Breast Reconstruction

Policy Number: SURGERY 095.27 T2
Effective Date: November 1, 2022

Instructions for Use

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Coverage Rationale

See Benefit Considerations

Breast reconstruction post mastectomy and for treatment of Poland's Syndrome 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.

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

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

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

Required Clinical Information
Breast Reconstruction

Note: These documentation requirements only apply when a Pre-Determination is requested. Mastectomy after a diagnosis of breast cancer does not require Prior Authorization/Advance Notification.
 	
Medical notes documenting the following, when applicable:
• Diagnosis
• History of the medical condition(s) requiring treatment or surgical intervention
• Chief complaint, including history of the complaint
• Physical exam including weight, height, and calculated body surface area
• Relevant medical and family history
• Relevant surgical history, including dates and whether the surgery is for removal, replacement (of an implant; specify type: silicon or saline), or revision of a previous surgery
• Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested; consultation with requesting surgeon may be of benefit to select the optimal images
  ○ Note: Diagnostic images must be labeled with:
  ▪ The date taken
  ▪ Applicable case number obtained at time of notification, or member's name and ID number on the image(s)
  ○ Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted
• Reports of all recent imaging studies and applicable diagnostics
• CPT codes 19370 and 19371 require submission of high-quality photograph(s)
  ○ Note: All photographs must be labeled with the:
  ▪ Date taken and
  ▪ Applicable case number obtained at time of notification, or member's name and ID number on the photograph(s)
  ○ Submission of color photographs can be submitted via the external portal at www.uhcprovider.com/paan; faxes of color photos will not be accepted
• Complications which necessitate the need for removal of the prosthetic; for capsular contracture, include Baker grade and functional impairment
• Physicians plan of care including estimated volume of breast tissue per breast to be removed

Definitions

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Acellular Dermal Matrix: 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).

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).

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

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).

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

- In accordance with generally accepted standards of medical practice
- Clinically appropriate, in terms of type, frequency, extent, service site and duration, and considered effective for sickness, injury, mental Illness, substance-related and addictive disorders, disease or its symptoms
- Not mainly for your convenience or that of your doctor or other health care provider
- Not more costly than an alternative drug, service(s), service site or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of sickness, Injury, disease or symptoms (COC)

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).

Women's Health and Cancer Rights Act of 1998, § 713 (a): A federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy. The law states: “In general - a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a Mastectomy shall provide, in case of a participant or beneficiary who is receiving benefits in connection with a Mastectomy and who elects breast reconstruction in connection with such Mastectomy, coverage for (1) reconstruction of the breast on which the Mastectomy has been performed; (2) surgery and reconstruction of the other breast to produce symmetrical appearance; and (3) prostheses and physical complications all stages of Mastectomy, including lymphedemas in a manner determined in consultation with the attending physician and the patient.”

Prior Authorization Requirements

Prior authorization is required in all sites of service.

Exception: Prior authorization is not required for reconstructive procedures following a Mastectomy for breast cancer (or prophylaxis).

Notes:

- Participating providers in the office setting: Prior authorization is required for services performed in the office of a participating provider.

- Non-participating/out-of-network providers in the office setting: Prior authorization is not required but is encouraged for out-of-network services. If prior authorization is not obtained, Oxford will review for out-of-network benefits and medical necessity after the service is rendered.

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 the member specific benefit plan document 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

CPT Code	Description
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant
19499	Unlisted procedure, breast

HCPCS Code	Description
L8600	Implantable breast prosthesis, silicone or equal
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S2067	Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
S2068	Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S8950	Complex lymphedema therapy, each 15 minutes

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

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

Diagnosis Code	Description
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
D48.61	Neoplasm of uncertain behavior of right breast
D48.62	Neoplasm of uncertain behavior of left breast
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's Syndrome and other disorders that cause breast disfigurement, disfigurement caused by radiation or trauma, and removal of breast implants with or without a capsulectomy/capsulotomy.

Benefit Considerations

Refer to the member specific benefit plan document 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.

The following are eligible for coverage as reconstructive and medically necessary:
In accordance with Women's Health and Cancer Rights Act of 1998, the following services are covered (with or without a diagnosis of cancer):

- Reconstruction of the breast on which the Mastectomy was performed
- Surgery and reconstruction of the other breast to produce a symmetrical appearance, including nipple tattooing

- Prosthesis (implanted and/or external)
- Treatment of physical complications of Mastectomy, including lymphedema
- Treatment of Poland Syndrome with breast reconstruction; this is considered reconstructive surgery although no Functional Impairment may exist.

Note: The Women's Health and Cancer Rights Act of 1998 does not provide a timeframe by which the member is required to have the reconstruction performed post Mastectomy.

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

Winocour S 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.

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.

Dermal Matrix

Vashi reported on the use of DermACELL acellular dermal matrix 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 acellular dermal matrix 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 acellular dermal matrix. 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.

Pittman et al (2017) compared the clinical outcomes between available acellular dermal matrixes DermACELL and AlloDerm Ready To Use (TRU). 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.

Treatment for Lymphedema

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 Sates 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 a randomized controlled trial, 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 acellular dermal matrix 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 28, 2022)

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 21, 2022)

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 21, 2022)

On March 31, 2021, the FDA issued a safety advisory notification regarding acellular dermal matrix 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 June 21, 2022)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare Coverage Determination Guideline (CDG) that was researched, developed and approved by the UnitedHealthcare Medical Policy Committee. [*MP.003.20*]

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Policy History/Revision Information

Date	Summary of Changes

11/01/2022	**Title Change/Template Update**
	• Reorganized and renamed policy; combined content previously included in the Clinical Policies titled:
	  ○ *Breast Reconstruction Post Mastectomy and Poland Syndrome*
	  ○ *Breast Repair/Reconstruction Not Following Mastectomy*
	Related Policies
	• Removed reference link to the Clinical Policy titled:
	  ○ *Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements*
	  ○ *Skin and Soft Tissue Substitutes*
	Coverage Rationale
	• Revised language to indicate:
	  ○ Breast reconstruction post Mastectomy for the treatment of Poland's Syndrome is considered Reconstructive and Medically Necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Breast Reconstruction
	  ○ 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 dermal matrix including but not limited to AlloDerm, Cortiva® AlloMax™, DermACELL, or FlexHD
	  ○ Treatment for complications post mastectomy is covered and considered Medically Necessary for the following:
	  ▪ Lymphedema post Mastectomy, including 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:
	  ▪ Members 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
	  ○ 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
	  ▪ Correction of an inverted nipple(s) resulting from a Congenital Anomaly
	Documentation Requirements
	• Updated list of *Required Clinical Information* to reflect/include:
	  ○ Diagnosis
	  ○ History of the medical condition(s) requiring treatment or surgical intervention
	  ○ Chief complaint, including history of the complaint

Date	Summary of Changes
	○ Physical exam including weight, height, and calculated body surface area ○ Relevant medical and family history ○ Relevant surgical history, including dates and whether the surgery is for removal, replacement (of an implant; specify type: silicon or saline), or revision of a previous surgery ○ Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested; consultation with requesting surgeon may be of benefit to select the optimal images ▪ Note: Diagnostic images must be labeled with: – The date taken – Applicable case number obtained at time of notification, or member's name and ID number on the image(s) ▪ Submission of diagnostic imaging is required via the external portal at uhcprovider.com/paan; faxes will not be accepted ○ Reports of all recent imaging studies and applicable diagnostics ○ CPT codes 19370 and 19371 require submission of high-quality photograph(s) ▪ Note: All photographs must be labeled with the: – Date taken and – Applicable case number obtained at time of notification, or member's name and ID number on the photograph(s) ▪ Submission of color photographs can be submitted via the external portal at uhcprovider.com/paan; faxes of color photos will not be accepted ○ Complications which necessitate the need for removal of the prosthetic; for capsular contracture, include Baker grade and functional impairment ○ Physicians plan of care including estimated volume of breast tissue per breast to be removed **Definitions** • Added definition of: ○ Acellular Dermal Matrix ○ Congenital Defect ○ Mastopexy/Breast Lift ○ Medically Necessary • Removed definition of: ○ Deep Inferior Epigastric Perforator (DIEP) Flap ○ Functional or Physical Impairment ○ Gluteal Artery Perforator (GAP) Free Flap ○ Latissimus Dorsi Flap (LD) ○ Poland Syndrome ○ Sickness ○ Transverse Rectus Abdominus Myocutaneous (TRAM) Flap • Updated definition of: ○ Anaplastic Lymphoma ○ Mastectomy ○ Reconstructive Procedures ○ Women's Health and Cancer Rights Act of 1998, §713(a) **Applicable Codes** • Removed CPT codes 19301, 19302, 19303, 19305, 19306, 19307, and 19318 **Supporting Information** • Added *Description of Services*, *Clinical Evidence*, and *FDA* sections • Updated *Benefit Considerations* and *References* sections to reflect the most current information • Archived previous policy versions SURGERY 095.26 T2 and SURGERY 094.19 T2

Instructions for Use

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

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical 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.