

#### UnitedHealthcare® Community Plan Medical Policy

# **Breast Reconstruction (for North Carolina Only)**

Policy Number: CSNC.MP.003.05 Effective Date: December 1, 2023

Instructions for Use

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#### **Related Policies**

- Breast Reduction Surgery (for North Carolina Only)
- Cosmetic and Reconstructive Procedures (for North Carolina Only)
- Gynecomastia Surgery (for North Carolina Only)
- Pneumatic Compression Devices (for North Carolina Only)

## **Application**

This Medical Policy only applies to the state of North Carolina.

## **Coverage Rationale**

For breast reconstructive surgery medical necessity clinical coverage criteria, refer to the <u>North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy, Physician: 1A-12, Breast Surgeries.</u>

Treatment for complications post Mastectomy are covered and considered Medically Necessary for the following:

- Lymphedema, including the following:
  - Complex decongestive physiotherapy (CDP)
    - Lymphedema pumps (these pumps are considered Durable Medical Equipment)
    - Compression lymphedema sleeves (these sleeves are considered a prosthetic device)
    - Elastic bandages and wraps associated with medically necessary treatments for the complications of lymphedema
- Post-operative infection(s)

#### **Definitions**

Check the federal, state or contractual definitions that supersede the definitions below.

**Mastectomy**: Surgery to remove all or part of the breast. There are different types of mastectomy that differ in the amount of tissue and lymph nodes removed (NCI, 2018).

**Medically Necessary**: Health care services that are all of the following:

- In accordance with generally accepted standards of medical practice
- Clinically appropriate, in terms of type, frequency, extent, service site and duration, and considered effective for sickness, injury, mental Illness, substance-related and addictive disorders, disease or its symptoms

- Not mainly for your convenience or that of your doctor or other health care provider
- Not more costly than an alternative drug, service(s), service site or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of sickness, Injury, disease or symptoms (COC)

# **Applicable Codes**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less  Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm  Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20.0 sq cm, or part thereof (List separately in addition to code for primary procedure)  Replacement of tissue expander with permanent implant  Removal of tissue expander without insertion of implant  Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area  Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)  Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate  Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)  Inplantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (i.e., breast, trunk) (List separately in addition to code for primary procedure)  Mastopesy  Breast augmentation with implant  Removal of intact breast implant, including implant contents (e.g., saline, silicone gel)  Insertion of breast implant on same day of mastectomy (i.e., immediate)  Insertion of breast implant on same day of mastectomy (i.e., immediate)  Insertion of replacement of breast implant on separate day from mastectomy  Nipple/areola reconstruction; with free flap (e.g., fTRAM, DIEP, SIEA, GAP flap)  Breast reconstruction; with free flap (e.g., fTRAM, DIEP, SIEA, GAP flap)	CPT Code	Description
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CPT Code	Description
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
19499	Unlisted procedure, breast

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HCPCS Code	Description
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 with 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
S8950	Complex lymphedema therapy, each 15 minutes

Diagnosis Code	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast

Diagnosis Code	Description
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C79.81	Secondary malignant neoplasm of breast
C84.7A	Anaplastic large cell lymphoma, ALK-negative, breast
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast

Diagnosis Code	Description
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
D48.61	Neoplasm of uncertain behavior of right breast
D48.62	Neoplasm of uncertain behavior of left breast
197.2	Postmastectomy lymphedema syndrome
N65.0	Deformity of reconstructed breast
N65.1	Disproportion of reconstructed breast
Q79.8	Other congenital malformations of musculoskeletal system
T85.43XA	Leakage of breast prosthesis and implant, initial encounter
T85.43XD	Leakage of breast prosthesis and implant, subsequent encounter
T85.43XS	Leakage of breast prosthesis and implant, sequela
Z42.1	Encounter for breast reconstruction following mastectomy
Z45.811	Encounter for adjustment or removal of right breast implant
Z45.812	Encounter for adjustment or removal of left breast implant
Z45.819	Encounter for adjustment or removal of unspecified breast implant
Z85.3	Personal history of malignant neoplasm of breast
Z90.10	Acquired absence of unspecified breast and nipple
Z90.11	Acquired absence of right breast and nipple
Z90.12	Acquired absence of left breast and nipple
Z90.13	Acquired absence of bilateral breasts and nipples

## **Description of Services**

Reconstructive breast surgery may be required to restore the normal appearance of the breasts after a lumpectomy or mastectomy for the treatment of breast cancer. This can include mastopexy to the contra-lateral breast and may involve a variety of procedures. Reconstruction can occur immediately after surgery or be delayed until a patient completes radiation and/or chemotherapy or decides if they want breast reconstruction.

Breast reconstruction surgery may also be indicated for conditions unrelated to breast cancer. These include treatment for Poland's Syndrome and other disorders that cause breast disfigurement, disfigurement caused by radiation or trauma, and removal of breast implants with or without a capsulectomy/capsulotomy.

#### **Clinical Evidence**

#### Treatment for Lymphedema

Blom et al. (2022) conducted an RCT to evaluate the proportion of women with mild breast cancer-related arm lymphedema (BCRAL) showing progression/no progression of lymphedema after treatment with or without compression garments, and the differences in changes of lymphedema relative volume (LRV), local tissue water, and subjective symptoms during 6 months. The study included 75 women randomized into two groups (compression or non-compression) diagnosed with mild BCRAL. Both groups received self-care instructions and the compression group were treated with a standard compression garment. The proportion of LRV was measured by water displacement method and the changes in local tissue water were measured by Tissue Dielectric Constant (TCD). The results showed a smaller proportion of LRV progression was in found in the compression group compared to non-compression group at 1-, 2-and 6-months follow-up ( $p \le 0.013$ ). At 6 months 16% had progression of LRV in the compression group compared to 57% in the non-compression group (p = 0.001). Thus 43% in the noncompression

group showed no progression and could manage without compression. Also, the compression group had a larger reduction in LRV at all time points ( $p \le 0.005$ ), and in the highest TDC ration, when same site followed at 6 months (p = 0.025). Subjective symptoms did not differ between groups, except at 1 month, where the compression group experienced more reducted tension. There were no differences in adherence to self-care. The authors concluded early treatment with a compression garment can prevent progression in mild BCRAL when compared to no compression garment. The authors recommend future research to evaluate the long-term effects and factors influencing progression of mild BCRAL is needed. Limitations include lack of blinding and small study size.

Rickson, SG (2018) published a clinical practice article in the New England Journal of Medicine. In this article he indicates that breast cancer related lymphedema is the most common form of lymphedema in the United Sates and the major risk factor is axillary lymph-node dissection and adjuvant radiation therapy. The risk of lymphedema after breast cancer treatment varies widely from 14 to 40%. Increasingly conservative approaches to surgery and radiotherapy have driven the estimated incidence closer to the lower limits of this range; sentinel-node sampling techniques reduce the estimated risk of breast cancer–associated lymphedema to 6 to 10%. Treatment generally involves manual lymphatic drainage (a massage technique that stimulates lymphatic contractility), skin care, serial application of multilayer bandaging, and exercise. Exercise does not exacerbate and may ameliorate symptoms in patients with established lymphedema. For patients with an elevated body-mass index, weight reduction and maintenance strategies are indicated. Debulking surgeries appear to be helpful in the later, advanced stages of disease; there is also some evidence for benefit from microsurgery, but more data are needed regarding its effectiveness.

## **U.S. Food and Drug Administration (FDA)**

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Reconstructive breast surgeries are procedures and therefore not regulated by the FDA. However, implants, tissue expanders, and ADM products used during the surgery require FDA approval. Refer to the following website for additional information: <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</a>. (Accessed May 12, 2023)

In 2019, at the request of the FDA, Allergan issued a worldwide recall of their BIOCELL textured breast implant products. These included Natrelle Saline-Filled breast implants, Natrelle Silicone-Filled breast implants, Natrelle Inspira Silicone-Filled breast implants, and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants. The recall also includes tissue expanders used by patients prior to breast augmentation or reconstruction, including Natrelle 133 Plus Tissue Expander and Natrelle 133 Tissue Expander with Suture Tabs. Refer to the following website for additional information: <a href="https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan">https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan</a>. (Accessed May 12, 2023)

On October 27, 2021, the FDA took several new actions to strengthen breast implant safety communication to help those considering implants make informed decision. Refer to the following website for complete information regarding this update: <a href="https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants">https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants</a>. (Accessed May 12, 2023)

On March 31, 2021, the FDA issued a safety advisory notification regarding ADM products used in implant-based breast reconstruction. The FDA has not cleared or approved any ADMs for use in breast reconstruction and certain ADM products may have a higher risk of complications when used for this off-label indication. Refer to the following website for further information: <a href="https://www.fda.gov/medical-devices/safety-communications/acellular-dermal-matrix-adm-products-used-implant-based-breast-reconstruction-differ-complication">https://www.fda.gov/medical-devices/safety-communications/acellular-dermal-matrix-adm-products-used-implant-based-breast-reconstruction-differ-complication</a>. (Accessed May 12. 2023)

#### References

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UnitedHealthcare Insurance Company Generic Certificate of Coverage (COC) 2018.

# Policy History/Revision Information

Date	Summary of Changes
12/01/2023	Supporting Information
	Updated Clinical Evidence and References sections to reflect the most current information
	Archived previous policy version CSNC.CDG.003.04

#### **Instructions for Use**

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.