



Louisiana

Risk-Reducing Mastectomy

Policy # 00141

Original Effective Date: 09/27/2004

Current Effective Date: 01/01/2019

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 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 at high risk of breast cancer when ANY of the following criteria are met:

- Lobular carcinoma in situ (LCIS); or
- 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 for all other indications, including but not limited to contralateral risk-reducing mastectomy in women with breast cancer who do not meet risk criteria to be **investigational**.*

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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, e.g., *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 $\geq 20\%$). 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);
- 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 (e.g., *BRCA1*, *BRCA2*), having received radiotherapy to the chest, or the presence of lesions associated with an increased cancer risk such as

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lobular carcinoma in situ. Lobular carcinoma in situ is both a risk factor for all types of cancer, including bilateral cancer and, in some cases, a precursor to invasive lobular cancer. For those who develop invasive cancer, up to 35% may have bilateral cancer. 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 (i.e., contralateral risk-reducing mastectomy). Use of contralateral risk-reducing mastectomy has increased in the United States. 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.

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 5 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. FDA.

Centers for Medicare and Medicaid Services (CMS)

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.

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will

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be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

RISK-REDUCING MASTECTOMY

Clinical Context and Test Purpose

The purpose of risk-reducing mastectomy in patients who have a high risk of breast cancer precluding excision or biopsy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does risk-reducing mastectomy improve the net health outcome in women at high risk of breast cancer or precluding excision or biopsy?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is women at high risk of breast cancer or precluding excision or biopsy. High risk is generally considered to be a lifetime risk of 20% or greater. The following list of factors may indicate a high risk of breast cancer:

- lobular carcinoma in situ
- a known *BRCA1* or *BRCA2* variant
- another gene variant associated with high risk, e.g., *TP53* (Li-Fraumeni syndrome), *PTEN* (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), *CDH1*, and *STK11*
- received radiotherapy to the chest between 10 and 30 years of age.

Interventions

The therapy being considered is a risk-reducing mastectomy.

Comparators

The following practices are currently being used to make decisions about patients at high risk of breast cancer or who have precluding excision or biopsy: active surveillance and standard of care. Standard of care may involve chemoprevention.

Outcomes

The general outcomes of interest are overall survival (OS), disease-specific survival (DSS), breast cancer incidence, and potential adverse events from the procedure.

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Timing

To detect adverse events from the procedure, follow-up is postprocedure and may extend to a year. To measure breast cancer incidence and mortality, follow-up may extend 10 to 20 years.

Setting

Risk-reducing mastectomy is given in a tertiary care center.

Systematic Reviews

This evidence review was informed by a TEC (Technology Evaluation Center) Assessment (1999) that concluded risk-reducing mastectomy met the TEC criteria for patients with a family history of breast cancer. The Assessment largely focused on a 1999 retrospective cohort analysis that found approximately 13 moderate-risk women would have to have a risk-reducing mastectomy to prevent 1 cancer. For those at high risk of breast cancer, reduction in breast cancer incidence ranged from 90% to 94%. Four to 8 high-risk women would need to undergo a risk-reducing mastectomy to prevent a single occurrence of breast cancer.

A Cochrane review by Lostumbo et al (2010) examined the impact of risk-reducing mastectomy on mortality and other health outcomes. Reviewers did not identify any RCTs. Thirty-nine observational studies with some methodologic limitations were identified. The studies presented data on 7384 women with a wide range of risk factors for breast cancer who underwent a risk-reducing mastectomy. Studies on the incidence of breast cancer and/or disease-specific mortality reported reductions after a bilateral risk-reducing mastectomy, particularly for those with *BRCA1* or *BRCA2* variants. Reviewers concluded that, while the available observational data suggested bilateral risk-reducing mastectomy reduced the rate of breast cancer mortality, more rigorous studies (ideally RCTs) were needed, and that bilateral risk-reducing mastectomy should only be considered for patients at very high risk of disease.

Several recent systematic reviews have evaluated the impact of a risk-reducing mastectomy on health outcomes in women with *BRCA* variants. Li et al (2016) identified 15 controlled studies evaluating the impact of prophylactic surgeries including bilateral risk-reducing mastectomy on women with *BRCA1* or *BRCA2* variants. In a meta-analysis of 6 studies with 2555 *BRCA1* or *BRCA2* variant carriers, compared with controls who did not receive a risk-reducing mastectomy, there was a significantly lower risk of subsequent breast cancer in women who had a bilateral risk-reducing mastectomy (relative risk [RR], 0.11; 95% confidence interval [CI], 0.04 to 0.32). However, in a meta-analysis of 2 studies in *BRCA1* or *BRCA2* variant carriers with no history of breast cancer, there was no significant effect on breast cancer-specific mortality (hazard ratio [HR], 0.29; 95% CI, 0.03 to 2.61) or on all-cause mortality (HR=0.29; 95% CI, 0.03 to 2.61). Similarly, Ludwig et al (2016) identified 10 studies on the incidence of breast cancer after bilateral risk-reducing mastectomy in *BRCA1* or *BRCA2* carriers and found a significant reduction in breast cancer risk ranging from 89.5% to 100%. These reviewers did not conduct pooled analyses of studies on the impact of a risk-reducing mastectomy on mortality.

Section Summary: Risk-Reducing Mastectomy

Evidence from systematic reviews has found that the incidence of breast cancer is reduced in women at high risk of breast cancer, especially those with *BRCA1*, *BRCA2*, and other pathogenic variants and those

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with a formal high-risk familial risk assessment. Fewer studies have examined the impact of a risk-reducing mastectomy on overall or breast cancer–specific survival.

CONTRALATERAL PROPHYLACTIC MASTECTOMY

Clinical Context and Test Purpose

The purpose of contralateral risk-reducing mastectomy in patients who have unilateral breast cancer but are not otherwise at high risk is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of contralateral risk-reducing mastectomy improve the net health outcome in women with unilateral breast cancer but are not otherwise at high risk?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is women with unilateral breast cancer but are not otherwise at high risk.

Interventions

The therapy being considered is a contralateral risk-reducing mastectomy.

Comparators

The following practices are currently being used to make decisions about patients with unilateral breast cancer but who are not otherwise at high risk: active surveillance and standard of care.

Outcomes

The general outcomes of interest are breast cancer incidence, OS, and DSS. Surgical complication rates are also of interest.

Timing

To detect adverse events from the procedure, follow-up is postprocedure and may extend to a year. To measure disease-related mortality, follow-up may extend 10 to 20 years.

Setting

Risk-reducing mastectomy is given in a tertiary care center.

Incidence of a Second Primary Breast Cancer

The potential for contralateral risk-reducing mastectomy to impact survival is related to its association with a reduced risk of subsequent primary breast cancer in the other breast (i.e., contralateral breast cancer [CBC]). In general, according to data from the U.S. Surveillance, Epidemiology and End Results (SEER) database, annual rates of CBC were stable between 1975 and 1985, after which rates declined about 3% per year (95% CI, 2.7% to 3.5%). Beginning in 1990, the annual decline in CBC rates was only in women

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with estrogen receptor–positive cancer, with no decrease in women with estrogen receptor–negative cancer. The investigators suggested that the decrease in CBC rates after estrogen receptor–positive cancer might be attributed at least in part to the increased availability of adjuvant hormone therapies.

Studies were sought assessing the risk of CBC in women who met high-risk and average-risk criteria. Molina-Montes et al (2014) published a systematic review of studies on the risk of a second primary breast cancer in women with and without *BRCA1* or *BRCA2* variants. Twenty studies were included (12 retrospective cohort studies, 2 prospective cohort studies, 6 case-control studies). Most studies included only women who had undergone genetic testing; it is likely that even those who tested negative had other risk factors that motivated testing. A meta-analysis found that the cumulative risk of a second primary breast cancer at 5 years after initial diagnosis was 14% (95% CI, 9% to 19%) in *BRCA1* or *BRCA2* variant carriers and 3% (95% CI, 2% to 5%) in noncarriers. The cumulative risk of a second primary cancer at 10 years after initial diagnosis was 22% (95% CI, 18% to 27%) in *BRCA1* or *BRCA2* variants and 5% (95% CI, 3% to 7%) in noncarriers.

Survival After Contralateral Risk-Reducing Mastectomy

As is the case for bilateral risk-reducing mastectomy, no RCTs evaluating the effect of contralateral risk-reducing mastectomy on health outcomes have been published. There are a number of observational studies, including some with large sample sizes, and a systematic review of those observational studies. Observational studies have attempted to control for potential confounders, but not all relevant factors were measured, and the possibility of selection bias remains.

A systematic review and meta-analysis of studies on contralateral risk-reducing mastectomy was published by Fayanju et al (2014). They conducted a literature search through March 2012 and identified 17 observational studies that compared the incidence of CBC in women with unilateral disease who did and did not undergo a contralateral risk-reducing mastectomy. Fourteen of the 17 studies were included in various meta-analyses. In a meta-analysis of 4 studies, mortality from breast cancer was lower in the group that had a contralateral risk-reducing mastectomy (RR=0.69; 95% CI, 0.56 to 0.85). Moreover, in a meta-analysis of data from 6 studies, OS was significantly higher in patients who underwent a contralateral risk-reducing mastectomy (n=10,666) than those did not (n=145,490; RR=1.09; 95% CI, 1.06 to 1.11). Reviewers also conducted a subgroup analysis by risk level. A meta-analysis of patients considered high risk, which included *BRCA* variant carriers and/or with a family history of breast cancer (4 studies, 616 undergoing contralateral risk-reducing mastectomy, 1318 not undergoing contralateral risk-reducing mastectomy) found that neither OS nor mortality from breast cancer differed significantly among women who had or did not have a contralateral risk-reducing mastectomy. The RR of breast cancer mortality with and without a contralateral risk-reducing mastectomy was 0.66 (95% CI, 0.27 to 1.64). For OS with and without a contralateral risk-reducing mastectomy, the RR was 1.09 (95% CI, 0.97 to 1.24). The absolute risk-reduction for metachronous breast cancer did not differ between women with and without a contralateral risk-reducing mastectomy when data from all 8 studies were analyzed (risk difference, -18.0%; 95% CI, -42.0% to 5.9%, but was significantly lower in women with a contralateral risk-reducing mastectomy in the 4 studies exclusively enrolling women at increased familial/genetic risk (risk difference, -24.0%; 95% CI, -35.6% to -12.4%). Commenting on the totality of findings, reviewers stated that the improvement in survival

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after a contralateral risk-reducing mastectomy in the general breast cancer population was likely not due to a decreased incidence of CBC, but rather was secondary to selection bias (e.g., contralateral risk-reducing mastectomy recipients may be otherwise healthier and have better access to health care).

Studies in the Fayanju systematic review were published between 1997 and 2005. More recent large observational analyses are described below, several of which analyzed data from the SEER database.

Wong et al (2017) evaluated 496,488 women diagnosed with unilateral invasive breast disease. Within this cohort, 58.6% (n=295,860) underwent breast-conserving surgery, 33.4% (n=165,888) had a unilateral mastectomy, and 7% (n=34,740) had a contralateral risk-reducing mastectomy. The median age was 50 years in the contralateral risk-reducing mastectomy group and 60 years in the breast conservation group (p<0.001). Patients were followed for a median of 8.25 years. In an analysis adjusting for age and other factors including stage of disease, OS was significantly higher after breast conservation than after a contralateral risk-reducing mastectomy (HR=1.08; 95% CI, 1.03 to 1.14). Similarly, breast cancer-specific survival was significantly higher in the breast conservation group than in the contralateral risk-reducing mastectomy group (HR=1.08; 95% CI, 1.01 to 1.16).

An analysis of SEER data by Kruper et al (2014) suggested that the association between contralateral risk-reducing mastectomy and reduced mortality identified in some data analyses could be attributed at least in part to the selection of a healthier cohort of women for contralateral risk-reducing mastectomy. In the case-control analysis including 28,015 contralateral risk-reducing mastectomy patients and 28,015 unilateral mastectomy patients in the SEER database, patients were matched by age group, race/ethnicity, extent of surgery, tumor grade, tumor classification, node classification, estrogen receptor status, and propensity score. The investigators were unable to match for *BRCA* or another genetic variant status. When all matched patients were included, DSS and OS were significantly lower in women who underwent unilateral mastectomy compared with contralateral risk-reducing mastectomy. For DSS, the HR was 0.83 (95% CI, 0.77 to 0.90); for OS, it was 0.77 (95% CI, 0.73 to 0.82). Presumably, contralateral risk-reducing mastectomy would increase survival by lowering the risk of CBC. The authors conducted another analysis excluding women diagnosed with CBC; the remaining sample was still large (25,924 women with unilateral mastectomy, 26,299 women with contralateral risk-reducing mastectomy). In the analysis excluding women with CBC, DSS, and OS remained significantly lower in women who had unilateral vs contralateral risk-reducing mastectomy. For DSS, the HR was 0.87 (95% CI, 0.80 to 0.94); for OS, it was 0.76 (95% CI, 0.71 to 0.81). The investigators suggested that the survival benefits found in CBC patients were not due to prevention of CBC but to selection bias (e.g., healthier women choosing CBC). A limitation of the analysis was the inability to control for risk factors including gene variant status, family history, and a history of radiotherapy to the chest between ages 10 and 30 years.

Yao et al (2013) evaluated OS after contralateral risk-reducing mastectomy using data from the National Cancer Data Base. The database collects information from 1450 Commission of Cancer-accredited cancer programs. The analysis included 219,983 women who had a mastectomy for unilateral breast cancer; 14,994 (7%) of these women underwent a contralateral risk-reducing mastectomy at the time of their mastectomy surgery. The investigators did not report risk factors such as known genetic variants. The 5-

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year OS rate was 80%. In an analysis adjusting for confounding factors, the risk of death was significantly lower in women who had a contralateral risk-reducing mastectomy than in women who did not. The adjusted HR for OS was 0.88 (95% CI, 0.83 to 0.93). The absolute risk of death over 5 years with contralateral risk-reducing mastectomy was 2.0% lower than without. In subgroup analyses, there was a survival benefit after contralateral risk-reducing mastectomy for individuals 18 to 49 years and 50 to 69 years, but not for those 70 years or older. There was also a survival benefit for women with stage I and II tumors, but not stage III tumors.

In a subsequent study, Pesce et al (2014) focused on a subgroup of patients who were young (<45 years old) with stage I or II breast cancer. A total of 4338 (29.7%) of 14,627 women in this subgroup had a contralateral risk-reducing mastectomy. Median follow-up was 6.1 years. In a multivariate analysis controlling for potentially confounding factors, OS did not differ significantly between patients who underwent a unilateral mastectomy and those who also had a contralateral mastectomy (HR=0.93; 95% CI, 0.79 to 1.09). Moreover, among women younger than 45 years with estrogen receptor–negative cancer, there was no significant improvement in OS in those who had a contralateral risk-reducing mastectomy or a unilateral mastectomy (HR=1.13; 95% CI, 0.90 to 1.42).

Adverse Events

There are risks and benefits associated with contralateral risk-reducing mastectomy. In particular, several analyses have found higher rates of surgical complications in women undergoing contralateral risk-reducing mastectomy (bilateral mastectomy) compared with women undergoing unilateral mastectomy. Besides morbidity associated with these complications, surgical complications may delay receiving adjuvant therapy.

Silva et al (2015) published a large multicenter study including 20,501 women with unilateral breast cancer from the American College of Surgeons National Surgery Quality Improvement Program database. A total of 13,268 (64.7%) women underwent a unilateral mastectomy, and 7233 (35.3%) had a bilateral mastectomy. The analysis did not report on high-risk factors such as *BRCA* variant status or family history. All women had breast reconstruction; a higher proportion of women who had a unilateral mastectomy (19.5%) than bilateral mastectomy (8.9%) had autologous reconstruction; the remainder had implant-based reconstruction. The authors conducted analyses controlling for confounding variables (i.e., age, race, smoking, diabetes, chronic pulmonary disease, hypertension) and stratifying by type of implant. The rate of overall complications was significantly higher for women who had a bilateral mastectomy, regardless of reconstruction type. Among women with implant reconstructions, overall complication rates were 10.1% after a bilateral mastectomy and 8.8% after a unilateral mastectomy (adjusted odds ratio [OR], 1.20; 95% CI, 1.08 to 1.33). In women with autologous reconstructions, overall complication rates were 21.2% after a bilateral mastectomy and 14.7% after a unilateral mastectomy (adjusted OR=1.60; 95% CI, 1.28 to 1.99). The most common complication was reoperation within 30 days, followed by surgical site complications. Transfusion rates were also significantly higher ($p<0.001$) in women with bilateral mastectomies who had either type of reconstruction. The rates of medical complications were relatively low—approximately 1% of women who had implant reconstructions and 3% of women who had autologous reconstructions experienced a medical complication (i.e., pneumonia, renal insufficiency or failure, sepsis, urinary tract

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infection, venous thromboembolism)—and did not differ significantly between unilateral and bilateral mastectomies.

Several single-center studies have also reported significantly higher surgical complication rates after bilateral compared with unilateral mastectomy. For example, in a study by Miller et al (2013), which included 600 women with unilateral breast cancer, contralateral risk-reducing mastectomy remained associated with a significantly higher risk of any complication (OR=1.53; 95% CI, 1.04 to 2.25) and a significantly higher risk of major complications (OR=2.66; 95% CI, 1.37 to 5.19) compared with unilateral mastectomy. Moreover, in a study by Eck et al (2014), which assessed 352 women with unilateral breast cancer, 94 (27%) women had complications, 48 (14%) in the unilateral mastectomy group, and 46 (13%) in the bilateral mastectomy group. The difference between groups was not statistically significant ($p=0.11$), but this study might have been underpowered. Eck found a significant delay in adjuvant therapy after surgical complications: women with complications waited longer before receiving adjuvant therapy than those without complications (49 days vs 40 days, $p<0.001$).

Section Summary: Contralateral Prophylactic Mastectomy

Large observational studies have reported inconsistent findings on the survival benefit of contralateral risk-reducing mastectomy in women with unilateral breast cancer who do not otherwise meet high-risk criteria. Researchers have suggested that improvements in survival after contralateral risk-reducing mastectomy in the general breast cancer population found in some studies are due at least in part to selection bias. Moreover, there are risks of complications associated with both the surgical and the reconstruction procedures.

SUMMARY OF EVIDENCE

For individuals who have a high risk of breast cancer or precluding excision or biopsy who receive a risk-reducing mastectomy, the evidence includes systematic reviews and observational studies. Relevant outcomes are OS, DSS, 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 OS, DSS, 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.

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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 BPM [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 should be considered for those at significant risk of CBC

- 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.

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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 National Comprehensive Cancer Network (NCCN) has made recommendations on several cancers relevant to this evidence review. On breast cancer risk-reduction (v.2.2018), 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 situ] 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.1.2018) 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 genetic/familial high-risk assessment for breast and ovarian cancer (v.1.2018), 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, NCCN guidelines recommend that risk-reducing mastectomy be considered based on family history in women with certain genetic variants including *CHEK2*, *STK11*, and *CDH1*.

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Policy History

Original Effective Date: 09/27/2004

Current Effective Date: 01/01/2019

08/31/2004 Medical Director review

09/21/2004 Medical Policy Committee review

09/27/2004 Managed Care Advisory Council approval

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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
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. <i>CDH1</i> , or <i>STK11</i> 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 th criteria bullet for risk-reducing mastectomy in patients at high risk of breast cancer. Deleted the

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“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.

Next Scheduled Review Date: 10/2019

Coding

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Code Type	Code
CPT	19301, 19302, 19303, 19304, 19305, 19306, 19307
HCPCS	No codes
ICD-10 Diagnosis	D05.00-D05.92, Z15.01, Z40.01, Z80.3

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- 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);
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- 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.

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