MEDICAL POLICY

POLICY TITLE	**GERMLINE GENETIC TESTING FOR GENE VARIANTS ASSOCIATED WITH BREAST CANCER IN INDIVIDUALS AT HIGH BREAST CANCER RISK (CHEK2, ATM, AND BARD1) (FORMERLY GENE VARIANTS (PALB2, CHEK2, AND ATM) ASSOCIATED WITH BREAST CANCER IN INDIVIDUALS AT HIGH BREAST CANCER RISK)**
POLICY NUMBER	**MP 2.279**

Effective Date:	**10/1/2023**

I. POLICY

Testing for *CHEK2*, *ATM,* and *BARD1* variants in the assessment of breast cancer risk is considered **investigational.**

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the above **investigational** testing.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

POLICY GUIDELINES

Criteria for Genetic Risk Evaluation

The National Comprehensive Cancer Network (NCCN) provides criteria for genetic risk evaluation for individuals with no history of breast cancer and for those with a breast cancer. Updated versions of the criteria are available on the NCCN website.

The recommended testing strategy for BRCA1, BRCA2, and PALB2 is described in MP 2.211 - Germline Genetic Testing for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers (BRCA1, BRCA2, PALB2).

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.

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Genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

Cross-references:

MP 2.211 Germline Genetic Testing for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers (BRCA1, BRCA2, PALB2)
MP 2.255 Genetic testing for PTEN Hamartoma Tumor Syndrome
MP 2.274 Genetic testing for Li-Fraumeni Syndrome
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 Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO-The FEP program dictates that all drugs, devices, or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices, or biological products may be assessed based on medical necessity.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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BREAST CANCER AND GENETICS

The National Cancer Institute estimated there would be 287,850 new cases of female breast cancer (FBC) and 2,710 cases of male breast cancer (MBC) diagnosed in 2022, with an expected 43,250 deaths due to FBC and 530 deaths due to MBC. Although non-Hispanic, white women are more likely to be diagnosed with breast cancer than non-Hispanic Black, Asian/Pacific Islander, American Indian/Alaska Native and Hispanic women, non-Hispanic Black women have the highest risk of breast cancer mortality. Breast cancers can be classified as sporadic, familial, or hereditary. Most breast cancers are sporadic (70% to 75%), occurring in women without a family history of the disease. Familial cancers (15% to 25%) aggregate within families but lack clearly discernable patterns of inheritance and are likely polygenic. Hereditary cancers have discernable inheritance patterns, often occur at younger ages, may be bilateral, and comprise between 5% and 10% of breast cancers. Most inherited autosomal dominant breast cancer can be attributed to the *BRCA1* and *BRCA2* variants. For women who inherit a

pathogenic *BRCA1* and *BRCA2* variants, 45% to 72% will develop breast cancer by 70-80 years of age; risk in men with *BRCA1* and *BRCA2* variants is much lower (1% and 7%, respectively). Pathogenic variants in other highly penetrant genes (e.g., *TP53, CDH1, PTEN, STK11*) contribute to a smaller number of cancer cases. *CHEK2 and ATM* are believed to be moderately penetrant and *BARD1* has alternatively been described as moderate, low/moderate, and low penetrance.

Penetrance of Pathogenic Variants

Penetrance is the risk conferred by a pathogenic variant or the proportion of individuals with the variant expected to develop cancer. Variant penetrance is considered high, moderate, or low according to lifetime risk: high (greater than 50%), moderate (20% to 50%), and low (less than 20%) (Corresponding relative risks of approximately greater than or equal to 5, 1.5 to 5, and less than1.5). Variants in only a few breast cancer–susceptibility genes (*BRCA1* and *BRCA2* [hereditary breast/ovarian cancer syndrome], *TP53* [Li-Fraumeni syndrome], *PTEN* [Cowden syndrome], *CDH1* [hereditary diffuse gastric cancer], *STK11* [Peutz-Jeghers syndrome]) are considered highly penetrant. For example, a woman with a *BRCA1* or *BRCA2* variant has a relative risk of 11 to 12 compared with the general population. Penetrance can be modified by environmental factors and by family history, which is a particularly important modifier for low and moderate penetrance genes. Moreover, specific pathogenic variants within a gene may confer somewhat different risks.

Determining Variant Pathogenicity

Determining the pathogenicity of variants in a more commonly detected cancer-susceptibility gene (e.g., founder sequence mutations) is generally straightforward because associations are repeatedly observed. For uncommonly identified variants, such as those found in a few individuals or families, defining pathogenicity can be more difficult. For example, predicting the pathogenicity of previously unidentified variants typically requires in silico (computational) analysis predicting protein structure/function, evolutionary conservation, and splice site prediction. The approach to defining pathogenicity is clearly outlined in standards and reporting guidelines. Still, distinctions between a variant of uncertain significance and a pathogenic one from different laboratories may not always be identical.

Genes Associated with a Moderate Penetrance of Breast Cancer

CHEK2 Gene

The *CHEK2* (checkpoint kinase 2) gene is activated in response to DNA double-strand breakage and plays a role in cell-cycle control, DNA repair, and apoptosis.

In 2002, a single recurrent truncating mutation in the *CHEK2* gene (c.1100delC) was first reported as a cause of breast cancer, and studies have since confirmed this. The incidence of *CHEK2* variants varies widely among populations. It is most prevalent in Eastern and Northern

Europe, where the population frequency of the c.1100delC allele ranges from 0.5% to 1.4%; the allele is less frequent in North America and virtually absent in Spain and India. When compared with non-Hispanic, white individuals, prevalence appears to be lower in Black (odds ratio [OR] 0.17; 95% CI, 0.07 to 0.33), Asian (OR 0.14; 95% CI, 0.04 to 0.34), and Hispanic (OR 0.36; 95% CI, 0.18 to 0.62) individuals.

Although most data for truncating *CHEK2* variants are limited to the c.1100delC allele, 3 other founder variants of *CHEK2* (IVS2+1G>A, del5395, I157T) have been associated with breast cancer in Eastern Europe. Both IVS2+1G>A and del5395 are protein-truncating variants, and I157T is a missense variant. The truncating variants are associated with breast cancer in the Slavic populations of Poland, Belarus, Russia, and the Czech Republic. The I157T variant has a wider geographic distribution and has been reported to be associated with breast cancer in Poland, Finland, Germany, and Belarus.

ATM Gene

ATM (ataxia-telangiectasia mutated), located on chromosome 11q22.3, is associated with the autosomal recessive condition ataxia-telangiectasia. This condition is characterized by progressive cerebellar ataxia with onset between the ages of 1 and 4 years, telangiectasias of the conjunctivae, oculomotor apraxia, immune defects, and cancer predisposition. Female *ATM* heterozygotes carriers have a risk of breast cancer about twice as high as that of the general population; however, they do not appear to have an elevated ovarian cancer risk.

BARD1 Gene

The *BARD1* (BRCA1-associated RING [Really Interesting New Gene] domain) gene is located on chromosome 2 (sequence 2q34-q35). *BARD1* encodes a protein which interacts with the N-terminal region of *BRCA1*, and *BARD1* and *BRCA1* can form a heterodimer by their N-terminal RING finger domains which form a stable complex. *BARD1* variants have been associated with an increased risk of estrogen-receptor (ER) negative breast cancer, triple-negative breast cancer, and with breast cancer at a younger age (under age 50 years) in some studies, but do not appear to increase risk of ovarian cancer.

IDENTIFYING WOMEN AT RISK OF AN INHERITED SUSCEPTIBILITY TO BREAST CANCER

Breast cancer risk can be affected by genetic and nongenetic factors. The risk is increased in women experiencing an earlier age at menarche, nulliparity, late age of first pregnancy, fewer births, late menopause, proliferative breast disease, menopausal hormone therapy, alcohol, obesity, inactivity, and radiation. A family history of breast cancer confers between a 2- and 4-fold increased risk varying according to several factors: the number and closeness of affected relatives, age at which cancers developed, whether breast cancers were bilateral, and if other cancers occurred (e.g., ovarian). In men, family history is associated with increased risk of breast cancer, along with being older than 65 years, health conditions that result in elevated estrogen levels, and lifestyle factors (eg, obesity). For a woman without breast cancer, the probability of detecting a pathogenic variant can be estimated from a detailed multigenerational

pedigree (e.g., Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm), screening tools (e.g., BRCAPRO, Ontario Family History Assessment Tool, Manchester Scoring System, Referral Screening Tool, Pedigree Assessment Tool, Family History Screen), or by referring to guidelines that define specific family history criteria (e.g., The American College of Radiology). For women with breast cancer, family history also affects the likelihood of carrying a pathogenic variant.

Variant Interpretation

Valid variant classification is required to assess penetrance and is of particular concern for low prevalence variants. While there are guidelines for variant classification, the consistency of interpretation among laboratories is of interest. Balmaña et al (2016) examined the agreement in variant classification by different laboratories from tests for inherited cancer susceptibility from individuals undergoing panel testing. The Prospective Registry of Multiplex Testing is a volunteer sample of patients invited to participate when test results were provided to patients from participating laboratories. From 518 participants, 603 variants were interpreted by multiple laboratories and/or found in ClinVar. Discrepancies were most common with *CHEK2* and *ATM*. Given the nature of the sample, there was a significant potential for biased selection of women with either reported variants of uncertain significance or other uncertainty in interpretation. In addition, discrepancies were confined to missense variants. It is therefore difficult to draw conclusions concerning the frequency of discrepant conclusions among all tested women.

American Society of Breast Surgeons

A consensus guideline on genetic testing for hereditary breast cancer was updated in February 2019. Guidelines state that genetic testing should be made available to all individuals with a personal history of breast cancer and that such testing should include *BRCA1/BRCA2* and *PALB2*, with other genes as appropriate for the clinical scenario and patient family history. Furthermore, individuals who had previous genetic testing may benefit from updated testing. Finally, genetic testing should be made available to individuals without a personal history of breast cancer when they meet National Comprehensive Cancer Network (NCCN) guideline criteria. The guidelines also note that variants of uncertain significance are not clinically actionable.

For individuals with mutations in *ATM* and *CHEK2*, enhanced screening is recommended, however, the data are not sufficient to support risk-reducing mastectomy in the absence of other factors such as strong family history. For individuals with *BARD1* mutations, evidence is insufficient to support change in breast cancer risk management based on the presence of a mutation alone.

National Comprehensive Cancer Network

The NCCN (v.2.2022) guidelines on genetic/familial high-risk assessment for breast and ovarian cancer review single-gene tests for *CHEK2, ATM,* and *BARD1*. The guidelines state that for those that meet hereditary cancer testing criteria, testing for a specific familial pathogenic/likely pathogenic variant may be recommended for appropriate genes. For individuals who meet criteria with no known familial variants, comprehensive testing of a multigene panel may be considered. This testing may consider a number of genes, including but not limited to *CHEK2, ATM,* and *BARD1.* However, the inclusion of certain genes in the guideline does not imply the endorsement "for or against multigene testing for moderate-penetrance genes" and there are limited data on the degree of cancer risk associated with some genes in multigene panels. Testing an affected family member first has the highest likelihood of a positive result. The guidelines state that the panel recommends an annual mammogram for women with *CHEK2*, *ATM,* or *BARD1* mutations beginning at age 40, with consideration of annual breast magnetic resonance imaging. The guidelines also state there is insufficient evidence to draw conclusions on risk-reducing mastectomy in individuals with *CHEK2*, *ATM,* or *BARD1* mutations and that patients should be managed based on family history.

The NCCN guidelines on breast cancer screening and diagnosis (v.1. 2022) recommend the following:

- Annual mammogram.
- Annual breast magnetic resonance imaging if the patient has >20% risk of breast cancer based on models largely dependent on family history.
- Consideration of a risk-reducing strategies based on family history.

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. *CHEK2*, *ATM and BARD1* testing are available under the auspices of the Clinical Laboratory Improvement Amendments. Laboratories offering testing and voluntarily listing is available through the National Center for Biotechnology Genetic Testing Registry. 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.

Customized next-generation sequencing panels provide simultaneous analysis of multiple cancer predisposition genes, and typically include both moderate- and high-penetrant genes.

IV. RATIONALE

TOP

SUMMARY OF EVIDENCE

For individuals with risk of hereditary breast/ovarian cancer who receive genetic testing for a *CHEK2* variant, the evidence includes studies of variant prevalence and studies of breast cancer risk. The relevant outcomes are overall survival, disease-specific survival, and test validity. The available studies on clinical validity have demonstrated that *CHEK2* variants are of moderate penetrance, and confer a risk of breast cancer two to four times that of the general population. Direct evidence for the clinical utility of genetic testing for *CHEK2* variants in individuals with risk of hereditary breast/ovarian cancer was not identified. It is unclear the relative risk associated with the moderate penetrance variants other than *PALB2* would increase risk enough beyond that already conferred by familial risk to change screening behavior. In contrast to high-penetrance variants, there is unlikely to be a similar benefit-to-risk calculus for risk-reducing mastectomy in women with a moderate penetrance variant such as *CHEK2* . The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with risk of hereditary breast/ovarian cancer who receive genetic testing for an *ATM* variant, the evidence includes studies of variant prevalence and studies of breast cancer risk. The relevant outcomes are overall survival, disease-specific survival, and test validity. The available studies on clinical validity have demonstrated that *ATM* variants are of moderate penetrance; moreover, *ATM* variants confer a risk of breast cancer two to four times that of the general population. Direct evidence for the clinical utility of genetic testing for *ATM* variants in individuals with risk of hereditary breast/ovarian cancer was not identified. It is unclear that the relative risk associated with the moderate penetrance variants would increase risk enough beyond that already conferred by familial risk to change screening behavior. In contrast to high-penetrance variants, there is unlikely to be a similar benefit-to-risk calculus for preventive interventions in women with an *ATM* variant. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with risk of HBOC who receive genetic testing for a *BARD1* variant, the evidence includes studies of variant prevalence and studies of breast cancer risk. Relevant outcomes are OS, disease-specific survival, and test validity. The available studies on clinical validity have demonstrated that *BARD1* variants are of low to moderate penetrance; *BARD1* variants confer a risk of breast cancer about 2 to 3 times that of the general population. Direct evidence for the clinical utility of genetic testing for *BARD1* variants in individuals with risk of HBOC was not identified. It is unclear that the RR associated with the low to moderate penetrance variants would increase risk enough beyond that already conferred by familial risk to change screening behavior. In contrast to high-penetrance variants, there is unlikely to be a similar benefit-to-risk calculus for preventive interventions in women with a low to moderate penetrance

variant such as *BARD1*. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS TOP

NA

VI. BENEFIT VARIATIONS TOP

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 Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER TOP

Capital Blue Cross'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 Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION TOP

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.

Investigational, therefore not covered:

Procedure Codes								
81408	81479	0102U	0129U	0131U	0136U			

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POLICY NUMBER	MP 2.279

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
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
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified 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

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POLICY NUMBER	MP 2.279

ICD-10-CM Diagnosis Code	Description
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
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
Q85.81	PTEN hamartoma tumor syndrome
Q85.82	Other Cowden syndrome
Z80.3	Family history of malignant neoplasm of breast
Z80.41	Family history of malignant neoplasm of ovary

IX. REFERENCES

TOP

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X. POLICY HISTORY

TOP

MP 2.279	**CAC 6/2/15** New policy adopting BCBSA. PALB2 genetic testing is investigational.
	CAC 5/31/16 Consensus review. Policy statement unchanged. Policy Guidelines and Appendix added. Description/Background, Rationale, and References updated. Coding reviewed.
	Administrative Update 11/22/16 Variation reformatting
	CAC 5/23/17 Minor revision. • Genetic Testing for CHEK2 Mutations (previously addressed within MP-2.282) and ATM testing were added to this policy. A policy statement was added that CHEK2 and ATM variant testing in the assessment of breast cancer risk is considered investigational.

POLICY TITLE	GERMLINE GENETIC TESTING FOR GENE VARIANTS ASSOCIATED WITH BREAST CANCER IN INDIVIDUALS AT HIGH BREAST CANCER RISK (CHEK2, ATM, AND BARD1) (FORMERLY GENE VARIANTS (PALB2, CHEK2, AND ATM) ASSOCIATED WITH BREAST CANCER IN INDIVIDUALS AT HIGH BREAST CANCER RISK)
POLICY NUMBER	MP 2.279

	• MP-2.282, Genetic Testing for CHEK2 Mutations for Breast Cancer, will be archived. • PALB2 testing in patients that meet the criteria for genetic risk assessment is now considered medically necessary. The policy statement has been revised. • The policy title was changed to “Moderate Penetrance Variants Associated with Breast Cancer in Individuals at High Breast Cancer Risk.” Description/Background, Rationale, and Reference sections updated. Coding Reviewed.
	1/2/2018 Consensus review. No change to policy statements. References, Background, and rationale updated.
	1/14/19 Consensus review. No change to the policy statements. Background and references updated. Policy guidelines and rationale revised. Appendix removed.
	10/1/19 Coding updated. New code 0137U added to policy.
	1/1/20 Coding updated. New codes added 81307 and 81308.
	2/17/20 Consensus review. No change to policy statement. Coding reviewed.
	10/12/21 Consensus review. Title changed to "Gene Variants (PALB2, CHEK2, and ATM) Associated With Breast Cancer in Individuals at High Breast Cancer Risk". Policy statements unchanged. Addition of NCCN statement, FEP statement revised, Description/Background section updated. Added unspecified diagnosis codes.
	7/29/2022 Administrative review. Added 2 new ICD-10 codes (Q85.81-Q85.82). Effective date 10/1/2022
	10/27/2022 Minor review. Removed PALB2 from this policy as it will now be housed in MP 2.211. Added BARD1 testing as INV per BCBSA. Changed title. Updated background, rationale, references. Added codes 0102U, 0129U, 0131U and 0136U as INV, and removed codes related to PALB2.
	9/12/2023 Administrative review. Revised code Q85.81, eff. 10/1/2023

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