



# Louisiana

## Risk-Reducing Mastectomy

Policy # 00141

Original Effective Date: 09/27/2004

Current Effective Date: 11/11/2024

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider risk-reducing mastectomy in individuals without breast cancer who are at high risk of breast cancer to be **eligible for coverage**.\*\*

#### Patient Selection Criteria:

Coverage eligibility will be considered for risk-reducing mastectomy in individuals without breast cancer who are at high risk of breast cancer when **ANY** of the following criteria are met:

- A known *BRCA1* or *BRCA2* pathogenic or likely pathogenic gene variant; **OR**
- Another pathogenic or likely pathogenic gene variant associated with high breast cancer risk, i.e., *TP53* (Li-Fraumeni syndrome), *PTEN* (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), *CDH1*, *STK11* and *PALB2*; **OR**
- High risk (lifetime risk 20% or greater) of developing breast cancer as identified by a model that is largely defined by family history, i.e. National Cancer Institute Breast Cancer Risk Assessment Tool (also called the Gail model); **OR**
- Strong family history of breast cancer based on **ANY** of the following:
  - A first-degree blood relative diagnosed with bilateral breast cancer; **OR**
  - A first-degree blood relative diagnosed with breast cancer before age 45; **OR**
  - Two or more first-degree blood relatives with breast cancer irrespective of age at diagnosis;

**OR**

- Received radiation therapy to the chest between the ages of 10 and 30 years.

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## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers risk-reducing mastectomy in individuals without breast cancer for all other indications to be **investigational**.\*

### *Note:*

*This medical policy and criteria are not applicable to contralateral risk-reducing mastectomy in individuals following a breast cancer diagnosis. Treating physicians shall consider recognized, evidence-based standards such as those by the National Comprehensive Cancer Network in making recommendations. Decisions regarding treatment procedures following a breast cancer diagnosis are to be made by the patient and treating physician.*

## Policy Guidelines

It is strongly recommended that all candidates for risk-reducing mastectomy undergo counseling regarding cancer risks from a health professional other than the operating surgeon skilled to assess cancer risk and to discuss various treatment options, including increased surveillance or chemoprevention with tamoxifen or raloxifene.

There is no standardized method for determining an individual's risk of breast cancer that incorporates all possible risk factors. There are validated risk prediction models, but they are based primarily on family history.

Some known individual risk factors confer a high risk by themselves. The following list includes factors known to indicate a high risk of breast cancer:

- Lobular carcinoma in situ
- A known *BRCA1* or *BRCA2* variant
- Another gene variant associated with high risk, eg, *TP53* (Li-Fraumeni syndrome), *PTEN* (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), *CDH1*, *STK11*, and *PALB2*
- Received radiotherapy to the chest between 10 and 30 years of age.

NCCN v.2.2024 (MS-27) guidelines note that the NCCN Panel strongly recommends risk-reduction therapy in individuals with AH (ductal and/or lobular atypical hyperplasia) or LCIS (lobular

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carcinoma in situ). While risk-reducing mastectomy has been previously considered for LCIS, the currently preferred approach for LCIS is a risk-reducing endocrine agent. “Individuals with AH (ductal and/or lobular atypical hyperplasia) have an 86% reduction in risk with an endocrine agent. LCIS (lobular carcinoma in situ) has a >50% reduction in risk with an endocrine agent. Risk-reducing endocrine agents should be strongly recommended for individuals with AH and LCIS (for risk-reducing endocrine therapy agent options, see BRISK-6).”

It is also noted (BRISK-5) that risk-reducing mastectomy should generally be considered in individuals with a pathogenic/likely pathogenic genetic variant in high penetrance breast cancer susceptibility genes (See NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic), compelling family history, or those receiving chest wall radiation before 30 years of age. There is no established benefit of risk-reducing mastectomy in individuals with pathogenic/likely pathogenic variants in moderate or low-penetrance breast cancer susceptibility genes in the absence of a compelling family history.

A number of other factors may increase the risk of breast cancer but do not by themselves indicate high risk (generally considered to be a lifetime risk of  $\geq 20\%$ ). It is possible that combinations of these factors may be indicative of high risk, but it is not possible to give quantitative estimates of risk. As a result, it may be necessary to individualize the estimate of risk by taking into account numerous risk factors.

A number of risk factors, not individually indicating high risk, are included in the National Cancer Institute Breast Cancer Risk Assessment Tool, also called the Gail model.

Another breast cancer risk assessment tool, used in the Women Informed to Screen Depending on Measures of Risk trial, is the Breast Cancer Surveillance Consortium (BCSC) Risk Calculator (<https://tools.bcsc-scc.org/bc5yearrisk/calculator.htm>). The following information is used in that assessment tool:

- History of breast cancer, ductal carcinoma in situ, breast augmentation, or mastectomy
- Age/race/ethnicity
- Number of first-degree relatives (mother, sister, or daughter) diagnosed with breast cancer
- Prior breast biopsies (positive or negative)

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- Breast Imaging Reporting and Data System (BI-RADS) breast density (radiologic assessment of breast tissue density by radiologists who interpret mammograms).

### **Background/Overview**

Risk-reducing mastectomy may be considered in individuals thought to be at high-risk of developing breast cancer, either due to family history, presence of genetic variants (eg, *BRCA1*, *BRCA2*, *PALB2*), having received radiotherapy to the chest, or the presence of lesions associated with an increased cancer risk such as lobular carcinoma in situ. Therefore, bilateral risk-reducing mastectomy may be performed to eliminate the risk of cancer arising elsewhere; chemoprevention and close surveillance are alternative risk-reduction strategies. Risk-reducing mastectomies are typically bilateral but can also describe a unilateral mastectomy in a patient who has previously undergone or is currently undergoing a mastectomy in the opposite breast for invasive cancer (ie, contralateral risk-reducing mastectomy). Use of contralateral risk-reducing mastectomy has increased in the U.S. An analysis of data from the National Cancer Database found that the rate of contralateral risk-reducing mastectomy in individuals diagnosed with unilateral stage I, II, or III breast cancer increased from approximately 4% in 1998 to 9.4% in 2002. Another analysis of data from the National Cancer Database (N=765,487) found that individuals with unilateral stage I breast cancer commonly underwent contralateral risk-reducing mastectomy, with an increase between 2006 (6%) and 2016 (9%).

The appropriateness of a risk-reducing mastectomy is a complicated risk-benefit analysis that requires estimates of a patient's risk of breast cancer, typically based on the patient's family history of breast cancer and other factors. Several models are available to assess risk of breast cancer. The specific risk factors included in the models vary, but all incorporate characteristics related to age, reproductive history, and family history. Race should also be considered when assessing risk. According to an analysis of the Surveillance, Epidemiology, and End Results program (SEER) from 2000 to 2015 (N=459,916), the risk of invasive contralateral breast cancer was higher in Black (hazard ratio, 1.44; 95% confidence interval, 1.35 to 1.54) and Hispanic individuals (hazard ratio, 1.11; 95% confidence interval, 1.02 to 1.20) compared to White individuals. In addition to the patient's risk assessment, the choice of a risk-reducing mastectomy is based on patient tolerance for risk, consideration of changes to appearance and need for additional cosmetic surgery, and the risk-reduction offered by mastectomy versus other options.

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## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Mastectomy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

### **Description**

Risk-reducing mastectomy is defined as the removal of the breast in the absence of malignant disease to reduce the risk of breast cancer occurrence.

### **Summary of Evidence**

For individuals who have a high-risk of breast cancer or extensive mammographic abnormalities precluding excision or biopsy who receive a risk-reducing mastectomy, the evidence includes systematic reviews. Relevant outcomes are overall survival (OS), disease-specific survival, functional outcomes, and treatment-related morbidity. Studies have found that a risk-reducing mastectomy lowers subsequent breast cancer incidence and increases survival in select high-risk patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have unilateral breast cancer but are not otherwise at high-risk who receive a contralateral risk-reducing mastectomy, the evidence includes systematic reviews and observational studies. Relevant outcomes are OS, disease-specific survival, functional outcomes, and treatment-related morbidity. Available studies do not demonstrate a consistent survival benefit in individuals without high-risk criteria. Moreover, there are risks associated with a contralateral risk-reducing mastectomy for both the primary surgical and reconstruction procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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## **Supplemental Information**

### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### **2016 Input**

In response to requests, input was received from 1 specialty society and 6 academic medical centers while this policy was under review in 2016. Input addressed the use of contralateral prophylactic (risk-reducing) mastectomy in women with unilateral breast cancer who are not otherwise at high-risk for developing breast cancer in the contralateral breast. The input was mixed. Clinicians offered suggestions for modifying high-risk criteria but there was no consensus on potential additional risk factors.

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **American College of Medical Genetics and Genomics**

In 2021, the American College of Medical Genetics and Genomics (ACMG) published a guideline on the management of individuals with *PALB2* variants, which recommends that risk-reducing mastectomy be considered as an option based on personal risk. In 2023, the ACMG published a guideline on the management of individuals with *CHEK2* variants, which also recommends that risk-reducing mastectomy be considered as an option based on personal risk.

### **American Society for Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology**

In 2020, the American Society for Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology published joint guidelines on management of hereditary breast

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cancer. The guideline discusses management of patients with breast cancer with germline mutations in breast cancer susceptibility genes (eg, *BRCA1/2*, *ATM*, *TP53*) and makes the following recommendations regarding risk-reducing mastectomy:

"Surgical management of the index malignancy (...contralateral risk-reducing mastectomy [CRRM]) in *BRCA1/2* mutation carriers should be discussed, considering the increased risk of CBC [contralateral breast cancer] and possible increased risk of an ipsilateral new primary breast cancer compared with noncarriers (Type: formal consensus; Evidence quality: intermediate; Strength of recommendation: strong)."

"For women with breast cancer who have a *BRCA1/2* mutation and who have been treated or are being treated with unilateral mastectomy, CRRM should be offered. CRRM is associated with a decreased risk of CBC; there is insufficient evidence for improved survival."

"Decisions regarding risk-reducing mastectomy (bilateral or contralateral) are highly personal and must be individualized for every patient. Studies show that women who opt for prophylactic mastectomy report positive outcomes, including decreased concern about developing breast cancer. This benefit must be weighed against possible problems with implants or reconstructive therapy and potential adverse feelings related to body image, femininity, and sexuality. Most patients who opt for prophylactic mastectomy demonstrate satisfaction with their decision."

"For women with breast cancer who have a mutation in a moderate-penetrance breast cancer predisposition gene and who have been treated or are being treated with unilateral mastectomy, the decision regarding CRRM should not be based predominantly on mutation status. Additional factors that predict CBC such as age at diagnosis and family history should be considered, as they are in all cases. The impact of CRRM on decreasing risk of CBC is dependent on the risk of CBC for each individual gene. Data regarding the risk of CBC resulting from moderate-penetrance genes are limited (Type: formal consensus; Evidence quality: low; Strength of recommendation: moderate)."

The guideline also provides recommendations for assessing the risk of CBC and role of risk-reducing mastectomy in *BRCA1/2* mutation carriers (Evidence quality: low; Strength of recommendation: moderate) and in women with breast cancer who have a *BRCA1/2* mutation who have been treated or are being treated with unilateral mastectomy when considering contralateral risk-reducing

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mastectomy (Evidence quality: intermediate; Strength of recommendation: moderate). The guideline recommends consideration of the following:

- Age at diagnosis (the strongest predictor of future CBC)
- Family history of breast cancer
- Overall prognosis from this or other cancers (eg, ovarian)
- Ability of patient to undergo appropriate breast surveillance (magnetic resonance imaging [MRI])
- Comorbidities
- Life expectancy.

### **American Society of Breast Surgeons**

In 2016, a consensus statement from the American Society of Breast Surgeons made the following recommendations on contralateral risk-reducing mastectomy:

"CPM [contralateral prophylactic mastectomy] should be considered for those at significant risk of CBC [contralateral breast cancer]

- Documented *BRCA1/2* carrier
- Strong family history, but patient has not undergone genetic testing
- History of mantle chest radiation before age 30 years.

CPM can be considered for those at lower risk of CBC

- Gene carrier of... *CHEK-2, PALB2, p53, CDH1*
- Strong family history, patient *BRCA* negative, no known *BRCA* family member.

CPM may be considered for other reasons

- To limit contralateral breast surveillance (dense breasts, failed surveillance, recall fatigue)
- To improve reconstructed breast symmetry
- To manage risk aversion ... [or] extreme anxiety." (note: anxiety may be better managed through psychological support strategies.)

CPM should be discouraged

- Average-risk women with unilateral breast cancer
- Women with advanced index cancer

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- Women at high risk for surgical complications (e.g.,...comorbidities, obesity, smoker, diabetes)
- *BRCA* negative with a family of *BRCA*-positive carriers
- Male breast cancer, including *BRCA* carriers.

### **National Cancer Institute**

In 2024, the National Cancer Institute updated its fact sheet on risk-reducing surgery for breast cancer. The fact sheet stated individuals women with the following characteristics may consider bilateral risk-reducing mastectomy if they are known to have inherited a harmful mutation that increases their risk of developing breast cancer. The Institute states that individuals who are at high risk of breast cancer but have not inherited a harmful mutation, should talk to their doctors about the potential advantages and disadvantages of a risk-reducing mastectomy. These individuals include those who have radiation therapy to the chest (including the breasts) prior to the age of thirty, as well as those who have pleomorphic lobular carcinoma in situ (PLCIS) together with a strong family history of breast cancer.

- Deleterious variant in *BRCA1* or *BRCA2*
- Strong family history of breast cancer
- Lobular carcinoma in situ and family history of breast cancer
- Radiotherapy to the chest before the age of 50 years.

Considering contralateral risk-reducing mastectomy, the Institute stated that some individuals who have been diagnosed with cancer in one breast, especially those who are known to be at very high risk, may think about having the contralateral breast, removed; however, it is noted that physicians frequently advise against contralateral preventive mastectomy because these patients have a very low chance of getting breast cancer again, especially if they had adjuvant chemotherapy or hormone therapy during their treatment. Additionally, a contralateral mastectomy may raise the risk of complications and cause delays in treatment for the diagnosed cancer. Furthermore, there is currently insufficient evidence to suggest that contralateral prophylactic mastectomy lowers mortality. "Given that most women with breast cancer have a low risk of developing the disease in their contralateral breast, women who are not known to be at a very high risk but who remain concerned about cancer development in their other breast may want to consider options other than surgery to further reduce their risk of a contralateral breast cancer."

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### **National Comprehensive Cancer Network**

The National Comprehensive Cancer Network (NCCN) has made recommendations on several cancers relevant to this medical policy. On breast cancer risk-reduction (v.2.2024), the NCCN recommends:

"Risk-reducing mastectomy should generally be considered in individuals only in women with a pathogenic/likely pathogenic genetic variant mutation (not variants of undetermined significance) conferring a high risk for in high penetrance breast cancer susceptibility genes, compelling family history, or those receiving chest wall radiation before 30 years of age possibly with prior thoracic RT [radiation therapy] at <30 years of age. The value of risk-reducing mastectomy in individuals with pathogenic/likely pathogenic mutations in other genes associated with a 2-fold or greater risk for breast cancer ... in the absence of a compelling family history of breast cancer is unknown. Risk estimation is a complex and individualized process; the NCCN Panel does not recommend a specific risk cutoff for decision making regarding risk reducing mastectomy. Individualizing management is important"

For invasive breast cancer (v. 4.2024) the NCCN has discouraged contralateral risk-reducing mastectomy, except for certain high-risk situations (noted in the risk-reduction guideline previously discussed). The guidelines state:

"...risk reduction mastectomy of a breast contralateral to a known unilateral breast cancer treated with mastectomy or breast-conserving therapy is discouraged by the panel. "

As part of a genetic/familial high-risk assessment for breast, ovarian, and pancreatic cancer (v.3.2024), the NCCN recommends that the option of risk-reduction mastectomy be discussed in women with *BRCA*-related breast and/or ovarian syndrome, Li-Fraumeni syndrome, and Cowden syndrome or *PTEN* hamartoma tumor syndrome. In addition, the NCCN guidelines recommend that risk-reducing mastectomy be considered based on family history in women with certain genetic variants including *ATM*, *NF1*, *STK11*, *PALB2*, *CHEK2*, and *CDH1*.

### **Society of Surgical Oncology**

In 2017, the Society of Surgical Oncology updated its position statement on risk-reducing mastectomy. The position statement concluded the following about risk-reducing mastectomy:

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"There is no single-risk threshold above which risk-reducing mastectomy is clearly indicated, and it is important for treating physicians and surgeons to explain to individuals not only the risk assessment but also all available treatment strategies to facilitate a shared decision-making process."

"The available data suggest that BMP [bilateral prophylactic mastectomy] confers a survival advantage in women with the highest risk who undergo the procedure at a relatively early age ... the impact of CPM [contralateral prophylactic mastectomy] in women with invasive breast cancer is more difficult to assess ... however, CPM does not appear to confer a survival advantage."

### **U.S. Preventive Services Task Force Recommendations**

No U.S. Preventive Services Task Force recommendations for prophylactic mastectomy have been identified.

### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### **Ongoing and Unpublished Clinical Trials**

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in August 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

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## **Policy History**

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08/31/2004	Medical Director review
09/21/2004	Medical Policy Committee review
09/27/2004	Managed Care Advisory Council approval
09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review

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	Coverage eligibility unchanged
09/22/2005	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
10/04/2006	Medical Director review
10/18/2006	Medical Policy Committee approval. Policy statement unchanged. Addition of FDA and or other governmental regulatory approval. References added.
10/10/2007	Medical Director review
10/17/2007	Medical Policy Committee approval. No change to coverage eligibility.
10/01/2008	Medical Director review
10/22/2008	Medical Policy Committee approval. No change to coverage eligibility.
10/01/2009	Medical Policy Committee approval
10/14/2009	Medical Policy Implementation Committee approval. Added moderately increased risk for breast cancer to be eligible for coverage with criteria. Added last two criteria bullets for high risk breast cancer.
10/14/2010	Medical Policy Committee review
10/20/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/11/2012	Medical Policy Committee review
10/31/2012	Medical Policy Implementation Committee approval. The term “p53” was updated to the more current “TP53” terminology in the Patient Selection Criteria.
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. High risk criteria revised. Investigational statement reworded.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015	Medical Policy Committee review

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- 10/21/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 10/06/2016 Medical Policy Committee review
- 10/19/2016 Medical Policy Implementation Committee approval. Removed coverage statement on lobular carcinoma in situ and added LCIS to criteria for high risk. *CDH1*, or *STK11* mutation added to high risk criteria. Removed moderate risk from policy statement and a coverage statement for extensive abnormalities.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 10/05/2017 Medical Policy Committee review
- 10/18/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 10/04/2018 Medical Policy Committee review
- 10/17/2018 Medical Policy Implementation Committee approval. Title changed from “Prophylactic Mastectomy” to “Risk-Reducing Mastectomy”. “Prophylactic” mastectomy changed to “risk-reducing” mastectomy throughout the policy to reflect preferred terminology in the literature and by NCCN. Added examples of the National Cancer Institute Breast Cancer Risk Assessment Tool (also called the Gail model), or the Breast Cancer Surveillance Consortium (BCSC) Risk Calculator to the 4<sup>th</sup> criteria bullet for risk-reducing mastectomy in patients at high risk of breast cancer. Deleted the “When Services Are Eligible for Coverage” section. Added a Policy Guidelines section. Removed references to “extensive mammographic abnormalities” throughout the policy.
- 10/01/2020 Medical Policy Committee review
- 10/07/2020 Medical Policy Implementation Committee approval. Added the specification of patients without breast cancer to the eligible for coverage and investigational statements. Removed lobular carcinoma in situ (LCIS) from the Patient Selection Criteria. Removed “including but not limited to contralateral risk reducing mastectomy in women with breast cancer who do not meet risk criteria” from the investigational statement. A *Note* was added at the end of the coverage section with specific language from the HB 347 to reinforce that evidence-based standards (e.g. NCCN) are to be considered and decisions are to be made by the patient and treating provider.
- 10/07/2021 Medical Policy Committee review

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- 10/13/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 10/06/2022 Medical Policy Committee review
- 10/11/2022 Medical Policy Implementation Committee approval. Added “pathogenic or likely pathogenic gene” to describe variants in the eligible for coverage criteria. Added PALB2 to the eligible for coverage criteria list of gene variants for risk-reducing mastectomy in patients without breast cancer who are at high risk of breast cancer.
- 10/05/2023 Medical Policy Committee review
- 10/11/2023 Medical Policy Implementation Committee approval. Replaced “patients” with “individuals” in the Coverage section. Updated NCCN Guidelines to version 1.2024 with addition information in the Supplemental Information section. Updated the NCCN reference to version 1.2024.
- 10/03/2024 Medical Policy Committee review
- 10/08/2024 Medical Policy Implementation Committee approval. Removed the Breast Cancer Surveillance Consortium (BCSC) Risk Calculator from the third criteria bullet on high-risk. Added 4<sup>th</sup> criteria bullet with subcriteria for strong family history of breast cancer.

Next Scheduled Review Date: 10/2025

## Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	19303
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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