

#### UnitedHealthcare® Community Plan Medical Policy

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

Policy Number: CSNC.MP.003.06 Effective Date: October 1, 2024

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)
- <u>Pneumatic Compression Devices (for North Carolina Only)</u>

### **Application**

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

### **Coverage Rationale**

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

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).

### **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.

CPT 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	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm
*11922	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)
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant
15271	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
15272	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)
*15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
*15772	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)
15777	Implantation 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)
19316	Mastopexy
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)
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
19355	Correction of inverted nipples
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
19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, 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, 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

HCPCS Code	Description
*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

Codes labeled with an asterisk (\*) are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program.

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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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 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**

#### Non-Surgical Treatment for Lymphedema

Muñoz-Alcaraz et al. (2023) conducted a systematic review to determine the effect on health-related quality of life (HRQoL) of different conservative interventions in the rehabilitation of breast cancer-related lymphedema (BCRL) in the upper limb in women. The study included eight clinical trials (n = 1293) from multiple countries all women with stage I, II, or III BCRL. The conservative treatments utilized in the studies were compression elements (33.33%), manual drainage therapy (22.22%), care education (11%), more advanced therapies such as electrical moxibustion, myofascial release and electrotherapy. Other programs showed improvement in patients HRQoL such as aquatic lymphatic therapy and antiedema proprioceptive treatment. The assessment tools and scales used to assess the HRQoL in the studies varied. The most commonly used scale were the 36-Item Short Form Health Survey (SF-36) and the Functional Assessment of Cancer Therapy-Breast Limb Lymphedema 27 Value (ULL-27). The results showed the most recommended approach for improvement of HRQoL in BCRL would be complex decongestive therapy (CDT), excluding the manual lymphatic drainage (MLD) component. The impact of garment use remains controversial with mixed recommendations. In addition, the research does not support the use of laser therapy and electrical moxibustion. The authors concluded there is limited and controversial information about the effects of various conservative treatments for upper limb BCRL on HRQoL in women. The limitations of the study were heterogeneity of the modalities, outcome measurement instruments, and comparison of different interventions with different patient types.

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 noncompression) 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 6months follow-up (p ≤ 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  $\leq$  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 longterm effects and factors influencing progression of mild BCRAL is needed. Limitations include lack of blinding and small study size.

### 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 July 22, 2024)

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 July 22, 2024)

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 July 22, 2024)

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/news-events/fda-brief/fda-brief-fda-warns-about-differing-complication-rates-acellular-dermal-matrix-type-surgical-mesh">https://www.fda.gov/news-events/fda-brief/fda-brief-fda-warns-about-differing-complication-rates-acellular-dermal-matrix-type-surgical-mesh</a> (Accessed July 22, 2024)

#### References

Blom KY, Johansson KI, Nilsson-Wikmar LB, et al. Early intervention with compression garments prevents progression in mild breast cancer-related arm lymphedema: a randomized controlled trial. Acta Oncol. 2022 Jul;61(7):897-905.

Muñoz-Alcaraz MN, Jiménez-Vílchez AJ, Pérula-de Torres LÁ, et al. Effect of conservative rehabilitation interventions on health-related quality of life in women with upper limb lymphedema secondary to breast cancer: A systematic review. Healthcare (Basel). 2023 Sep 17;11(18):2568.

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policy for Physicians, Breast Surgeries, No: 1A-12. Breast Surgeries: https://medicaid.ncdhhs.gov/1a-12-breast-surgeries/download?attachment. Accessed July 22, 2024.

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

### **Policy History/Revision Information**

Date	Summary of Changes
10/01/2024	<ul> <li>Definitions</li> <li>Removed definition of "Medically Necessary"</li> <li>Applicable Codes</li> <li>Added notation to indicate CPT/HCPCS codes 11922, 15771, 15772, 19396, 19499, L8600, S2066, S2067, S2068, and S8950 are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program</li> </ul>
	<ul> <li>Supporting Information</li> <li>Updated Clinical Evidence, FDA, and References sections to reflect the most current information</li> <li>Archived previous policy version CSNC.MP.003.05</li> </ul>

#### **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.

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