Prophylactic Mastectomy

**Introduction**

Prophylactic mastectomy is surgery that removes one or both breasts. The goal of this surgery is to reduce the risk of developing breast cancer. This policy describes when prophylactic mastectomy may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

**Policy Coverage Criteria**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Prophylactic Mastectomy | **Prophylactic mastectomy may be considered medically necessary for patients at high risk of breast cancer when the at least one of the following criteria is met:**
  - Personal history of breast cancer and one or more of the following:
    - Diagnosed age ≤ 45 years
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Two breast cancer primaries, when first breast cancer was diagnosed age ≤ 50 years</td>
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<tr>
<td>o Diagnosed age ≤ 50 years with one or more close blood relative with breast cancer at any age or with a limited family history</td>
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<tr>
<td>o Diagnosed age ≤ 60 years with a triple negative breast cancer</td>
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<tr>
<td>o Diagnosed at any age with one or more close blood relative breast cancer diagnosed ≤ 50 years</td>
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<tr>
<td>o Diagnosed at any age with two or more close blood relatives with breast cancer diagnosed any age</td>
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<tr>
<td>o Diagnosed at any age with one or more close blood relative with epithelial ovarian cancer</td>
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<tr>
<td>o Diagnosed at any age with two or more close blood relatives with pancreatic cancer or aggressive prostate cancer (Gleason score ≥7) at any age</td>
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<tr>
<td>o Close male blood relative with breast cancer</td>
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<tr>
<td>o Personal history of male breast cancer</td>
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<tr>
<td>o For an individual of an ethnicity associated with a higher mutation frequency (eg, Ashkenazi Jewish) no additional family history may be required</td>
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<tr>
<td>• Personal history of epithelial ovarian, fallopian tube, or primary peritoneal cancer</td>
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<tr>
<td>• Personal history of pancreatic cancer or aggressive prostate cancer (Gleason score ≥7) at any age with ≥2 close blood relatives with breast and/or ovarian and/or pancreatic or aggressive prostate cancer (Gleason score ≥7) at any age</td>
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<tr>
<td>• Two or more first-degree relatives with breast cancer</td>
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<tr>
<td>• One first-degree relative and two or more second- or third-degree relatives with breast cancer</td>
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<tr>
<td>• One first-degree relative with breast cancer before the age of 45 years and another relative with breast cancer</td>
<td></td>
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<tr>
<td>• One first-degree relative with breast cancer and one or more relatives with ovarian cancer</td>
<td></td>
</tr>
<tr>
<td>• Two second- or third-degree relatives with breast cancer and one or more with ovarian cancer</td>
<td></td>
</tr>
<tr>
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</tr>
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</tbody>
</table>
| • One second- or third-degree relative with breast cancer and two or more with ovarian cancer  
• Three or more second- or third-degree relatives with breast cancer  
• One first-degree relative with bilateral breast cancer  
• The presence of a BRCA1 or BRCA2 mutation (see Related Policies)  
• The presence of a TP53 or PTEN mutation  
• History of prior thoracic radiation therapy (such as for Hodgkin’s disease) <30 years of age  
• Extensive mammographic abnormalities (eg, calcifications) exist such that adequate biopsy is impossible and strong concern about breast cancer risk  
• Additional criteria for CPM includes at least one of the following:  
  o Diagnosis of invasive ductal or lobular carcinoma  
  o Ductal carcinoma in situ (DCIS) of intermediate or high grade or LCIS with features of pleomorphic lobular carcinoma |

| Testing | Blood or tissue samples from other non-covered family members occasionally are required to provide the medical information necessary for the proper medical care of a patient. Such testing for molecular-based testing for BRCA and other specific heritable disorders in non-members is considered medically necessary when all of the following conditions are met:  
• The information is needed to adequately assess risk in the patient  
• The information will be used in the immediate care plan of the patient  
• The non-covered family member’s benefit plan (if any) will not cover the test and the denial is based on specific plan exclusion |

**Note:** See Related Information below for Limitations
### Code

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>Mastectomy, simple, complete</td>
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### Related Information

### Limitations

1. Genetic testing of a non-covered family member of a covered patient for the sole purpose of obtaining non-related genetic information is not covered.

2. Prophylactic mastectomy:
   - Subcutaneous prophylactic mastectomy is not recommended for coverage.
   - A board certified or board eligible surgeon with expertise in breast cancer must recommend the prophylactic mastectomy.
   - When the indication for prophylactic mastectomy is based on pathology, a board certified or board eligible pathologist must validate the report.

### Evidence Review

### Background

BreastCancer.org defines prophylactic mastectomy as a surgery that removes one or both breasts to reduce the risk of developing breast cancer. According to the National Cancer Institute, prophylactic mastectomy in high-risk women may be able to reduce the risk of developing breast cancer by 90%.
High-risk individuals may include:

- Family history of breast cancer, especially before age 50
- Tested positive for BRCA1, BRCA2, or PALB2 gene mutations
- Diagnosis of lobular carcinoma in situ (LCIS)
- Radiation therapy to the chest prior to age 30
- Widely spread breast microcalcifications and/or dense breasts

When prophylactic mastectomy is being considered, the National Comprehensive Cancer Network (NCCN) Guidelines note that the small benefits must be balanced with the risk of recurrent disease from the known breast cancer, the psychological and social issues associated with bilateral mastectomy, and the overall risks of contralateral mastectomy.

References


History

<table>
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<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>09/16/19</td>
<td>New policy, approved August 13, 2019, effective January 1, 2020. Prophylactic mastectomy may be considered medically necessary for patients at high risk of breast cancer when the at least one of the criteria in this policy is met. Blood or tissue samples from other non-covered family molecular-based testing for BRCA and other specific heritable disorders in non-members is considered medically necessary when all conditions are met.</td>
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</tbody>
</table>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

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200 Independence Avenue SW, Room S09F, HHH Building
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