

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy
Policy Number	10.01.01
Category	Contract Clarification
Original Effective Date	10/18/01
Committee Approval Date	10/18/01, 01/24/02, 01/23/03, 02/26/04, 04/28/05, 06/22/06, 06/28/07, 06/26/08, 06/25/09, 06/24/10, 06/24/11, 06/28/12, 09/04/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17
Current Effective Date	08/22/24
Archived Date	08/25/17
Archive Review Date	08/23/18, 08/22/19, 8/27/20, 08/19/21, 08/18/22, 08/17/23, 08/22/24
Product Disclaimer	<ul style="list-style-type: none"> Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY STATEMENT

- I. Federal and state mandates applicable to any of the following services will supersede this policy.
- II. Based upon our criteria and assessment of the peer-reviewed literature, reconstructive breast surgery during or after surgical mastectomy, including partial mastectomy (e.g., lumpectomy, segmentectomy, quadrantectomy) for benign or malignant disease, is considered **medically appropriate**, and may include the following services:
 - A. All stages of reconstruction, including, but not limited to:
 1. Breast implants;
 2. Abdominal flap reconstruction;
 3. Chest wall reconstruction;
 4. Nipple/areola reconstruction and tattooing; and
 5. Surgery for symmetry of the contralateral (opposite) breast;
 - B. Basic breast prosthetic(s) and mastectomy bras;
 - C. Treatment of physical complications of mastectomy, including lymphedema (*In accordance with Corporate Medical Policy #1.01.17 Powered Compression Devices/Lymphedema Pumps*).
- III. Based upon our criteria and assessment of the peer-reviewed literature, a risk-reducing mastectomy is considered a **medically appropriate** prophylactic treatment for individuals with **ANY** of the following high-risk breast cancer factors:
 - A. Lobular carcinoma in situ;
 - B. A known BRCA1 or BRCA2 variant;
 - C. Another gene variant associated with high risk (e.g., TP53 [Li-Fraumeni syndrome], PTEN [Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome], CDH1, STK11, and PALB2);
 - D. Received radiotherapy to the chest between the ages of 10 and 30 years (e.g., Hodgkin's disease).

Medical Policy: BREAST RECONSTRUCTION SURGERY AND PROPHYLACTIC BREAST CANCER RISK-REDUCING MASTECTOMY

Policy Number: 10.01.01

Page: 2 of 8

- IV. Based upon our criteria and assessment of the peer-reviewed literature, the following techniques are considered **medically appropriate** alternatives to a medically appropriate risk-reducing conventional mastectomy:
- A. A skin-sparing mastectomy;
 - B. A nipple-sparing mastectomy;
 - C. A two-stage procedure including an oncoplastic breast reduction followed by a risk-reducing mastectomy and breast reconstruction.

Refer to Corporate Medical Policy #1.01.17 Powered Compression Devices/Lymphedema Pumps

Refer to Corporate Medical Policy #7.01.11 Cosmetic and Reconstructive Procedures

Refer to Corporate Medical Policy #7.01.35 Bioengineered Tissue Products for Wound Treatment and Surgical Interventions

Refer to Corporate Medical Policy #7.01.39 Reduction Mammoplasty (Mammoplasty)

Refer to Corporate Medical Policy #7.01.84 Gender Affirming Surgery and Treatments for Commercial and Medicare Advantage Members

Refer to Corporate Medical Policy #7.01.105 Gender Reassignment/ Gender Affirming Surgery and Treatments for Medicaid Managed Care Plan and Health and Recovery Plan Members

POLICY GUIDELINE

It is recommended that all individuals considering risk-based mastectomy have counseling provided by a health professional (other than the operating surgeon) who is skilled to assess cancer risk. This discussion should include an explanation of the risks and benefits of various screening and treatment options (e.g., increased surveillance or chemoprevention).

DESCRIPTION

Reconstructive breast surgery is a surgical procedure that is designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. The nature and extent of the reconstructive breast surgery depends upon the initial surgery or treatment that an individual receives to remove all or a portion of a breast.

The reconstructive surgery may be performed in a single stage or several stages/phases and either during or after a surgical procedure to remove breast tissue. Reconstruction may include, but is not limited to:

- I. Insertion of saline or silicone filled prosthetic implants;
- II. Extensive flap reconstruction (e.g., deep inferior epigastric perforator [DIEP] flap, gluteal artery perforator [GAP] flap, latissimus dorsi flap, superficial inferior epigastric artery [SIEA] flap, transverse rectus abdominus myocutaneous [TRAM] flap);
- III. Chest wall reconstruction;
- IV. Nipple/areola reconstruction and tattooing;
- V. Surgery for symmetry of the contralateral (opposite) breast.

Conventional mastectomy is a surgical procedure that involves removing the entirety of the breast tissue, skin overlying the breast, and the nipple-areola complex. A risk-reducing mastectomy, also referred to as a preventative or prophylactic mastectomy, is the surgical removal of both breasts for the purpose of reducing cancer risk and is meant for individuals who are considered very high risk. The surgery may be performed as a total mastectomy, where the nipple and areola are removed or via a nipple-sparing technique that preserves the nipple and areola. Total mastectomy provides a vaguely higher level of risk reduction (as high as 95% in women who have disease causing variants [BRCA 1 /BRCA2]) compared to nipple-sparing mastectomy, which allows for more natural-looking breasts after reconstruction.

Medical Policy: BREAST RECONSTRUCTION SURGERY AND PROPHYLACTIC BREAST CANCER RISK-REDUCING MASTECTOMY

Policy Number: 10.01.01

Page: 3 of 8

The Federal Women's Health and Cancer Rights Act (WHCRA) of 1998, as well as the New York Insurance Law, mandate coverage of all stages of reconstructive surgery for individuals who have or have not been diagnosed with breast cancer, in the manner determined by the attending physician and the patient to be appropriate which can include surgery and reconstruction of the contralateral breast to produce symmetrical appearance, chest wall reconstruction, prosthesis, treatment of physical complications following mastectomy and prophylactic mastectomies for all group health plans, whether insured or self-funded, that provide medical and surgical benefits.

RATIONALE

A Cochrane review by Carbine et al (2018) examined the impact of risk-reducing mastectomy on mortality and other health outcomes. Reviewers did not identify any randomized controlled trials. Sixty-one observational studies with some methodologic limitations were identified. The studies presented data on 15,077 individuals with a wide range of risk factors for breast cancer who underwent a risk-reducing mastectomy. Studies on the incidence of breast cancer and disease-specific mortality (n=21) reported reductions in both after a bilateral risk-reducing mastectomy, particularly for those with BRCA1 or BRCA2 variants.

NCCN Guidelines V.3.2024 Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic recommends that the option of risk reducing mastectomy (RRM) be discussed for carriers of the following genetic variants: BRCA-Pathogenic/Likely Pathogenic Variant-Positive, CDH-, PLB2, STK11, and Li-Fraumeni. For those with clinical Cowden syndrome/PTEN hamartoma tumor syndrome, consideration of risk-reducing surgery should be based on family history. Counseling should include a discussion regarding degree of protection, reconstruction options, and risks.

In 2020, The American Society of Breast Surgeons (ASBrS) published a consensus statement on contralateral prophylactic mastectomy (CPM) (Boughey et al), concluding that CPM should be considered for those at significant risk of contralateral breast cancer who are documented BRCA1/2 carriers, strong family history where patient has not undergone genetic testing, and history of mantle chest radiation before age 30 years. CPM for those at lower risk of contralateral breast cancer but whom should be considered for CPM include Gene carriers of non-BRCA genes (e.g., CHECK-2, PALB2, p53, CDH1), strong family history where patient is BRCA negative and no known BRCA family member. CPM should additionally be considered for other reasons including to limit contralateral breast surveillance, improve reconstructed breast symmetry, manage risk aversion, to manage extreme anxiety. ASBrS discourages CPM in average-risk women with unilateral breast cancer, women with advanced index cancer, women at high-risk for surgical complications, women who have tested BRCA negative with a family of BRCA positive carriers, and for male breast cancer, including BRCA carriers.

The American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology published joint guidelines for the management of hereditary breast cancer (Tung et al. 2020). The guidelines include the following recommendations related to breast conserving surgery (BCS) which are based on formal consensus:

- I. The following factors should be considered for assessing risk of contralateral breast cancer (CBC) and role of risk-reducing mastectomy in BRCA1/2 mutation carriers: age at diagnosis (the strongest predictor of future CBC), family history of breast cancer, overall prognosis from this or other cancers (e.g., ovarian), ability of patient to undergo appropriate breast surveillance (magnetic resonance imaging [MRI]), comorbidities, and life expectancy (Evidence quality: low; Strength of recommendation: moderate);
- II. Patients with newly diagnosed breast cancer who have a mutation in a moderate-penetrance breast cancer susceptibility gene, mutation status alone should not determine local therapy decisions for the index tumor or contralateral risk-reducing mastectomy (CRRM) (Evidence quality: low, Strength of recommendation: moderate);
- III. In patients with breast cancer with a mutation in a moderate-penetrance breast cancer susceptibility gene, BCT should be offered to those for whom BCT is an appropriate treatment option. There is a lack of data regarding ipsilateral breast cancer events after BCT among patients with moderate-risk mutations (Evidence quality: low; Strength of recommendation: moderate);

Medical Policy: BREAST RECONSTRUCTION SURGERY AND PROPHYLACTIC BREAST CANCER RISK-REDUCING MASTECTOMY

Policy Number: 10.01.01

Page: 4 of 8

- IV. For women with newly diagnosed breast cancer undergoing mastectomy who have a deleterious mutation in BRCA1/2, nipple-sparing mastectomy is a reasonable oncologic approach to consider in appropriately selected patients (Evidence quality: intermediate; Strength of recommendation: moderate);
- V. For women with newly diagnosed breast cancer undergoing mastectomy who have a deleterious mutation in a moderate penetrance gene, nipple-sparing mastectomy is a reasonable oncologic approach to consider in appropriately selected patients (Evidence quality: low; strength of recommendation: moderate);
- VI. Surgical management of the index malignancy (including BCT, ipsilateral therapeutic and contralateral risk-reducing mastectomy in BRCA1/BRCA 2 mutation carriers should be discussed (Evidence quality: intermediate, strength of recommendation: strong);
- VII. For women with breast cancer who have a BRCA1/BRCA 2 mutation and who have been treated or are being treated with unilateral mastectomy, CRRM should be offered. CRRM is associated with a decreased risk of CBC; there is insufficient evidence for improved survival. The following factors should be considered for assessing risk of CBC and role of risk-reducing mastectomy: age at diagnosis (the strongest predictor of future CBC), family history of breast cancer, overall prognosis from this or other cancers (e.g., ovarian), ability of patient to undergo appropriate breast surveillance (MRI), comorbidities, and life expectancy (Evidence quality: intermediate; strength of recommendation: moderate).
- VIII. For women with breast cancer who have a mutation in a moderate-penetrance breast cancer predisposition gene and who have been treated or are being treated with unilateral mastectomy, the decision regarding CRRM should not be based predominantly on mutation status. Additional factors that predict CBC such as age at diagnosis and family history should be considered, as they are in all cases. The impact of CRRM on decreasing risk of CBC is dependent on the risk of CBC for each individual gene. Data regarding the risk of CBC resulting from moderate-penetrance genes are limited (Type: formal consensus; Evidence quality: low; strength of recommendation: moderate);
- IX. For patients with breast cancer with a deleterious germline BRCA1/2 mutation interested in CRRM, physicians should discuss the option of nipple-sparing mastectomy as a reasonable oncologic option (Type: formal consensus; Evidence quality: intermediate; strength of recommendation: strong).
- X. For patients with breast cancer with a mutation in a moderate-penetrance gene who are interested in CRRM, physicians should discuss the option of nipple-sparing mastectomy as a reasonable oncologic option (Evidence quality: low; strength of recommendation: moderate).

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT Codes

Code	Description
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less
11921	6.1 to 20.0 sq cm
11922	each additional 20.0 sq cm, or part thereof
13100	Repair, complex, trunk; 1.1 cm to 2.5 cm
13101	Repair, complex, trunk; 2.6 cm to 7.5 cm
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less

Medical Policy: BREAST RECONSTRUCTION SURGERY AND PROPHYLACTIC BREAST CANCER RISK-REDUCING MASTECTOMY

Policy Number: 10.01.01

Page: 5 of 8

Code	Description
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30 sq cm
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
15650	Transfer, intermediate, of any pedicle flap (abdomen to wrist, Walking tube), any location
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15740	Flap; island pedicle requiring identification and dissection of an anatomically named axial vessel
15770	Graft; derma-fat-fascia
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50cc or less injectate
15772	each additional 50cc injectate or part thereof
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction with latissimus dorsi flap
19364	Breast reconstruction with free flap (e.g. fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single pedicled transverse rectus abdominis myocutaneous (TRAM) flap, including closure of donor site
19368	requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction; with bipediced transverse rectus abdominis myocutaneous (TRAM) flap
19370	Revision of peri-implant capsule, breast, including capsulotomy capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction
19396	Preparation of moulage for custom breast implant
21601	Excision of chest wall tumor including rib(s)
21602	Excision of chest wall tumor including rib(s) with plastic reconstruction, without mediastinal lymphadenectomy
21603	Excision of chest wall tumor including rib(s) with plastic reconstruction, with mediastinal lymphadenectomy
21740	Reconstructive repair of pectus excavatum or carinatum; open
21742	Reconstructive repair of pectus excavatum or carinatum minimally invasive approach (Nuss procedure), without thoracoscopy
21743	Reconstructive repair of pectus excavatum or carinatum minimally invasive approach (Nuss procedure), with thoracoscopy

Medical Policy: BREAST RECONSTRUCTION SURGERY AND PROPHYLACTIC BREAST CANCER RISK-REDUCING MASTECTOMY**Policy Number: 10.01.01****Page: 6 of 8***Copyright 2024 American Medical Association, Chicago, IL***HCPSC Codes**

Code	Description
L8001	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral, any size, any type
L8002	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral, any size, any type
L8600	Implantable breast prosthesis, silicone or equal
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S2067	Breast reconstruction of a single breast with “stacked” deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
S2068	Breast reconstruction w/ deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site, and shaping the flap into a breast, unilateral

ICD10 Codes

Code	Description
C50.011-C50.019	Malignant neoplasm of nipple and areola (code range)
C50.111-C50.119	Malignant neoplasm of central portion of female breast (code range)
C50.211-C50.219	Malignant neoplasm of upper-inner quadrant of female breast (code range)
C50.311-C50.319	Malignant neoplasm of lower-inner quadrant of female breast (code range)
C50.411-C50.419	Malignant neoplasm of upper-outer quadrant of female breast (code range)
C50.511-C50.519	Malignant neoplasm of lower-outer quadrant of female breast (code range)
C50.611-C50.619	Malignant neoplasm of axillary tail of female breast (code range)
C50.811-C50.819	Malignant neoplasm of overlapping sites of female breast (code range)
C50.911-C50.919	Malignant neoplasm of unspecified site of female breast (code range)
C79.81	Secondary malignant neoplasm of breast
C84.7A	Breast implant associated anaplastic large cell lymphoma (BIA-ALCL)
D05.00-D05.92	Carcinoma in situ of breast (code range)
D24.1-D24.9	Benign neoplasm of breast (code range)
D49.3	Neoplasm of unspecified behavior of breast
Z15.01	Genetic susceptibility to malignant neoplasm of breast
Z15.02	Genetic susceptibility to malignant neoplasm of ovary
Z40.01	Encounter for prophylactic removal of breast
Z40.02	Encounter for prophylactic removal of ovary(s)
Z40.03	Encounter for prophylactic removal of fallopian tube(s)
Z42.1	Encounter for breast reconstruction following mastectomy
Z80.3	Family history of malignant neoplasm of breast
Z85.3	Personal history of malignant neoplasm of breast
Z90.10-Z90.13	Acquired absence of breast and nipple (code range)

Medical Policy: BREAST RECONSTRUCTION SURGERY AND PROPHYLACTIC BREAST CANCER RISK-REDUCING MASTECTOMY

Policy Number: 10.01.01

Page: 7 of 8

REFERENCES

*Agency for Healthcare Research and Quality. Evidence reports: breast reconstruction after mastectomy. Last revised 2021 Jul 14 [<https://effectivehealthcare.ahrq.gov/products/breast-reconstruction-mastectomy/research>] accessed 07/22/24.

American Cancer Society. breast reconstruction after mastectomy. Cancer Reference Information. Last revised 2022 Sept 19 [<https://www.cancer.org/cancer/types/breast-cancer/reconstruction-surgery.html>] accessed 07/10/24.

*American Society of Plastic Surgeons. Breast reconstruction following diagnosis and treatment for breast cancer. Archived practice parameter. 2004 Sep [<http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/key-issues/BreastReconstructionFollowingDiagnosisandTreatmentforBreastCancer.pdf>] accessed 07/10/24.

American Society of Plastic Surgeons. Breast reconstruction. 2024 [<https://www.plasticsurgery.org/reconstructive-procedures/breast-reconstruction>] accessed 07/10/24.

Chatterjee A, Gass J, Patel K, et al. A consensus definition and classification system of oncoplastic surgery developed by the American Society of Breast Surgeons. *Ann Surg Oncol* 2019;26:3436–3444.

Griffin C, et al. Outcomes of women undergoing mastectomy for unilateral breast cancer who elect to undergo contralateral mastectomy for symmetry: a systematic review. *Ann Surg Oncol* 2024;31:303-315.

Kuruvilla AS, et al. Oncologic safety in autologous fat grafting after breast conservation therapy. *Ann Plast Surg* 2023;90:106-110.

Mota BS, et al. Skin-sparing mastectomy for the treatment of breast cancer. Cochrane Database of Systematic Reviews 2023;3:CD010993.

*National Cancer Institute. Surgery to reduce the risk of breast cancer. 26 Jun 2024 [<https://www.cancer.gov/types/breast/risk-reducing-surgery-fact-sheet>] accessed 07/15/24.

*New York State Insurance Laws § 3216, § 3221, and § 4303 (x) (1) [<http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO>] accessed 07/11/24.

*New York State Department of Financial Services. Insurance Circular Letter No.2. July 2016 [[Insurance Circular Letter No. 2 \(2016\): Health Insurance Coverage for the Prevention and Treatment of Breast Cancer | Department of Financial Services \(ny.gov\)](#)] accessed 07/11/24.

Pietkowski AA, et al. Effect of total breast reconstruction with autologous fat transfer using an expansion device vs. implants on quality of life among patients with breast cancer, a randomized clinical trial. *JAMA Surgery* 2023 May 1;158(5)456-464.

Regan JP. Breast Reconstruction. National Library of Medicine: Stat Pearls. 23 July 2023 [<https://www.ncbi.nlm.nih.gov/books/NBK470317/>] accessed 07/10/24.

Tung NM, et al. Management of hereditary breast cancer: American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Guideline. *J Clin Oncol* 38:2080-2106.

*U.S. Department of Labor. Women’s Health and Cancer Rights Act. 2018 Sep. [<https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/your-rights-after-a-mastectomy.pdf>] accessed 07/10/24.

*Key Article

KEY WORDS

Breast reconstruction

Medical Policy: BREAST RECONSTRUCTION SURGERY AND PROPHYLACTIC BREAST CANCER RISK-REDUCING MASTECTOMY

Policy Number: 10.01.01

Page: 8 of 8

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) (140.2) for Breast Reconstruction following Mastectomy. Please refer to the following websites for Medicare Members: [<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=64&ncdver=1&keyword=breast%20reconstruction&keywordType=starts&areaId=s41&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>] accessed 07/10/24.