Prophylactic Mastectomy (70109)

Medical Benefit
Effective Date: 10/01/16
Next Review Date: 07/18

Preauthorization
Yes
Review Dates: 09/07, 09/08, 09/09, 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

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<th>Populations</th>
<th>Interventions</th>
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<tr>
<td>Individuals: • With high risk of breast cancer or extensive mammographic abnormalities precluding incision or biopsy</td>
<td>Interventions of interest are: • Prophylactic mastectomy</td>
<td>Comparators of interest are: • Active surveillance • Standard care</td>
<td>Relevant outcomes include: • Overall survival • Disease-specific survival • Functional outcomes • Treatment-related morbidity</td>
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<tr>
<td>Individuals: • With unilateral breast cancer but are not otherwise at high risk</td>
<td>Interventions of interest are: • Contralateral prophylactic mastectomy</td>
<td>Comparators of interest are: • Active surveillance • Standard care</td>
<td>Relevant outcomes include: • Overall survival • Disease-specific survival • Functional outcomes • Treatment-related morbidity</td>
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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.

Summary of Evidence

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 (e.g., 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.

Policy

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 such extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy or excision is impossible.

Prophylactic mastectomy is considered **investigational** for all other indications.

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 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, e.g., 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 radiation therapy to the chest between the ages of 10 and 30 years.

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. Risk factors in the model can be accessed online ([http://www.cancer.gov/bcrisktool/Default.aspx](http://www.cancer.gov/bcrisktool/Default.aspx)).

Contralateral prophylactic mastectomy is discouraged in women with a history of or current diagnosis of unilateral breast cancer, when the preceding criteria for high risk are not met. When considered, the small benefit from the contralateral prophylactic mastectomy, the risk of recurrence from the known ipsilateral breast cancer, psychological issues and social issues (existing, as well as those which may be precipitated by the anticipated mastectomy) and the risk of the surgery must be evaluated. After breast conserving treatment for breast cancer, a contralateral prophylactic mastectomy is very strongly discouraged. 13
Background

PM may be considered in women thought to be at high risk of developing breast cancer, either due to family history, presence of genetic mutations (e.g., 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 (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). Use of CPM has increased 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 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. Moreover, the choice of PM is based on patient tolerance for risk, consideration of changes to appearance and need for additional cosmetic surgery, and the risk reduction offered by PM versus other options.

Regulatory Status

Mastectomy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

Related Protocols

Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing
Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome

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.