# Geisinger

# Geisinger Health Plan Policies and Procedure Manual

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.

**<u>Gail model:</u>** 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. <u>**Claus model:**</u> 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.

<u>Tryer-Cuzick model</u>: 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 <u>www.cms.gov</u> 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 supercede this policy. For PA Medicaid Business segment, this policy applies as written.

#### **REFERENCES:**

Hartmann LC, Schaid DJ, Woods JE, Crotty TP, Myers JL, et. al., "Efficacy of Bilateral Prophylactic Mastectomy in Women with a Family History of Breast Cancer", *The New England Journal Of Medicine*, 340(2):77-84, 14 Jan 1999.

Peralta EA, Ellenhorn JDI, Wagman LD, Dagis A, Anderson JS, Chu DZJ, "Contralateral Prophylactic Mastectomy Improves the Outcome of Selected Patients Undergoing Mastectomy for Breast Cancer", *The American Journal of Surgery*, 180(6):439-445, Dec 2000.

Meiser B, Butow P, Friedlander M, Schnieden V, Gattas M, Kirk J, Suthers G, Haan E, Tucker K, "Intention to Undergo Prophylactic Bilateral Mastectomy in Women at Increased Risk of Developing Hereditary Breast Cancer", *Journal of Clinical Oncology*, 18(11):2250-2257, June 2000.

Eisen A, Rebbeck TR, Wood WC, Weber BL, "Prophylactic Surgery in Women With a Hereditary Predisposition to Breast and Ovarian Cancer", *Journal of Clinical Oncology*, 18(9):1980-1995, May 2000.

Technology Evaluation Center, <u>TEC Evaluation</u>. "Bilateral Prophylactic Mastectomy on Women with an Increased Risk of Breast Cancer", August 1999; 14(14):1-31.

Dixon JM, McDonald C, Elton RA, Miller WR, "Risk of Breast cancer in Women With Palpable Breast Cysts: A Prospective Study", *The Lancet*, 353(9166):1742-1745, 22 May 1999.

Pruthi S, "Detection and Evaluation of a Palpable Breast Mass", Mayo Clinic Proceedings, 76(6):641-648, June 2001.

Walling A, "Does Development of Cysts Increase Breast Cancer Risk?", American Family Physician, Oct. 15, 1999.

American Medical Women's Association, <u>Position Paper on Breast Cancer Prevention</u>, <u>http://www.amwa-doc.org/publications/Position\_Papers/breastcancerprevent</u>.

Society of Surgical Oncology, Position Statement on Prophylactic Mastectomy, <u>http://www.surgonc.org/sso/mastectomy.htm</u>

Winifred S. Hayes, Hayes Inc. Online, Prophylactic Mastectomy, September 2002.

National Comprehensive Cancer Network® (NCCN) [website]. Genetic/familial high-risk assessment: breast and ovarian. Clinical practice guidelines in oncology. Version 3.2024

National Cancer Institute (NCI) a. Genetics of breast and ovarian cancer (PDQ®). Updated June 24, 2016

Southery, MC, Goldgar DE, et al. PALB2, CHEK2, and ATM rare variants and cancer risk: data from COGS. J Med genet 2016;53:800-811.

Casadei S, Norquist BM, et al. Contribution of inherited mutations in the BRCA2-interacting protein PALB2 fo familial breast cancer. Cancer Res 2011;71:2222-2229

Boughey JC, Attai DJ, Chen SL, et al. Contralateral Prophylactic Mastectomy Consensus Statement from the American Society of Breast Surgeons: Additional Considerations and a Framework for Shared Decision Making. Ann Surg Oncol. 2016;23(10):3106-3111.

Nass SJ, Nekhlyudov L. Commentary on the Consensus Statement of the American Society of Breast Surgeons on Contralateral Prophylactic Mastectomy. Ann Surg Oncol. 2017; 24:611-613.

Tuttle TM, Barrio AV, Klimberg VS, et al. Guidelines for Guidelines: An Assessment of the American Society of Breast Surgeons Contralateral Prophylactic Mastectomy Consensus Statement. Ann Surg Onc. 2017;24(1):1-2.

Li X, You R, Wang X, et al. Effectiveness of Prophylactic Surgeries in BRCA1 or BRCA2 Mutation Carriers: A Meta-analysis and Systematic Review. Clin Cancer Res. 2016;22(15):3971-3981.

Frey JD, Salibian AA, Schnabel FR, Choi M, Karp NS. Non-BRCA1/2 Breast Cancer Susceptibility Genes: A New Frontier with Clinical Consequences for Plastic Surgeons. Plast Reconstr Surg Glob Open. 2017 Nov 20;5(11):e1564.

Li J, Meeks H, Feng BJ, et al; kConFab Investigators. Targeted massively parallel sequencing of a panel of putative breast cancer susceptibility genes in a large cohort of multiple-case breast and ovarian cancer families. J Med Genet. 2016;53:34–42

Tejada-Bergés T. Breast cancer: genetics and risk assessment. Clin Obstet Gynecol. 2016;59:673-687

Cobain EF, Milliron KJ, Merajver SD. Updates on breast cancer genetics: clinical implications of detecting syndromes of inherited increased susceptibility to breast cancer. Semin Oncol. 2016;43:528–535

Lerner-Ellis J, Khalouei S, Sopik V, et al. Genetic risk assessment and prevention: the role of genetic testing panels in breast cancer. Expert Rev Anticancer Ther. 2015;15:1315–1326

van Marcke C, De Leener A, Berlière M, et al. Routine use of gene panel testing in hereditary breast cancer should be performed with caution. Crit Rev Oncol Hematol. 2016;108:33–39.

Wright FC, Look Hong NJ, Quan ML, et al. Indications for Contralateral Prophylactic Mastectomy: A Consensus Statement Using Modified Delphi Methodology. Ann Surg. 2017.

Hunt KK, Euhus DM, Boughey JC, et al. Society of Surgical Oncology Breast Disease Working Group Statement on prophylactic (risk-reducing) mastectomy. Ann Surg Oncol. Feb 2017;24(2):375-397.

Song C-V, Teo S-H, Taib NA, Yip C-H. Surgery for BRCA, TP53 and PALB2: a literature review. Ecancermedicalscience. 2018;12.

Teoh V, Tasoulis M, and Gui G. Contralateral Prophylactic Mastectomy in women with unilateral breast cancer who are genetic carriers, have a strong family history or are just young at presentation. Cancers. 2020;12:140

Tischkowitz M, Balmaña J, Foulkes WD, et al. Management of individuals with germline variants in PALB2: a clinical practice resource of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2021 Aug;23(8):1416-1423.

Baskin AS, Wang T, Bredbeck BC, et al. Trends in Contralateral Prophylactic Mastectomy Utilization for Small Unilateral Breast Cancer. J Surg Res. 2021 Jun;262:71-84

National Comprehensive Cancer Network® (NCCN) [website] Breast Cancer Risk Reduction v2.2024

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

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

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.