Risk-Reducing Mastectomy

Policy # 00141
Original Effective Date: 09/27/2004
Current Effective Date: 01/01/2021

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.

Note: Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (BRCA1 or BRCA2) is addressed separately in medical policy 00047.

Note: Genetic Cancer Susceptibility Panels Using Next Generation Sequencing is addressed separately in medical policy 00382.

Note: Moderate Penetrance Variants Associated With Breast Cancer in Individuals at High Risk Breast Risk is addressed separately in medical policy 00504.

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 patients 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 patients without breast cancer who are at high risk of breast cancer when ANY of the following criteria are met:

- A known *BRCA1* or *BRCA2* variant; OR
- Another gene variant associated with high risk, e.g. *TP53* (Li-Fraumeni syndrome), *PTEN* (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), *CDH1, or STK11* mutation; OR
- High risk (lifetime risk 20% or greater) of developing breast cancer as identified by models that are largely defined by family history, i.e. National Cancer Institute Breast Cancer Risk Assessment Tool (also called the Gail model), or the Breast Cancer Surveillance Consortium (BCSC) Risk Calculator; OR

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

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 patients 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 women 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 skilled other than the operating surgeon 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 a woman'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*, and *STK11*, or

- received radiotherapy to the chest between 10 and 30 years of age.

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 ≥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)
- BI-RADS breast density (radiologic assessment of breast tissue density by radiologists who interpret mammograms).

Background/Overview

Risk-reducing mastectomy may be considered in women thought to be at high-risk of developing breast cancer, either due to family history, presence of genetic variants (eg, *BRCA1*, *BRCA2*), 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 women diagnosed with unilateral stage I, II, or III breast cancer increased from approximately 4% in 1998 to 9.4% in 2002.

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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 risks, such as the Claus model and the Gail model. Breast cancer history in first- and second-degree relatives is used to estimate breast cancer risk in the Claus model. The Gail model uses the following five risk factors: age at evaluation, age at menarche, age at first live birth, the number of breast biopsies, and the number of first-degree relatives with breast cancer. 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 vs other options.

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

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.

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 and observational studies. Relevant outcomes are overall survival, 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 a meaningful 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 overall survival, disease-specific survival, functional outcomes, and treatment-related morbidity. Available studies do not demonstrate a consistent survival benefit in women 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 the effects of the technology on health outcomes.

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.

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

Society of Surgical Oncology

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

> "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."

National Cancer Institute
The National Cancer Institute (2013) updated its fact sheet on risk-reducing surgery for breast cancer. The fact sheet stated women with the following characteristics may consider bilateral risk-reducing mastectomy:

- 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: "Given that 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 their risk of a contralateral breast cancer."

American Society of Breast Surgeons
A consensus statement from the American Society of Breast Surgeons (2016) 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*, p*53*, *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 breast symmetry in reconstruction.
- To manage risk aversion … [or] extreme anxiety." (note: anxiety may better be measured through psychological support.)

CPM should be discouraged

- Average-risk women with unilateral breast cancer.
- Women with advanced stage index cancer….
- Women at high risk of surgical complications (e.g.,...comorbidities, obesity, smoking, diabetes).
- ...*BRCA* negative with a family of *BRCA*-positive carriers.
- "Males with breast cancer, including *BRCA* carriers."

National Comprehensive Cancer Network
The NCCN has made recommendations on several cancers relevant to this evidence review. On breast cancer risk-reduction (v.1.2019), the NCCN recommends:

> "Risk-reducing mastectomy should generally be considered only in women with a genetic mutation conferring a high risk for breast cancer..., compelling family history, or possibly with LCIS [lobular carcinoma in situs] or prior thoracic radiation therapy at <30 years of age…. The value of risk-reducing mastectomy in women with deleterious 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."

For invasive breast cancer (v.1.2019) 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:

> "the small benefits from contralateral prophylactic mastectomy for women with unilateral breast cancer must be balanced with the risk of recurrent disease from the known ipsilateral breast cancer, psychological and social issues of bilateral mastectomy, and the risks of contralateral mastectomy. The use of a prophylactic mastectomy contralateral to a breast treated with breast-conserving therapy is very strongly discouraged."

As part of a genetic/familial high-risk assessment for breast and ovarian cancer (v.3.2019), 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 *CHEK2*, *STK11*, and *CDH1*.

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 in June 2019 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 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

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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 to track BCBSA. Investigational statement reworded to track BCBSA.
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
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

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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 4th criteria bullet for risk-reducing mastectomy in patients at high risk of breast cancer. Deleted the "When Services Are Eligible for Coverage" section. Added the Policy Guidelines section from BCBSA's policy. 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.
Next Scheduled Review Date: 10/2021

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 2019 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	19301, 19302, 19303, 19305, 19306, 19307
HCPCS	No codes
ICD-10 Diagnosis	D05.00-D05.92, Z15.01, Z40.01, Z80.3

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

**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.

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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.