03/04/2013- codes reviewed
	CAC 3/26/13 Minor. • For ***BRCA1* and *BRCA2* Mutation Testing in Cancer-Affected Individuals** o Policy statement edited for clarity and redundancy around epithelial ovarian/fallopian tube/primary peritoneal cancer by; ▪ deleting "Women who do not have a known family history of breast, epithelial ovarian, fallopian tube or primary peritoneal cancer" and adding "Women who are affected with breast cancer or pancreatic cancer who are not from families with a high risk of BRCA1 and BRCA2 mutation as defined in the Policy Guidelines". ▪ deleting bullet "epithelial ovarian/fallopian tube/primary peritoneal cancer at any age". o Medical necessary statement for testing added for women with breast cancer and two or more close relatives with pancreatic cancer. • Medically necessary testing for Genomic Rearrangements of the *BRCA1* and *BRCA2* Genes (BART) changed to remove additional criteria required for testing. Deleted the following; o there are 3 or more family members (one lineage) affected with breast or ovarian or fallopian tube or primary peritoneal **c**ancer (see High-risk *BRCA1* or *BRCA2* Definitions (USPSTF and NCCN) section above); **or** o who have a risk of a BRCA mutation of at least 10%
	CAC 11/26/13 Consensus review. References updated. No changes to the policy statements. Policy revised to remove FEP variation**.** NCCN guidelines/testing criteria updated.
	CAC 5/20/14 Policy being revised to adopt BCBSA. Policy updated to replace 2005 USPTSF recommendations with 2013 USPTSF recommendations.

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	References updated. Rationale added. Policy statements and guidelines rewritten for clarity with no substantive content changes. Policy title changed to "Genetic Testing for Hereditary Breast and/or Ovarian Cancer". Policy coded.
	Administrative posting 1/1/15- FEP variation revised to reflect genetic counseling and evaluation services required for preventive BRCA testing**.**
	CAC 7/21/15 Minor review. Information on CHEK2 testing extracted from this policy and moved to new policy MP 2.282 Genetic Testing for CHEK2 Mutations for Breast Cancer created. Testing strategy added to Policy Guidelines; Policy statement addressing type of testing (i.e., large genomic rearrangements) rather than patient selection/criteria for testing was deleted. Deleted statement indicating testing for genomic rearrangements of the *BRCA1* and *BRCA2* genes may be considered **medically necessary** in patients who meet criteria for *BRCA* testing, whose testing for point mutations is negative. Title changed to reflect focus on hereditary breast and ovarian cancer syndrome (HBOC). Now titled Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (BRCA1/BRCA2) (formerly Genetic Testing for Hereditary Breast and/or Ovarian Cancer. LCD changed from L33638 to L35062 Rationale and references updated.
	Administrative 1/20/16: 2016 coding update (81162).
	CAC 5/31/16 Minor review. For those with a personal history of cancer, changed MN criteria for testing to include anyone with a personal history of a BRCA related cancer without additional criteria required. Coding reviewed.
	12/1/16 Admin update. Changed Medicare variation referencing L35062 Biomarkers Overview to L36715 BRCA1 and BRCA2 Genetic Testing. Variation reformatting. Variation Reformatting 12/5/16
	Admin 1/1/17 Products changed from SeniorBlue to BlueJourney
	CAC 7/25/17 Consensus. No change to policy statements. References and rationale updated. Coding Reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	3/29/18 Consensus review. No changes to the policy statements. Throughout the policy the word "mutation" was revised to "variant" when indicated. Background, rationale, references, and appendix updated.
	1/1/19 Admin Update: Added new codes 81163-81167. Removed deleted CPT codes.
	2/28/19 Minor review. First medically necessary policy statement updated to reflect changes to NCCN recommendation. Title of policy changed to "Genetic Testing for BRCA1 or BRCA2 for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers". Formerly Genetic Testing for Hereditary Breast/Ovarian Cancer Syndrome (BRCA1/BRCA2). Coding reviewed and updated.

POLICY TITLE	GENETIC TESTING FOR BRCA1 OR BRCA2 FOR HEREDITARY BREAST/OVARIAN CANCER SYNDROME AND OTHER HIGH-RISK CANCERS
POLICY NUMBER	MP-2.211

	10/1/19 Coding update. New code 0138U added.
	3/6/20 Consensus review. Policy statement unchanged. References, policy guidelines and regulatory status updated. Coding reviewed.
	7/1/20 Administrative review. New code 0172U added.

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