Page: 1 of 13

# MEDICAL POLICY



Medical Policy Title	Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy
Policy Number	10.01.01
<b>Current Effective Date</b>	August 21, 2025
<b>Next Review Date</b>	August 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to <u>Product Disclaimer</u>)

# **POLICY STATEMENT(S)**

- I. Federal and state mandates applicable to any of the following services will supersede this policy (see Policy Guidelines).
- II. 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;
    - 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. 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).

Reducing Mastectomy
Policy Number: 10.01.01

Page: 2 of 13

- IV. 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.

#### **RELATED POLICIES**

# **Corporate Medical Policy**

- 1.01.17 Powered Compression Devices/Lymphedema Pumps
- 7.01.11 Cosmetic and Reconstructive Procedures
- 7.01.35 Bioengineered Tissue Products for Wound Treatment and Surgical Interventions
- 7.01.39 Reduction Mammaplasty (Mammoplasty)
- 7.01.84 Gender Affirming Surgery and Treatments for Commercial and Medicare Advantage Members
- 7.01.105 Gender Reassignment/ Gender Affirming Surgery and Treatments for Medicaid Managed Care Plan (MMCP) and Health and Recovery Plan (HARP) Members

## POLICY GUIDELINE(S)

- I. 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.
- II. 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.

Reducing Mastectomy Policy Number: 10.01.01

Page: 3 of 13

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.

#### SUPPORTIVE LITERATURE

Wong et al (2017) updated and examined national trends in contralateral prophylactic mastectomy (CPM) and examined if survival differed for invasive breast cancer patients based on hormone receptor status and age. These investigators identified women diagnosed with unilateral stage I to III breast cancer between 1998 and 2012 within the Surveillance, Epidemiology, and End Results registry. They compared characteristics and temporal trends between patients undergoing breast-conserving surgery, unilateral mastectomy, and CPM. Of 496,488 women diagnosed with unilateral invasive breast cancer, 59.6% underwent breast-conserving surgery, 33.4% underwent unilateral mastectomy, and 7.0% underwent CPM. Overall, the proportion of women undergoing CPM increased from 3.9% in 2002 to 12.7% in 2012 (p < 0.001). Reconstructive surgery was performed in 48.3% of CPM patients compared with only 16.0% of unilateral mastectomy patients, with rates of reconstruction with CPM rising from 35.3% in 2002 to 55.4% in 2012 (p < 0.001). When compared with breast-conserving therapy, these researchers found no significant improvement in breast cancerspecific survival (BCSS) or overall survival (OS) for women undergoing CPM (BCSS: HR 1.08, 95% CI: 1.01 to 1.16; OS: HR 1.08, 95% CI: 1.03 to 1.14), regardless of hormone receptor status or age. The authors concluded that the use of CPM more than tripled during the study period despite evidence

Reducing Mastectomy Policy Number: 10.01.01

Page: 4 of 13

suggesting no survival benefit over breast conservation. They stated that further examination on how to optimally counsel women about surgical options is needed.

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.

The previously summarized Cochrane review by Carbine et al (2018) also assessed various outcomes, including mortality and disease-free survival, among individuals who received a contralateral risk-reducing mastectomy. Twenty-six observational studies assessed outcomes in these individuals. While results showed a reduced incidence of CBC among those who received a contralateral risk-reducing mastectomy, results on disease-specific mortality were inconsistent. Seven of the included studies showed no survival advantage. One additional study showed an improvement in all-cause mortality associated with contralateral risk-reducing mastectomy; however, significance was lost after adjustment for bilateral risk-reducing salpingo-oophorectomy. The authors attributed the variability in mortality findings, in part, to selection bias, since younger, healthier individuals may be more likely to opt for contralateral risk-reducing mastectomy.

Filipe et al (2022) performed a systematic review and meta-analysis that compared the postoperative complication rate of robotic nipple-sparring mastectomy (RNSM) to nipple-sparring mastectomy (NSM). The primary outcome was determining the overall postoperative complication rate of traditional NSM and RNSM. Secondary outcomes were comparing the specific postoperative complication rates: implant loss, hematoma, (flap)necrosis, infection, and seroma. Forty-nine studies containing 13,886 cases of (R)NSM were included. No statistically significant differences were found regarding postoperative complications (RNSM 3.9%, NSM 7.0%, p = 0.070), postoperative implant loss (RNSM 4.1%, NSM 3.2%, p = 0.523), hematomas (RNSM 4.3%, NSM 2.0%, p = 0.059), necrosis (RNSM 4.3%, NSM 7.4%, p = 0.230), infection (RNSM 8.3%, NSM 4.0%, p = 0.054) or seromas (RNSM 3.0%, NSM 2.0%, p = 0.421). Overall, there are no statistically significant differences in complication rates between NSM and RNSM.

Schelletter et al (2025) conducted a systematic review and meta-analysis aimed to provide a comprehensive, quantitative assessment on the risk associated with implant-based reconstruction in CPM versus therapeutic mastectomy (TM). Five studies were included in the final analysis, representing 3543 patients who underwent 6401 mastectomies (3260 TM and 3141 CPM), followed by prosthetic breast reconstruction including tissue expanders and direct-to-implant procedures. Reconstructions after TM were associated with a statistically significantly higher risk of postoperative infections (OR = 2.03 [95% CI: 1.50 - 2.73]) and explanation rates (OR = 2.41 [95% CI: 1.77 - 3.28]). No significant differences were observed between the two groups in the occurrence of

Reducing Mastectomy Policy Number: 10.01.01

Page: 5 of 13

hematoma, seroma, necrosis, and capsular contracture. Authors concluded that implant-based breast reconstruction after CPM demonstrates a lower risk of postoperative complications compared with TM.

# PROFESSIONAL GUIDELINE(S)

NCCN Guidelines V.1.2026 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, CDH1, PALB2, 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);

Reducing Mastectomy Policy Number: 10.01.01

Page: 6 of 13

- 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);
- 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).

Reducing Mastectomy
Policy Number: 10.01.01

Page: 7 of 13

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).

#### **REGULATORY STATUS**

Various breast reconstruction implants have been cleared for marketing by the FDA for specified indications. FDA device approval status can be determined using the following link: <a href="https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm">https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm</a> [accessed 2025 Jul 10]

## CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

### **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 (List separately in addition to code for primary procedure)
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
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

Reducing Mastectomy
Policy Number: 10.01.01

Page: 8 of 13

Code	Description
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 (List separately in addition to code for primary procedure)
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 bipedicled 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, readvancement 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)

Reducing Mastectomy
Policy Number: 10.01.01

Page: 9 of 13

Code	Description
21602	Excision of chest wall tumor involving 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

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# **HCPCS 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**

Reducing Mastectomy
Policy Number: 10.01.01

Page: 10 of 13

Description
Malignant inflammatory neoplasm of unspecified breast (effective 10/01/25)
Malignant inflammatory neoplasm of right breast (effective 10/01/25)
Malignant inflammatory neoplasm of left breast (effective 10/01/25)
Malignant neoplasm of nipple and areola (code range)
Malignant neoplasm of central portion of female breast (code range)
Malignant neoplasm of upper-inner quadrant of female breast (code range)
Malignant neoplasm of lower-inner quadrant of female breast (code range)
Malignant neoplasm of upper-outer quadrant of female breast (code range)
Malignant neoplasm of lower-outer quadrant of female breast (code range)
Malignant neoplasm of axillary tail of female breast (code range)
Malignant neoplasm of overlapping sites of female breast (code range)
Malignant neoplasm of unspecified site of female breast (code range)
Secondary malignant neoplasm of breast
Breast implant associated anaplastic large cell lymphoma (BIA-ALCL)
Carcinoma in situ of breast (code range)
Benign neoplasm of breast (code range)
Neoplasm of unspecified behavior of breast
Genetic susceptibility to malignant neoplasm of breast

Reducing Mastectomy Policy Number: 10.01.01

Page: 11 of 13

Code	Description
Z15.02	Genetic susceptibility to malignant neoplasm of ovary
Z15.05	Genetic susceptibility to malignant neoplasm of fallopian tube(s) (effective 10/01/25)
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)

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Reducing Mastectomy Policy Number: 10.01.01

Page: 12 of 13

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Reducing Mastectomy
Policy Number: 10.01.01

Page: 13 of 13

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### **SEARCH TERMS**

Not Applicable

# CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Breast Reconstruction Following Mastectomy (140.2) [accessed 25 Jul 03]

#### PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

#### **Committee Approval Dates**

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, 08/23/18, 08/22/19, 08/27/20, 08/19/21, 08/18/22, 08/17/23, 08/22/24, 08/21/25

Date	Summary of Changes
08/21/25	Annual review, policy intent unchanged
01/01/25	Summary of changes tracking implemented.
10/18/01	Original effective date