# Medical Policy

BlueCross BlueShield of Kansas
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## Title: Prophylactic Mastectomy

**Professional**
Original Effective Date: June 7, 2004
Revision Date(s): October 28, 2011; July 13, 2012; November 29, 2013
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**Institutional**
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## DESCRIPTION

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.

Prophylactic mastectomies 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 BRCA1 or BRCA2, having received radiation therapy 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. Prophylactic 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 an invasive cancer.

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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.

* Characteristics of the Gail and Claus models http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/HealthProfessional/page1#Section_66

## POLICY

A. Unilateral or bilateral prophylactic mastectomy may be considered **medically necessary** in patients at high risk of breast cancer with one of the following:

1. Presence of a BRCA1 or BRCA2 mutation
2. Received radiation therapy to the chest between the ages of 10 and 30 years.
3. Presence of lobular carcinoma in situ,
4. Extensive mammographic abnormalities (i.e., calcifications)
5. Lifetime risk of breast cancer of 20% or greater as identified by the Gail or Claus model (Characteristics of the Gail and Claus models http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/HealthProfessional/page1#Section_66)
6. Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes.

B. Prophylactic mastectomy is considered **experimental / investigational** in women who do not meet high risk criteria.

**Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

Policy Guidelines

It is strongly recommended that all candidates for prophylactic mastectomy undergo counseling regarding cancer risks from a health professional skilled in assessing cancer risk. Cancer risk assessment should include a complete family history and use of the Gail or Claus model to estimate the risk of cancer. Various treatment options should be discussed, including increased surveillance or chemoprevention with tamoxifen or raloxifene.

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## RATIONALE

This policy was created in 1995 and updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period July 2011 through February 5, 2013. Following is a summary of key findings.

This policy was initially based on a 1999 TEC Assessment that concluded that prophylactic mastectomy (PM) met the TEC criteria for patients with a family history of breast cancer. (1) However, patients with a family history represent a broad spectrum, ranging from those at high risk due to a family history consistent with hereditary breast cancer to those at more moderate risk, i.e., with a single affected relative.

The TEC Assessment focused on one 1999 study, a retrospective cohort analysis of 639 women with a family history of breast cancer who underwent bilateral PM between 1960 and 1993 at Mayo Clinic. (2) A total of 90% of the mastectomies were subcutaneous. The patients were subdivided into 2 groups: high-risk patients had a family history suggestive of hereditary breast cancer (n=214), while the remaining 425 patients were arbitrarily considered to have a moderately increased risk. However, it should be emphasized that all women had some sort of family history of breast cancer. For each group, the reduction in the incidence of mortality due to breast cancer was estimated by comparison to a control group (sisters of high-risk patients) or predicted outcomes (using the Gail model for moderate-risk patients).

For patients at moderate risk of breast cancer, 37.4 cancers were predicted by the Gail model, and 4 were observed for an incidence reduction of 89.5%. Approximately 13 moderate-risk women would have to have PM to prevent 1 cancer. For those at high risk of breast cancer, reduction in breast cancer incidence ranged from 90–94%. Four to 8 high-risk women would need to undergo PM to prevent 1 occurrence of breast cancer.

While all patients in the Hartmann et al. study (2) had a family history of breast cancer, it should not be concluded that all patients with a family history of breast cancer are candidates for a PM. Essentially the decision is a complicated patient-driven risk-benefit analysis of the individual cancer risk. While the cancer risk is greatest for those considered at high risk, whether or not the cancer risk associated with moderate-risk patients warrants a PM is a difficult question. While high risk is more objectively defined either by a family history alone or the presence of a BRCA1 or BRCA2 mutation, moderate risk may be conferred by a wide range of family histories in association with different breast pathologies.

The Hartmann et al. (2) study evaluated by the TEC Assessment was a retrospective cohort study that arbitrarily assigned all women not at high risk to be at moderate risk. It is not known what kind of risk assessment was performed, if any, prior to the mastectomy procedure. In the study, of the 425 women in the moderate-risk category, 268 had at least 1 affected first-degree relative, 46 had 2 aunts, cousins, or both with breast cancer and fewer second-degree or third-degree relatives. This group includes a wide variety of patients, with the spectrum potentially ranging from a patient with a first-degree relative with bilateral premenopausal breast cancer to a patient whose elderly mother is diagnosed with breast cancer. The Gail model has been used as patient selection criteria to identify women at increased risk of breast cancer who would be candidates for chemoprevention with tamoxifen. The Breast Cancer Chemoprevention Trial accepted patients between the ages of 35 and 59 years with a 5-year predicted risk of breast cancer of 1.66%, according to the Gail model. (3) Presumably, at the very least, the predicted cancer risk of candidates for PM should exceed that of candidates for chemoprevention.

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Additional factors have been associated with a high rate of cancer including the pTP53 (Li-Fraumeni syndrome) and PTEN (Cowden and Bannayan-Riley-Ruvalcaba syndromes) genetic mutations. Patients who received prior radiation therapy to the chest between the ages of 10 and 30 years of age also have an increased risk of breast cancer which can reach almost 30% by age 55 years. (4) Patients with lobular carcinoma in situ (LCIS), which is usually identified incidental to breast biopsy, are also at increased risk of cancer. Two reviewers report that compared to the general population, women with LCIS face an 8- to 10-fold increased risk of cancer, equaling 26% after 20 years in one study. (5) In a commentary on this review, Visvanathan noted that up to 35% of these women who develop breast cancer have bilateral disease, which is why some undergo bilateral prophylactic mastectomy. (6) In a second commentary, Visscher and Hartmann state that the distinction between LCIS and atypical lobular hyperplasia is often problematic and based on the degree of lobular involvement. (7) More generally, there appears to be considerable uncertainty about the nature and optimal treatment for LCIS, despite some useful findings from genetic profiling.

An updated Cochrane review was published by Lostumbo and colleagues in 2010. (8) The 39 included studies were observational studies with some methodologic limitations. There were no randomized trials. The studies presented data on 7,384 women with a wide range of risk factors for breast cancer who underwent PM. Bilateral prophylactic mastectomy (BPM) studies on the incidence of breast cancer and/or disease-specific mortality reported reductions after BPM, particularly for those with BRCA 1/2 mutations. For contralateral prophylactic mastectomy (CPM), studies consistently reported reductions in incidence of contralateral breast cancer but were inconsistent about improvements in disease-specific survival. Sixteen studies assessed psychosocial measures; most of these reported high levels of satisfaction with the decision to have PM but more variable satisfaction with cosmetic results. Worry over breast cancer was significantly reduced after BPM when compared to baseline worry levels. Case series reporting on adverse events from PM with or without reconstruction reported rates of unanticipated re-operations from 4% in those without reconstruction to 49% in patients with reconstruction. The authors' summary and conclusions are as follows: "Sixteen observational studies have been published since the last version of the review, without altering our conclusions. While published observational studies demonstrated that BPM was effective in reducing both the incidence of, and death from, breast cancer, more rigorous prospective studies (ideally randomized trials) are needed. BPM should be considered only among those at very high risk of disease. There is insufficient evidence that CPM improves survival and studies that control for multiple confounding variables are needed."

Many published studies identified in literature review updates reported on factors that influenced decisions about PM. Studies also discussed both patient satisfaction and quality of life after the procedure. Additionally, studies on comparative/cost effectiveness supporting PM versus surveillance have been identified. (9, 10)

A number of studies in recent years have pointed to the increasing use in the United States of CPM in women with a diagnosed breast cancer in the other breast. In a study based on the American College of Surgeons' National Cancer Data Base, use of CPM increased from 0.4% of women diagnosed with unilateral breast cancer in 1998 to 4.7% in 2005, for a total of 23,218 CPMs of the 1,166,456 cases reviewed. (11) Patient's average age was 61.2 years. Data on genetic mutations in these patients was not reported. But in a multivariable analysis, the authors found that the greatest comparative increases between 1998-1999 versus 2006-2007 was among white patients younger than 40-years old residing in areas of high socioeconomic status, who had

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private or managed care insurance plans, and were treated at high-volume medical centers in the Midwest. Women with in situ disease were more likely to have CPM.

In a study of 2,965 mastectomy patients for unilateral cancer at Memorial Sloan-Kettering Cancer Center, 407 (13%) underwent either immediate (90%) or delayed (within 1 year) CPM. (12) The percentage undergoing CPM rose from 6.7% (15 patients) in 1997 to 24.2% (119 patients) in 2005. Of the patients undergoing CPM, 69% had a family history of breast cancer, 34% had completed clinical genetic counseling, and 9% (37 patients) had BRCA 1/2 mutations. The mean age was 44.8 years (range, 20-80). Sixty-three percent of the index (i.e., ipsilateral) cancers were invasive ductal cancer, 22% were pure ductal carcinoma in situ (DCIS), 9% were invasive lobular cancers, and 7% were infiltrating mammary (mixed) cancers. Based on histologic findings from the CPM specimens, 6% of the women had contralateral cancer and 28% had a "high-risk lesion", defined as atypical ductal or lobular hyperplasia or LCIS. The authors report a 4- to 5-fold increased risk of developing breast cancer for women with atypical ductal hyperplasia (based on studies from the 1990s) and 8- to 9-fold for women with LCIS (based on studies from the 1970s and early 2000s). On multivariate analysis, patient age (>50) (OR=3.09; 95% CI: 1.682 to 5.692; p=0.0003) and progesterone receptor positivity (OR=3.37; 95% CI: 1.651 to 6.871; p=0.0008) were significantly associated with either malignancy or high-risk lesion compared to having only benign findings. The odds ratio for use of hormone replacement therapy for more than one year was 2.45 (95% CI: 1.021 to 5.865; p=0.0447). The authors did not adjust for multiple comparisons because of the "retrospective and exploratory" nature of the analysis.

Chung and colleagues compared the characteristics of 177 women undergoing CPM with 178 age- and stage-matched controls at a single institution. (13) The median age at diagnosis was 48.5 years (range, 24-82). Of the 355 patients, 19.1% had DCIS and the remainder had invasive disease. The proportion of women undergoing CPM to treat unilateral breast cancer increased from 19.4% in 1995-1999 to 56.6% during 2000-2004 and 64.7% during 2005-2008 (p<0.0001). There was no difference between those who underwent CPM and those who did not in terms of histology, grade, hormone-receptor status, or presence of multifocality. Women who had CPM were twice as likely to have undergone preoperative magnetic resonance imaging (MRI) (p<0.001). Patients in the CPM group were statistically significantly more likely to have a history of previous breast biopsy, family history of breast cancer, or BRCA gene mutation. Histopathology of the contralateral breast found that 6.6% of the women undergoing CPM had occult cancer; 7 of 11 patients had DCIS. With a median follow-up of 61 months (range, 2-171 months), 1.7% of the women who did not undergo CPM had developed contralateral breast cancer.

Two other factors should be noted regarding CPM: First, the index (ipsilateral cancer) poses the greatest risk to the patient. (14) Second, the use of endocrine therapy reduces the risk of contralateral breast cancer. (13)

## Ongoing Clinical Trials

A search of online site ClinicalTrials.gov in February 2013 found one registry study of prophylactic mastectomy for breast cancer risk reduction. This registry will examine patient quality of life, cancer occurrence, adverse events, and survival annually for 10 years (NCT00555503). There is also a trial on decision making regarding prophylactic mastectomy and oophorectomy in women seeking genetic counseling and testing for BRCA1/2 mutations, that is active but no longer recruiting patients (NCT00579007).

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## Summary

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 prophylactic mastectomy primarily consists of observational studies and retrospective reviews; however, evidence demonstrates that prophylactic mastectomy reduces breast cancer incidence and increases survival in high-risk patients. Based on the scientific data consisting of large numbers of patients treated with follow-up, prophylactic mastectomy 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 in women with unilateral cancer in the other breast has risen over the last decade or two. The increase does not appear to be limited to women at high risk of cancer, although this characteristic is not reported in every study. The factors behind this increase continue to be explored. Contralateral prophylactic mastectomy is considered investigational in cases where the woman does not meet criteria for high risk.

## Practice Guidelines and Position Statements

This updated policy is in general agreement with the current National Comprehensive Cancer Network (NCCN) guidelines on breast cancer risk reduction, although they do not include patients with such extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy or excision is impossible. For women with a high risk of breast cancer based on a breast cancer risk assessment, such as the modified Gail model, they recommend risk reduction counseling, including possibly PM, in women with a 5-year breast cancer risk >1.7% and life expectancy >10 years. (15) The NCCN guidelines for contralateral prophylactic mastectomy (CPM) are included as part of the breast cancer guidelines. (16) These guidelines strongly discourage CPM in women treated with mastectomy for a known unilateral breast cancer and very strongly discourage CPM in women treated with breast-conserving surgery for a known unilateral breast cancer. CPM is recommended in only very limited, specific clinical situations, e.g., women 35-years old or younger or premenopausal with a known BRCA 1/2 mutation. The NCCN breast cancer guidelines also indicate bilateral PM may be considered for risk reduction in women age 35 or younger or premenopausal with a known BRCA 1 or 2 mutation and refer to the breast cancer risk reduction guidelines. Although not the topic of this policy, the NCCN guidelines discuss other risk reduction strategies as well. The NCCN guidelines on genetic-familial high-risk assessment also discuss PM. (17)

The Society of Surgical Oncology (SSO) developed a position statement on prophylactic mastectomy in 1993. (18) The position statement was updated in 2007 and indicates bilateral prophylactic mastectomy 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 lobular carcinoma in situ [LCIS].

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The SSO also indicates contralateral prophylactic mastectomy may be potentially indicated in patients:

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

## CODING

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

CPT/HCPCS

| | |
|---|---|
| 19303 | Mastectomy, simple, complete |
| 19304 | Mastectomy, subcutaneous |

DIAGNOSIS

| | |
|---|---|
| 174.0-174.9 | Malignant neoplasm of female breast |
| 175.0-175.9 | Malignant neoplasm of male breast |
| 198.81 | Secondary malignant neoplasm of breast |
| 233.0 | Carcinoma in situ of breast |
| V10.3 | Personal history of malignant neoplasm, breast |
| V50.41 | Elective surgery for purposes other than remedying health states; prophylactic organ removal; breast |

ICD-10 Diagnosis *(Effective October 1, 2014)*

| | |
|---|---|
| C50.011 | Malignant neoplasm of nipple and areola, right female breast |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast |
| C50.611 | Malignant neoplasm of axillary tail of right female breast |
| C50.612 | Malignant neoplasm of axillary tail of left female breast |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.911 | Malignant neoplasm of unspecified site of right female breast |

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|---|---|
| C50.912 | Malignant neoplasm of unspecified site of left female breast |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast |
| C50.022 | Malignant neoplasm of nipple and areola, left male breast |
| C50.121 | Malignant neoplasm of central portion of right male breast |
| C50.122 | Malignant neoplasm of central portion of left male breast |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast |
| C50.621 | Malignant neoplasm of axillary tail of right male breast |
| C50.622 | Malignant neoplasm of axillary tail of left male breast |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast |
| C50.821 | Malignant neoplasm of overlapping sites of right male breast |
| C50.822 | Malignant neoplasm of overlapping sites of left male breast |
| C50.829 | Malignant neoplasm of overlapping sites of unspecified male breast |
| C50.921 | Malignant neoplasm of unspecified site of right male breast |
| C50.922 | Malignant neoplasm of unspecified site of left male breast |
| C50.929 | Malignant neoplasm of unspecified site of unspecified male breast |
| D05.01 | Lobular carcinoma in situ of right breast |
| D05.02 | Lobular carcinoma in situ of left breast |
| D05.11 | Intraductal carcinoma in situ of right breast |
| D05.12 | Intraductal carcinoma in situ of left breast |
| D05.81 | Other specified type of carcinoma in situ of right breast |
| D05.82 | Other specified type of carcinoma in situ of left breast |
| D05.91 | Unspecified type of carcinoma in situ of right breast |
| D05.92 | Unspecified type of carcinoma in situ of left breast |
| Z85.3 | Personal history of malignant neoplasm of breast |
| Z40.01 | Encounter for prophylactic removal of breast |

## REVISIONS

| | |
|---|---|
| 10-28-2011 | Policy added to the bcbsks.com web site. |
| 07-13-2012 | Description section updated. |
| | In the Policy section:<br>▪ In Item #2, replaced "p" with "TP" to read "Presence of a TP53 or PTEN mutation" (Note—this was a clarification. No policy intent change.) |
| | Rationale section updated. |
| | Reference section updated. |

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|---|---|
| 11-29-2013 | Updated Description section. |
| | In Policy section:<br>▪ In Item A, removed "or moderately increased risk" to read "unilateral or bilateral prophylactic mastectomy may be considered medically necessary in patients at high risk of breast cancer with one of the following:"<br>▪ Removed Item A, #2<br>▪ Removed Item A, #7-#18<br>▪ Added new #6 to Item A, "Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes."<br>▪ Added Item B, "Prophylactic mastectomy is considered experimental / investigational in women who do not meet high risk criteria." |
| | Updated Rationale section. |
| | In Coding section:<br>▪ Added ICD-10 Diagnosis codes. *(Effective October 1, 2014)* |
| | Updated Reference section. |

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