

EFFECTIVE DATE: 06|01|2001

POLICY LAST UPDATED: 08|18|2015

Internal Policy Description

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

PMs may be considered in women thought to be at high risk of developing breast cancer, either due to a family history, presence of genetic mutations such as *BRC A1* or *BRC A2*, having received radiotherapy to the chest, or the presence of lesions associated with an increased cancer risk such as lobular carcinoma in situ (LCIS). LCIS is both a risk factor for all types of cancer, including bilateral cancer, and in some cases, a precursor for invasive lobular cancer. For those who develop invasive cancer, up to 35% may have bilateral cancer. Therefore, bilateral PM may be performed to eliminate the risk of cancer arising elsewhere; chemoprevention and close surveillance are alternative risk reduction strategies. PMs 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 an invasive cancer (i.e., CPM). The use of CPM has risen in recent years in the United States. An analysis of data from the National Cancer Data Base found that the rate of CPM in women diagnosed with unilateral stage I-III breast cancer increased from approximately 4% in 1998 to 9.4% in 2002.¹

The appropriateness of a PM 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, 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, number of breast biopsies, and number of first-degree relatives with breast cancer.

Based on the scientific data consisting of large numbers of patients treated with follow-up, PM for breast cancer risk reduction may be considered medically necessary in patients at high risk of breast cancer. The

choice of PM is based on patient tolerance for risk, consideration of the extreme disfiguration and need for additional cosmetic surgery, and the risk reduction offered by PM versus other options.

The use of contralateral prophylactic mastectomy (CPM) in women with unilateral cancer in the other breast has risen in recent years. There are insufficient data on a survival benefit of CPM, particularly for women who do not meet high-risk criteria. Moreover, there are potential risks, e.g., operative risks associated with CPM. National guidelines, including from the National Comprehensive Care Network, do not recommend that CPM be considered other than for certain high-risk women. Thus, CPM is considered investigational in cases in which the woman does not meet criteria for high risk.

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 *BRC A* 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 *BRC A1* gene or the *BRC A2* gene,

CODING

19303 Mastectomy, simple, complete

19304 Mastectomy, subcutaneous

RELATED POLICIES

None

PUBLISHED

Provider Update, October 2015

Provider Update, May 2008

Policy Update, July 2006

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