

(70109)

Medical Benefit		Effective Date: 10/01/13	Next Review Date: 07/15
Preauthorization	Yes	Review Dates: 09/07, 09/08, 09/09, 09/10, 07/11, 07/12, 07/13, 07/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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.

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 *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. 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., contralateral prophylactic mastectomy [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 five 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.

Related Protocol

Genetic Testing for Hereditary Breast and/or Ovarian Cancer

Policy (Formerly Corporate Medical Guideline)

Prophylactic mastectomy may be considered **medically necessary** in patients at high risk of breast cancer. (For definitions of risk levels, see Policy Guidelines.)

Prophylactic mastectomy may be considered **medically necessary** in patients with lobular carcinoma in situ.

Prophylactic mastectomy may be considered **medically necessary** in patients with such extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy or excision is impossible.

Prophylactic mastectomy is considered **investigational** for all other indications, including but not limited to contralateral prophylactic mastectomy in women with breast cancer who do not meet high risk criteria.

Policy Guideline

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.

Patients with a high risk of breast cancer may be defined as one or more of the following:

- a known BRCA1 or BRCA2 mutation or
- at high risk of BRCA1 or BRCA2 mutation due to a known presence of the mutation in relatives or
- Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes or
- high risk (lifetime risk about 20% to 25% or greater) of developing breast cancer as identified by models that are largely defined by family history or
- received radiation therapy to the chest between the ages of 10 and 30 years.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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13. Giuliano AE, Boolbol S, Degnim A et al. Society of Surgical Oncology: position statement on prophylactic mastectomy. Approved by the Society of Surgical Oncology Executive Council, March 2007. *Ann Surg Oncol* 2007; 14(9):2425-7.