

Medical Coverage Policy | Risk Reducing Mastectomy



EFFECTIVE DATE: 06|01|2001

POLICY LAST UPDATED: 08|02|2023

OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Risk reducing mastectomy is considered medically necessary in individuals at high risk of breast cancer.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery benefits/coverage.

BACKGROUND

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 2002.¹

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.² The specific risk factors included in the models vary, but all incorporate characteristics related to age, reproductive history, and family history. 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.

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 $\geq 20\%$). 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-sc.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)

Practice Guidelines and Position Statements

American Society for Clinical Oncology, American Society for Radiation Oncology, and 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."

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 cancer.¹⁹ 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 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 [contralateral risk-reducing mastectomy] 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 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.

Society of Surgical Oncology

In 2017, the Society of Surgical Oncology updated its position statement on risk-reducing mastectomy.²⁰ 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

In 2013, the National Cancer Institute updated its fact sheet on risk-reducing surgery for breast cancer.²¹ 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 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."

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 mastectomy²²:

"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
- 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.
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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.1.2021), the NCCN recommends:

"Risk-reducing mastectomy should generally be considered only in women with a pathogenic/likely pathogenic genetic mutation (not variants of undetermined significance) conferring a high risk for breast cancer..., compelling family history, or 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."²³

For invasive breast cancer (v.4.2021) the NCCN has discouraged contralateral risk-reducing mastectomy, except for certain high-risk situations (noted in the risk-reduction guideline previously discussed).²⁴ The guidelines state:

"....risk reduction mastectomy of a breast contralateral to a known unilateral breast cancer treated with mastectomy is discouraged by the panel. The use of a prophylactic mastectomy contralateral to a breast treated with lumpectomy is very strongly discouraged in all patients."

As part of a genetic/familial high-risk assessment for breast, ovarian, and pancreatic cancer (v.1.2021), 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.²⁵ In addition, the NCCN guidelines recommend that risk-reducing mastectomy be considered based on family history in women with certain genetic variants including *ATM*, *PALB2*, *CHEK2*, and *CDH1*.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) are covered;

19303 Mastectomy, simple, complete

RELATED POLICIES

Mastectomy Treatment, Breast Reconstruction and Hospital Stays Mandates

PUBLISHED

Provider Update, October 2023

Provider Update, July 2022

Provider Update, May 2021

Provider Update, May 2020

Provider Update, July 2017

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