

Medical Coverage Policy | Prophylactic Mastectomy



EFFECTIVE DATE: 06|01|2001

POLICY LAST UPDATED: 10|18|2016

OVERVIEW

Prophylactic mastectomy (PM) is defined as the removal of the breast in the absence of malignant disease to reduce the risk of breast cancer occurrence. The literature on PM primarily consists of observational studies and retrospective reviews; however, evidence demonstrates that PM reduces breast cancer incidence and increases survival in high-risk patients.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Prophylactic mastectomy is considered medically necessary in patients at high risk of breast cancer, (for definitions of risk levels, see Policy Guidelines section), in patients with lobular carcinoma in situ i.e., with such extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy or excision is impossible.

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

Prophylactic mastectomy (PM) is defined as the removal of the breast in the absence of malignant disease to reduce the risk of breast cancer occurrence.

The evidence for PM in women who have high risk of breast cancer or extensive mammographic abnormalities precluding incision or biopsy includes a TEC Assessment and systematic review of observational studies. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, and treatment-related morbidity. The studies found that PM reduces breast cancer incidence and increases survival in select patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for contralateral prophylactic mastectomy (CPM) in women who have unilateral breast cancer but are not otherwise at high risk includes observational studies. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, and treatment-related morbidity. Available studies do not clearly demonstrate a survival benefit in women without high-risk criteria. Moreover, there are potential risks (eg, surgical risks) associated with CPM. National guidelines, including those from the National Comprehensive Care Network, do not recommend that CPM be considered other than for certain high-risk women. The evidence is insufficient to determine the effects of the technology on health outcomes.

It is strongly recommended that all candidates for prophylactic mastectomy undergo counseling regarding cancer risks from a health professional skilled in assessing cancer risk other than the operating surgeon and discussion of the 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 or
- a known *BRCA1* or *BRCA2* mutation or
- another gene mutation associated with high risk, eg, *TP53* (Li-Fraumeni syndrome), *PTEN* (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), *CDH1*, and *STK11* or
- high risk (lifetime risk about 20% or greater) of developing breast cancer as identified by models
- that are largely defined by family history 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. 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 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.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

- Breast Cancer Risk Reduction, 2014 (v.1): "Risk-reduction mastectomy should generally be considered only in women with a genetic mutation conferring a high risk history for breast cancer (*BRCA 1/2*, *PTEN*, *TP53*, *CDH1*, *STK11*), compelling family history, or possibly with LCIS or prior thoracic radiation therapy at < 30 years of age. The value of risk-reduction mastectomy in women with deleterious mutations in other genes associated with a 2-fold or greater risk for breast cancer (based on large epidemiologic studies) in the absence of a compelling family history of breast cancer is unknown."³
- Breast cancer, 2014 (V.3) Except for certain high-risk situations (noted in the risk reduction guideline previously discussed), CPM is discouraged.¹³ The guideline states, "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 breastconserving therapy is very strongly discouraged."

Society of Surgical Oncology

The Society of Surgical Oncology developed a position statement on PM in 1993 and updated it in 2007.¹⁴ The position statement states that bilateral PM is potentially indicated in patients with:

- Known *BRCA 1* or *2* mutations or other genes that strongly predispose susceptibility to breast cancer,
- A history of multiple first-degree relatives with breast cancer history or multiple successive generations of breast and/or ovarian cancer, or
- Biopsy-confirmed, high-risk histology such as atypical ductal or lobular hyperplasia or LCIS.

The position statement also stated that CPM may be potentially indicated in patients:

- With high risk (as previously defined) of contralateral breast cancer, in whom surveillance would be difficult such as with dense breast tissue or diffuse indeterminate microcalcifications, or to improve symmetry.

National Cancer Institute

The National Cancer Institute issued a fact sheet in 2012 on surgery to reduce the risk of breast cancer.¹⁵ The fact sheet provided the following information: Prophylactic surgery to remove both breasts (called bilateral prophylactic mastectomy) can reduce the risk of breast cancer in women who have a strong family history of breast and/or ovarian cancer, who have a deleterious (disease-causing) mutation in the *BRCA1* gene or the *BRCA2* gene,

CODING

19303 Mastectomy, simple, complete

19304 Mastectomy, subcutaneous

RELATED POLICIES

None

PUBLISHED

Provider Update, January 2017

Provider Update, October 2015

Provider Update, May 2008

Policy Update, July 2006

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