

Policy: MP054

Section: Medical Benefit Policy

Subject: Prophylactic Mastectomy

I. Policy: Prophylactic Mastectomy

II. Purpose/Objective:

To provide a policy of coverage regarding Prophylactic Mastectomy

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

Gail model: a breast cancer risk assessment algorithm using 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.

Claus model: a breast cancer risk assessment algorithm used to predict the cumulative probability of disease in members based on a particular family history of breast cancer and known age of disease onset.

DESCRIPTION:

Prophylactic mastectomy is the removal of the breast in the absence of malignant disease in members with significant risk factors for breast carcinoma.

INDICATIONS:

Prophylactic mastectomy *may* be considered medically necessary for members with a high risk of hereditary breast cancer who meet the following criteria:

High Risk Criteria - the member must meet at least one of these criteria:

- Two or more first-degree relatives with breast cancer
- One first-degree relative and two or more second-degree or third-degree relatives with breast cancer
- One first-degree relative with breast cancer before the age of 45 years and one other relative with breast cancer
- One first-degree relative with breast cancer and one or more relatives with ovarian cancer
- Two second - degree or third-degree relatives with breast cancer and one or more with ovarian cancer
- One second-degree or third-degree relative with breast cancer and two or more with ovarian cancer
- Three or more second-degree or third-degree relatives with breast cancer
- One first-degree relative with bilateral breast cancer
- Presence of a BRCA1 or BRCA2 mutation in the member consistent with a BRCA1 or BRCA2 mutation in a family member with breast or ovarian cancer.
- Presence of a TP53 mutation (Li-Fraumeni syndrome), or PTEN mutation (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), in the member or a first degree relative
- For members with biopsies showing lobular carcinoma in situ (LCIS) or who are at high risk for breast cancer related to having a previous carcinoma in one breast.
- History of exposure or treatment with thoracic radiation before the age of 30
- Presence of PALB2, CDH1 or STK11 mutation in conjunction with family history of breast cancer. (Note: there are insufficient data to support risk-reducing mastectomy based on the presence of PALB2, CDH1 or STK11 mutation alone)

REQUIREMENT:

All members considering a prophylactic mastectomy must undergo counseling regarding cancer risks from a genetic counselor. Cancer risk should be assessed by performing a complete family history, use of the Gail or Claus model to estimate the risk of cancer, and discussion of the various treatment options, including increased surveillance should be included in the consultation.

EXCLUSIONS:

Prophylactic mastectomy is considered **experimental, investigational, and unproven** for members with atypical hyperplasia whose BRCA gene carrier status is unknown or negative and who does not have one of the above inclusion criteria.

Prophylactic mastectomy is considered **experimental, investigational, and unproven** for members with nonproliferative fibrocystic changes (benign breast changes or fibrocystic changes) or proliferative disease without atypia.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Prophylactic Mastectomy

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider

reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

19303 Mastectomy, simple complete

19304 Mastectomy, radical, including pectoral muscles, axillary lymph nodes

19306 Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban Type Operation)

19307 Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle)

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LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/03

Revised: 5/04 (Coding);6/06(references); 6/07 (coding), 5/11 (indications and references), 4/17 (criteria clarification); 4/18 (add gene mutation criteria)

Reviewed: 6/05, 6/08(wording), 5/09, 5/10, 5/12, 5/13, 5/14, 5/15, 5/16, 4/19, 4/20