Breast Reconstruction (for Tennessee Only)

Policy Number: CS011TN.T
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➲ Instructions for Use

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Related Policies

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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 the Benefit Considerations section of the policy.

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 TennCare Medicaid, Chapter 1200-13-13-.04: Covered Services.

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

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

Definitions

Refer to the federal, state, and contractual definitions 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).

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).

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.

Coding Clarification: Intraoperative assessment of vascular perfusion is considered an integral part of the breast reconstruction and is not separately reimbursable.

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

CPT Code	Description
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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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

Over an 8-year period at a UK tertiary referral center Rice et al. (2024) performed a new technique used to reconstruct the nipple areolar complex (NAC). Patient outcomes measures included complications, satisfaction, and need for revision

surgery. The study was completed by conducting a systematic review of current literature on the results and complications of grafting techniques for NAC reconstruction. The novel technique performed on 405 NAC reconstructions used a modified C-V flap with a full-thickness skin graft (FTSG) and later nipple tattoo if required. The results demonstrated partial flap necrosis occurred in 0.2% (n = 1) , no incidences of donor site complications reported, and no patients had to undergo revision surgeries. Thirty-six articles were included in the systematic review with 1564 patients. Twenty-four articles elected to harvest skin grafts from the upper inner thigh or groin and reported a low rate of hypopigmentation or poor color matching. Two patients were reported to have total necrosis, and 9 partial necrosis. Nine also reported rates of donor site dehiscence or irritation and donor site infection. Nine articles preferred the contralateral or ipsilateral areolar tissue as skin graft donor site and reported only minor complications. Other articles reported the use of upper arm skin, labia minora, labia majora, infragluteal crease, and only one mentioned using the scar created following transverse rectus abdominus muscle flap. Nine articles reported that no complications were encountered, and 5 did not mention complications rates in their results. The literature results suggested that color fading and unexpected pigmentation were more commonly encountered in grafts taken from the thighs and the contralateral breast. The authors concluded the combined technique for NAC reconstruction involving modified C-V flap and a FTSG taken from the abdomen to reconstruct the areola offers a consistent and more natural outcome and addresses the limitations and complications commonly encountered. The authors noted they obtained strong results in terms of esthetics, low rate of complications, and patient satisfaction. The study limitations include level 4 evidence, no control group and no formal patient reported outcomes. The study would be strengthened by controlled comparisons, standardized satisfaction measurements, and clearer reporting on cohort demographics and statistical outcomes.

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 lack of large-volume studies across all implant types, lack of standardized outcomes data and unavailability of cumulative outcomes.

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. One study represented two of nine stars on the Newcastle-Ottawa Scale, two studies represented three stars, six studies represented four stars, seven studies represented five stars, 11 studies represented six stars, and four studies represented seven 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.

Clemens et al. (2024) conducted a systematic review and meta-analysis to evaluate the existing evidence regarding the diagnosis and management of BIA-ALCL caused by textured implants. A total of 145 articles published between January 2011 and January 2023 were included in the synthesis of results, including 105 case reports or case series. The analysis

encompassed risk factors, clinical presentation, diagnostic approaches, the incidence and treatment modalities related to BIA-ALCL. The authors concluded ongoing research related to the pathogenesis, genetic drivers, and preventative and prophylactic measures is crucial for improving patient care. The authors noted plastic surgeons should be aware of the elevated risks by implant surface type, follow recommendations and implement patient surveillance to ensure patient safety and optimize outcomes. The literature is limited by the types and design of studies which does not allow for level A evidence or the highest strength of evidence classifications.

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 two 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)

Ng et al. (2024) conducted a systematic review and meta-analysis to compare postoperative complications and patient-reported outcomes between groups utilizing ADM during breast reconstruction and those without ADM. The inclusion criteria analyzed nine studies representing 3161 breasts from randomized controlled trials (RCTs) and prospective cohort studies. The results showed there were no significant difference in postoperative outcomes such as seroma formation ($p = 0.51$), hematomas ($p = 0.20$), infections ($p = 0.21$), wound dehiscence ($p = 0.09$), reoperations ($p = 0.70$), implant loss ($p = 0.27$), or skin necrosis ($p = 0.21$). Only two studies evaluated patient-reported outcomes including pain. There was no reported significant difference in BREAST-Q or pain scores. The authors concluded the meta-analysis showed comparable short- and long-term outcomes between ADM and non-ADM breast reconstruction. However, there is paucity of data in the domain of patient-reported outcomes, requiring further research. The limitations of the study include lack of standardization in ADM types, implant placement, limited heterogeneity, and small sample size.

The BREASTrial conducted by Mendenhall et al. (2023) evaluated the postoperative outcomes from three months to two years between two ADMs, AlloDerm and DermaMatrix. The single center, blinded, prospective, randomized trial included 128 patients (199 breasts), although only 108 patients (167 breasts) were available for the analysis in stage III. The results showed no difference in the overall complication rates between the AlloDerm and DermaMatrix groups (6% versus 13.2%; $p = 0.3$) or the severity of those complications ($p = 0.7$). Obesity was a positive predictor for complications, regardless of reconstruction ($p = 0.02$). Patient satisfaction was positive and did not vary between AlloDerm and DermaMatrix groups. The authors concluded the BREASTrial stages I to III indicate that AlloDerm and DermaMatrix exhibit similar histologic and clinical outcomes. However, caution should still be exercised when performing reconstruction

with ADM, particularly in obese patients. Limitations include recent ADM modifications since publication, histologic results of biopsy specimens, single-center study and homogeneous sample population.

In an 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.

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 anti-edema 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 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 ($p \leq 0.013$). At six 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 non-compression 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 six months ($p = 0.025$). Subjective symptoms did not differ between groups, except at one 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.

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 results, 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/pmn.cfm. (Accessed June 25, 2025)

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 June 25, 2025)

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 June 25, 2025)

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/news-events/fda-brief/fda-brief-fda-warns-about-differing-complication-rates-acellular-dermal-matrix-type-surgical-mesh. (Accessed June 25, 2025)

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Policy History/Revision Information

Date	Summary of Changes

11/01/2025	**Medical Records Documentation Used for Reviews**
	• Added language to indicate:
	  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
	  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested
	  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services
	  ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures
	  ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version CS011TN.S

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.