

Breast Reconstruction (for Tennessee Only)

Policy Number: CS011TN.R

Effective Date: December 1, 2023

[Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	1
Definitions	2
Applicable Codes	3
Description of Services	6
Benefit Considerations	6
Clinical Evidence	7
U.S. Food and Drug Administration	10
References	10
Policy History/Revision Information	11
Instructions for Use	11

Related Policies
• Breast Reduction Surgery (for Tennessee Only)
• Cosmetic and Reconstructive Procedures (for Tennessee Only)
• Gynecomastia Surgery (for Tennessee Only)
• Pneumatic Compression Devices (for Tennessee Only)

Application

This Medical Policy only applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

➔ See [Benefit Considerations](#)

Breast reconstruction during or post Mastectomy and for treatment of congenital disorder (e.g., Poland Syndrome, Turner Syndrome) or severe breast disfigurement (e.g., amastia, radiation) is considered [Reconstructive](#) and [Medically Necessary](#) in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Breast Reconstruction.

Click [here](#) to view the InterQual® criteria.

Breast reconstruction for asymmetry for all other indications is considered Cosmetic and not Medically Necessary (refer to [Benefit Considerations](#)).

The following procedures may be considered Reconstructive and Medically Necessary when performed with a breast Reconstructive Procedure:

- Creation of a nipple (by various techniques) and areola (tattooing)
- Mastopexy or breast reduction when required prior to Mastectomy to preserve the viability of the nipple
- Reconstruction with a breast implant with or without the following:
 - Implantation of a tissue expander as the initial phase of reconstruction
 - Use of an Acellular Dermal Matrix (ADM), including but not limited to Alloderm™, Cortiva® AlloMax™, DermACELL, or FlexHD

*The surgical procedure performed on a non-diseased breast to establish symmetry with the diseased breast will only be covered if the surgical procedure performed on a non-diseased breast occurs within five (5) years of the date the Reconstructive breast surgery was performed on a diseased breast. Refer to [Tenn. Comp. R. & Regs. 1200-13-13-.04](#).

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)

Removal of breast implants is considered Reconstructive and Medically Necessary for the following:

- Individuals implanted with the Allergan® BIOCELL textured breast implants regardless of reason for initial placement due to an increased risk of breast cancer related Anaplastic Large Cell Lymphoma
- With or without capsulectomy/capsulotomy in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Breast Implant Removal

Click [here](#) to view the InterQual® criteria.

Breast repair and reconstruction procedures not post Mastectomy are considered Reconstructive and Medically Necessary for the correction of inverted nipples when one of the following criteria are met:

- Documented history of chronic nipple discharge, bleeding, scabbing or ductal infection; or
- Correction of an inverted nipple(s) resulting from a [Congenital Anomaly](#)

Definitions

Check the definitions within the federal, state, and contractual requirements that supersede the definitions below.

Acellular Dermal Matrix (ADM): A type of surgical mesh developed from human or animal skin, in which the cells are removed, and the support structure is left in place (FDA, 2021).

Anaplastic Lymphoma: A rare type of non-Hodgkin lymphoma (NHL), and one of the subtypes of T cell lymphoma that comprises about one percent of all NHLs and approximately 16 percent of all T cell lymphomas (Lymphoma Research Foundation). Breast implant-associated anaplastic large cell lymphoma most commonly presents as a delayed fluid collection around a textured implant or as a mass in the fibrous capsule surrounding the implant (St. Cyr, 2020).

Congenital Anomaly: A physical developmental defect that is present at the time of birth, and that is identified within the first twelve months of birth (COC, 2018).

Cosmetic Procedures: Procedures or services that change or improve appearance without significantly improving physiological function (COC, 2018).

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).

Mastopexy/Breast Lift: A procedure that raises the breast, removes excess skin, and tightens surrounding tissue (ASPS, 2022).

Medically Necessary: Medically Necessary is defined by Tennessee Code Annotated, Section 71-5-144, and shall describe a medical item or service that meets the criteria set forth in that statute. The term “Medically Necessary,” as defined by Tennessee Code Annotated, Section 71-5-144, applies to TennCare enrollees. Implementation of the term “Medically Necessary” is provided for in these rules, consistent with the statutory provisions, which control in case of ambiguity. No enrollee shall be entitled to receive and TennCare shall not be required to pay for any items or services that fail fully to satisfy all

criteria of “Medically Necessary” items or services, as defined either in the statute or in the [Medical Necessity rule chapter at 1200-13-16](#).

Reconstructive Procedures: Surgery or other procedures which are related to an injury, sickness, or Congenital Anomaly. The primary result of the procedure is not a changed or improved physical appearance (COC, 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

CPT Code	Description
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

CPT® is a registered trademark of the American Medical Association

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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
I97.2	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 after a lumpectomy or Mastectomy for the treatment of breast cancer, to restore the normal appearance of the breasts. 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.

Benefit Considerations

Refer to the federal, state, and contractual requirements for information regarding coverage, limitations and exclusions that may supersede those listed below.

Note: A gap exception may be granted if there is not an in-network provider able to provide the requested Reconstructive Procedure.

Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic. Breast reconstruction for the following are considered cosmetic and excluded from coverage:

- Aberrant breast tissue
- Aspirations
- Biopsy (open or core)
- Duct lesions
- Excision of cysts
- Fibroadenomas or other benign or malignant tumors
- Nipple or areolar lesions
- Treatment of gynecomastia
- Revision of a prior reconstructed breast due to normal aging
- Tissue protruding at the end of a scar (“dog ear”/standing cone). Painful scars or donor site scar revisions must meet the definition of a Reconstructive Procedure to be considered for coverage

Additionally, the following Cosmetic Procedures are excluded from coverage when not related to Mastectomy:

- Breast enhancement (e.g., breast implants, mastopexy)
- Liposuction
- Breast surgery for the purpose of creating symmetrical breasts

Clinical Evidence

Nipple Reconstruction

A systematic review was conducted by Oliver et al. (2020) on the outcomes of allogenic and alloplastic implant materials utilized during nipple-areola reconstruction. The study included 592 nipple-areola complexes on 482 patients (15 case series) where alloplastic or allograft material was utilized to achieve and maintain nipple projection. The results showed patient satisfaction rate was 93.3% with their reconstruction. The alloplastic and allograft implants had an overall complication rate of 5.3% across all materials used. The most common complication was flap or graft necrosis, the highest complication rate was the Ceratite implant (18%) including flap/graft necrosis (13%) and extrusion of artificial bone (5%). The biodesign nipple reconstruction cylinder including other rigid implants reported complications of extrusion (3.6%), projection loss requiring revision (2.5%), wound dehiscence/drainage (1.5%), flap or graft necrosis (1.0%) and excessive bleeding (0.5%). ADM implants had complications with insufficient projection (0.8%) and excessive projection (1.6%) which required surgical revision. Lastly, injectable materials had minimal reported complications. The authors concluded allogeneic and alloplastic grafts are reliable and achieve satisfactory nipple projection with relatively low complication rates. The authors suggested clinical studies are necessary to better understand the feasibility and long-term outcomes of the use of allogeneic and alloplastic augmentation grafts. Study limitations include.

Winocour et al. (2016) performed a systematic review to look at the many techniques described for nipple reconstruction, with the principal limitation being excessive loss of projection. A variety of materials are available for projection augmentation, including autologous, allogeneic, and synthetic materials. In 2016, there has been no systematic review to study the efficacy, projection, and complication rates of different materials used in nipple reconstruction. The authors searched Medline, Embase, and PubMed databases, from inception to August of 2014, to identify any literature reporting outcomes of autologous, allogeneic, and synthetic grafts in nipple reconstruction. Retrospective and prospective studies with controlled and uncontrolled conditions were included. Studies reporting the use of autologous flap techniques without grafts and articles lacking post-operative outcomes were excluded. Study quality was assessed using the Newcastle-Ottawa Scale. A total of 31 studies met the inclusion criteria. 1 study represented 2 of 9 stars on the Newcastle-Ottawa Scale, 2 studies represented 3 stars, 6 studies represented 4 stars, 7 studies represented 5 stars, 11 studies represented 6 stars, and 4 studies represented 7 stars. The authors concluded that the findings of this review revealed heterogeneity in the type of material used within each category and inconsistent methodology used in outcomes assessment in nipple reconstruction. Overall, the quality of evidence was low. Synthetic materials had higher complication rates and allogeneic grafts had nipple projection comparable to that of autologous grafts. The authors stated that further investigation with high-level evidence is needed to determine the optimal material for nipple reconstruction.

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) can develop around breast implants. BIA-ALCL is a recently recognized non-Hodgkin lymphoma of T-cell origin that can develop around breast implants, most commonly those with textured surfaces. It has been associated with both silicone and saline implants and in breast cancer and cosmetic reconstruction. The exact pathogenesis of the disease remains unclear.

Santanelli et al. (2023) conducted a systematic review on 248 BIA-ALCL cases in the United States, Netherlands, Italy, and Australia which were retrospectively analyzed between October 2021 and April 2022. The mean age at first implantation was 42 years (range, of 15-80 years) and the mean age at diagnosis was 53 years (range, 24-87 years). Aesthetic indications were the reason for 52% of cases and reconstruction for 48%; macro-textured surface was linked to 73.8% and seroma to 83% of cases. The total follow-up time was 492 months, and mean event-free time (EFT) to development of BIA-ALCL was 129 months. BIA-ALCL occurred 99 times in the right side and 104 in the left: there were 2 cases of bilateral involvement. The incident rate was 96 new cases/1000 women per year after first implantation and was correlated to the number of replacements. The authors concluded there is association with earlier disease onset in older patients and in patients with BRCA1/2 and TP53 with the use of macro-textured implants. Replacement of implants in the asymptomatic, high-risk patients can be indicated to reduce the incidence rate and risk. The limitations of the study include the retrospective design and possible conflict of interest.

Cordeiro et al. (2020) conducted a prospective cohort study to determine the risk of BIA-ALCL of 3546 women who underwent breast reconstruction by a single surgeon in one institution from December 1992 to December 2017. During this time period, 3546 patients underwent 6023 breast reconstructions after breast cancer removal, or contralateral prophylactic mastectomy, using macro-textured surface expanders and implants. Median follow-up was 8.1 years (range, 3 months-30.9 years) and 10 women, 1/354 cases, developed ALCL after exposure of 11.5 years (range, 7.4-15.8 years). Overall risk of BIA-ALCL in this study was reported as 0.311 cases per 1000 person-years (95% CI 0.118 to 0.503). The authors concluded the incidence rate of BIA-ALCL may be higher than previously reported. The limitations of the study include possible selection bias and lack of control group.

St.Cyr et al. (2020) published a review article on the current understanding and management of BIA-ALCL. As of March 2018, approximately 529 BIA-ALCL cases had been reported in 23 countries. 16 patients have died, and all had extracapsular involvement. Patients with confirmed cases should be referred to a lymphoma specialist or breast medical oncologist for a complete oncologic evaluation before any surgical intervention. For disease confined to the fluid accumulation or capsule, or both, surgical removal of the implant and complete capsulectomy is the preferred treatment. Removal of the contralateral implant if present should be considered, as 4.6% of reported cases of BIA-ALCL have also involved the contralateral breast. Postoperative chemotherapy and/or radiation are not considered necessary for patients with limited-stage disease, as current evidence suggests complete remission can be attained with surgery and are reserved for advanced stages of the disease. In general, BIA-ALCL is a localized disease that follows an indolent course and has an excellent prognosis when the implant and capsule are completely removed.

Acellular Dermal Matrix (ADM)

In a randomized control trial (RCT) Arnaout et al. (2020) compared Alloderm-Ready to Use (RTU) with DermACELL in reducing drain duration in immediate subpectoral implant-based breast reconstruction. 62 patients undergoing mastectomy were randomized (41 Alloderm-RTU, 40 DermACELL) with similar baseline characteristics. The primary outcome was seroma formation, measured by the duration of postoperative drain placement. The results showed there was no significant difference in mean drain duration ($p = 0.16$), however the Alloderm-RTU group (1.6 days; 95%CI, 0.7 to 3.9) had longer trending duration. The overall rate of complications was similar between the two groups, although patients with Alloderm-RTU had 3 times as many infections (7.9% vs. 2.5%) and twice as many unplanned returns to the operating room (15.8% vs. 7.5%). The authors concluded there were no statistically significant differences in minor and major complications or drain duration between DermACELL over Alloderm-RTU in immediate subpectoral permanent implant-based breast reconstruction post-mastectomy. The limitations of the study include small sample size, single-center study design.

Pittman et al (2017) compared the clinical outcomes between available ADMs DermACELL and AlloDerm (RTU). A retrospective chart review was performed on 58 consecutive patients (100 breasts) reconstructed with either DermACELL ($n = 30$ patients; 50 breasts) or AlloDerm-RTU ($n = 28$ patients; 50 breasts). The mastectomies were performed by three different breast surgeons. All reconstructions were performed by the same Plastic surgeon (TAP). Statistical analysis was performed by Fisher's exact test. The average age, body mass index (BMI), percent having neo-adjuvant/adjuvant chemotherapy or breast

irradiation, and numbers of therapeutic and prophylactic mastectomies between the two groups was not statistically significant ($p < 0.05$). Complications in both cohorts of patients were clinically recorded for 90 days post immediate reconstruction. The authors reported that, when comparing outcomes, patients in the DermACELL group had significantly less incidence of 'red breast' (0 % versus 26 %, $p = 0.0001$) and fewer days before drain removal (15.8 versus 20.6, $p = 0.017$). No significant difference was seen in terms of seroma, hematoma, delayed healing, infection, flap necrosis, and explanation.

Vashi (2014) reported on the use of DermACELL ADM in two-stage postmastectomy breast reconstruction. Ten consecutive breast cancer patients were treated with mastectomies and immediate reconstruction from August to November 2011. There were 8 bilateral and 1 unilateral mastectomies for a total of 17 breasts, with one exclusion for chronic tobacco use. Reconstruction included the use of a new 6 × 16 cm sterile, room temperature ADM patch (DermACELL) soaked in a cefazolin bath. Results. Of the 17 breasts, 15 reconstructions were completed; 14 of them with expander to implant sequence and ADM. Histological analysis of biopsies obtained during trimming of the matrix at the second stage appeared nonremarkable with evidence of normal healing, cellularity, and vascular infiltration.

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 found in the compression group compared to non-compression group at 1-, 2- and 6-months follow-up ($p \leq 0.013$). 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 reduced 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.

Rockson, 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 States and the major risk factor is axillary lymph-node dissection and adjuvant radiation therapy. The risk of lymphedema after breast cancer treatment vary 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.

Inverted Nipples

Mangialardi et al. (2020) performed a literature search to provide a comprehensive review of the literature regarding surgical treatment for inverted nipples. Studies that described surgical treatment and included outcomes and recurrence rate were included. Thirty-three studies meet the inclusion criteria, 17 were retrospective studies, 16 were prospective studies, of which one was an RCT, and included a total 3369 inverted nipple cases. Eight studies described techniques with lactiferous ducts damaging, and 25 studies described techniques with lactiferous duct preservation using dermal flaps, sutures, or distractor systems. The average follow-up was 23.9 months. The results showed that overall, a satisfactory correction was reached in 88.6% of cases, with a recurrence rate of 3.89%. The authors concluded that heterogeneity and the subjective natures of reported outcomes make it more complicated to state which is the best surgical strategy to obtain satisfactory and stable, and that this study highlights the need for standardization to evaluate outcomes. Prospective studies with a standardized outcome

measurement method will be essential to better understand which is the ideal corrective strategy for patients affected by different grades of nipple inversion.

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: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm>. (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: <https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan>. (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: <https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants>. (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: <https://www.fda.gov/medical-devices/safety-communications/acellular-dermal-matrix-adm-products-used-implant-based-breast-reconstruction-differ-complication>. (Accessed May 12, 2023)

References

American Society of Plastic Surgeons (ASPS) 2022. American Society of Plastic Surgeons (ASPS). How to diagnose and treat breast implant-associated anaplastic large cell lymphoma.

Arnaout A, Zhang J, Frank S, et al. A randomized controlled trial comparing Alloderm-RTU with DermACELL in immediate subpectoral implant-based breast reconstruction. *Curr Oncol*. 2020 Dec 25;28(1):184-195.

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.

[Breastcancer.org](https://www.breastcancer.org). Accessed May 18, 2023.

Centers for Disease Control and Prevention (CDC). Birth defects surveillance toolkit. November 2020.

Centers for Medicare and Medicaid Services (CMS). Women's Health and Cancer Rights Act (WHCRA). Available at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet. Accessed May 18, 2023.

Clemens MW, et al. 2019 NCCN consensus guidelines on the diagnosis and treatment of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). *Aesthet Surg J*. 2019 Jan 31;39(Suppl_1):S3-S13.

Cordeiro PG, Ghione P, Ni A, et al. Risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in a cohort of 3546 women prospectively followed long term after reconstruction with textured breast implants. *J Plast Reconstr Aesthet Surg*. 2020 May;73(5):841-846.

Lymphoma Research Foundation. Anaplastic large cell lymphoma. 2022.

Mangialardi ML, Baldelli I, Salgarello M et al., Surgical correction of inverted nipples. *Plast Reconstr Surg Glob Open*. 2020 Jul 27;8(7):e2971.

National Cancer Institute (NCI). NCI Dictionaries. Mastectomy. Rockson SG. Lymphedema after breast cancer treatment. N Engl J Med 2018; 379:1937-1944.

Oliver JD, Beal C, Hu MS, et al. Allogeneic and alloplastic augmentation grafts in nipple-areola complex reconstruction: A systematic review and pooled outcomes analysis of complications and aesthetic outcomes. Aesthetic Plast Surg. 2020 Apr;44(2):308-314. doi: 10.1007/s00266-019-01539-7. Epub 2019 Nov 13. PMID: 31722063.

Pittman TA, Fan KL, Knapp A, et al. Comparison of Different Acellular Dermal Matrices in Breast Reconstruction: The 50/50 Study. Plast Reconstr Surg. 2017 Mar;139(3):521-528.

Santanelli Di Pompeo F, Panagiotakos D, Firmani G, et al. BIA-ALCL epidemiological findings from a retrospective study of 248 cases extracted from relevant case reports and series: A systematic review. Aesthet Surg J. 2023 Apr 10;43(5):545-555.

St. Cyr TL, Pockaj BA, Northfelt DW, et al. Breast implant-associated anaplastic large-cell lymphoma: current understanding and recommendations for management. *Plast Surg (Oakv)*. 2020;28(2):117-126.

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

U.S. Centers for Medicare & Medicaid Services (CMS). Healthcare.gov Glossary.

Vashi C. Clinical outcomes for breast cancer patients undergoing mastectomy and reconstruction with use of DermACELL, a sterile, room temperature acellular dermal matrix. *Plast Surg Int*. 2014;2014:704323.

Winocour S, Saksena A, Oh C, et al. A systematic review of comparison of autologous, allogeneic, and synthetic augmentation grafts in nipple reconstruction. *Plast Reconstr Surg*. 2016;137(1):14e-23e.

Policy History/Revision Information

Date	Summary of Changes
12/01/2023	<p>Coverage Rationale</p> <ul style="list-style-type: none">Added language to indicate breast reconstruction for asymmetry for all other indications [not listed in the policy as Reconstructive and Medically Necessary] is considered Cosmetic and not Medically Necessary; refer to the <i>Benefit Considerations</i> section of the policyReplaced language indicating “breast reconstruction post Mastectomy and for treatment of Poland’s Syndrome is considered Reconstructive and Medically Necessary in certain circumstances” with “breast reconstruction <i>during or</i> post Mastectomy and for treatment of <i>congenital disorders (e.g., Poland Syndrome, Turner Syndrome) or severe breast disfigurement (e.g., amastia, radiation)</i> is considered Reconstructive and Medically Necessary in certain circumstances” <p>Supporting Information</p> <ul style="list-style-type: none">Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current informationArchived previous policy version CS011TN.Q

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.