

Medical Coverage Policy | Risk Reducing Mastectomy (Formally Prophylactic Mastectomy)



EFFECTIVE DATE: 06 | 01 | 2001

POLICY LAST UPDATED: 03 | 17 | 2021

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 patients 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 (i.e., 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.

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.

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.bcscc.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

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*, *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 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 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.1.2019) 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*.

CODING

Medicare Advantage Plans and Commercial Products

The following codes are covered

19303 Mastectomy, simple, complete

19304 Mastectomy, subcutaneous

RELATED POLICIES

None

PUBLISHED

Provider Update, May 2021

Provider Update, May 2020

Provider Update, July 2017

Provider Update, January 2017

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