

02-12000-15

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Reviewed: 08/22/24

Revised: 09/15/24

Subject: Prophylactic Mastectomy

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Prophylactic mastectomy (risk-reducing mastectomy) is defined as the removal of the breast in the absence of malignant disease to reduce the risk of breast cancer occurrence.

Summary and Analysis of Evidence: According to the NCCN guideline (2024), “Risk-reducing mastectomy should generally be considered in individuals with a pathogenic/likely pathogenic genetic variant in high penetrance breast cancer susceptibility genes compelling family history, or those receiving chest wall radiation before 30 years of age. Risk-reducing mastectomy should generally be considered in individuals with a pathogenic/likely pathogenic genetic variant in high penetrance breast cancer susceptibility genes compelling family history, or those receiving chest wall radiation before 30 years of age.”

Bilateral prophylactic mastectomy has been shown to reduce the risk of breast cancer by at least 95 percent in women who have a deleterious (disease-causing) mutation in the *BRCA1* gene or the *BRCA2* gene and by up to 90 percent in women who have a strong family history of breast cancer. Risk-reducing (also called preventive or prophylactic) surgery can lower the risk of breast cancer in people who are at very high risk, such as women who carry a harmful mutation in a breast cancer susceptibility gene such as *BRCA1*, *BRCA2*, *TP53*, or *PTEN*. The main type of surgery to reduce breast cancer risk is the removal of both breasts, called bilateral risk-reducing mastectomy (or bilateral prophylactic mastectomy) (NCI, 2024).

POSITION STATEMENT:

Prophylactic mastectomy **meets the definition of medical necessity** for members at high risk of breast cancer.

Prophylactic mastectomy **meets the definition of medical necessity** for members with extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy or excision is impossible.

High risk of breast cancer may be defined as one or more of the following:

- Lobular carcinoma in situ; **OR**
- A known BRCA1 or BRCA2 mutation; **OR**
- Another gene mutation associated with increased risk of breast cancer (e.g., PTEN, TP53, CDH1, STK11, PALB2); **OR**
- Li-Fraumeni syndrome or Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes; **OR**
- High risk (lifetime risk about 20% or greater) of developing breast cancer as identified by models that are largely defined by family history after negative mutation testing; **OR**
- Received radiation therapy to the chest between 10 and 30 years of age.

It is recommended that candidates for prophylactic mastectomy consider undergoing counseling regarding cancer risks from a health professional skilled in assessing cancer risk other than the operating surgeon. Cancer risk should be assessed by performing a complete family history, with the use of the Gail or Claus model to estimate the risk of cancer. Also, discussion of the various treatment options with the candidate, including increased surveillance or chemoprevention with tamoxifen or raloxifene.

Prophylactic mastectomy is considered **experimental or investigational** for all other indications, including but not limited to contralateral prophylactic mastectomy in women with breast cancer who do not meet high-risk criteria for breast cancer.

BILLING/CODING INFORMATION:

There is no specific CPT or HCPCS codes to report prophylactic mastectomy.

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Cosmetic and Reconstructive Surgery (L38914) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

BRCA1 and BRCA2: breast cancer 1 susceptibility gene.

Mutation: in genetics, a permanent transmissible change in the genetic material.

RELATED GUIDELINES:

[Reconstructive Surgery/Cosmetic Surgery, 02-12000-01](#)

[Reduction Mammoplasty, 02-12000-11](#)

[Genetic Testing for Hereditary Breast or Ovarian Cancer, 05-82000-30](#)

[Prosthetics, 09-L0000-05](#)

OTHER:

Federal Law-SEC 713 Required Coverage for Reconstructive Surgery following Mastectomies

A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a mastectomy shall provide, in a case of a participant or beneficiary who is receiving benefits in connection with a mastectomy and who elects breast reconstruction in connection with such mastectomy, coverage for:

- 1) All stages of reconstruction of the breast on which the mastectomy has been performed;
- 2) Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
- 3) Prostheses and physical complications all stages of mastectomy, including lymphedemas; in a manner determined in consultation with the attending physician and the patient.

Florida Statute-Chapter 627-627.6417 Coverage for surgical procedures and devices incident to mastectomy.

Any health insurance policy that provides coverage for mastectomies must also provide coverage for prosthetic devices and breast reconstructive surgery incident to the mastectomy. Breast reconstructive surgery must be in a manner chosen by the treating physician, consistent with prevailing medical standards, and in consultation with the patient.

The term "mastectomy" means the removal of all or part of the breast for medically necessary reasons as determined by a licensed physician, and the term "breast reconstructive surgery" means surgery to reestablish symmetry between the two breasts.

Other names used to report prophylactic mastectomy:

Bilateral risk-reducing mastectomy.

Preventive mastectomy

Risk-reducing mastectomy

Risk reduction mastectomy

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/22/24.

GUIDELINE UPDATE INFORMATION:

01/01/01	Medical Coverage Guideline Developed.
05/15/03	Annual review. Added coverage statement for counseling and reconstructive surgery/prosthetic device. Added diagnosis V10.3. Deleted code 19180 and 19181. Added statement for the Florida State Mandate for "Breast Cancer Treatment".
01/15/05	Annual review; next review changed to NLR; no change in coverage.
09/15/07	Reformatted guideline. Updated description section. Revise 6th bullet under Position Statement, definition of high risk of breast cancer; change two (change to one) second-degree with breast cancer and one or more with ovarian cancer. Deleted reconstructive surgery/prosthetic device (implant) coverage statement. Updated references. Added Prosthetics, 09-L0000-05 to related guidelines section.
01/01/08	Updated guideline (Florida Statute 627.641). Updated references and related Internet links.
10/15/09	Updated description section. Added additional high-risk indications (presence of a p53 or PTEN mutation and received radiation therapy to the chest. Deleted first bullet under moderately increased risk of breast cancer; patients who do not meet the definition of high risk. Updated references.
02/15/13	Added Federal law for reconstructive surgery following mastectomies. Updated references.
05/11/14	Revision: Program Exceptions section updated.
03/15/17	Revision; updated description, revised position statement: added statement for high risk breast cancer and mammographic abnormalities and revised statement for lobular carcinoma in situ. Revised reimbursement information, definitions and updated references.
09/15/17	Revision; add clarification statement for high risk. Updated references.
05/15/18	Review; position statements maintained.
07/15/20	Review/update. No change in position statement. Updated description and references.
09/15/22	Review/update. No change to position statement. Added PALB2. Updated references.
05/23/23	Update to Program Exceptions section.
09/15/24	Review; no change to position statement. Updated references.

