

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.

Tyrer-Cuzick model: The Tyrer-Cuzick risk model or IBIS risk tool assesses a women's 10 year and lifetime risk of developing breast cancer.

Breast Cancer Risk Calculator: The tool uses a woman's personal medical and reproductive history and the history of breast cancer among her first-degree relatives (mother, sisters, daughters) to estimate absolute breast cancer risk or probability of developing invasive breast cancer in a defined age interval.

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 for cancer risk reduction 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:

- Members with a strong family history of breast cancer such as:
 - A family history of breast cancer in multiple first-degree relatives and/or multiple successive generations of family members with breast and/or ovarian cancer (family cancer syndrome); **and**
 - The member's risk of breast cancer is elevated based on a validated assessment tool such as the Breast Cancer Risk Calculator, Gail Model, or Tyrer-Cuzick Risk Calculator; **and**
 - The member has undergone counseling from an appropriate provider such as gynecologist, breast surgeon or genetic counselor to quantitate their risk;
- or**
- The member has tested positive for BRCA1, BRCA2, TP53, PTEN, PALB2 or other gene variants that strongly predispose susceptibility to breast cancer **or**
- The member has a high-risk histology: Atypical ductal or lobular hyperplasia, or lobular carcinoma in situ confirmed on biopsy; **or**
- Members with such extensive mammographic abnormalities (e.g., calcifications), cystic/dense breast tissue) that adequate biopsy is impossible; **or**
- Members with a personal history of breast cancer making it more likely to develop a new cancer in the opposite breast; **or**
- Members who received radiation therapy to the thoracic region before the age of 30. (e.g. radiation to treat Hodgkin's disease).

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 Breast Cancer Risk Calculator, Gail Model, or Tyrer-Cuzick Risk Calculator 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 for cancer risk reduction in members not meeting the criteria outlined in this policy is considered experimental, investigational, or unproven, and therefore **NOT COVERED**.

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.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, will be evaluated on a case by case basis.

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)

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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 supersede 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); 4/23 (revise criteria); 4/24 (revise criteria regarding gene variants)

Reviewed: 6/05, 6/08(wording), 5/09, 5/10, 5/12, 5/13, 5/14, 5/15, 5/16, 4/19, 4/20, 4/21, 4/22

CMS UM Oversight Committee Approval: 12/23, 7/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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