Breast Reconstruction ~~Post Mastectomy~~ (for Louisiana Only)

Policy Number: CS011LA.~~M~~N
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➲ Instructions for Use

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Application

This Medical Poicy only applies to the state of Louisiana.

Coverage Rationale

~~**Indications for Coverage**~~

Breast Reconstruction Post Mastectomy

Breast reconstruction post a medically necessary mastectomy and breast reconstruction for treatment of Poland's Syndrome is considered Reconstructive and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria refer to InterQual® 2021, Apr. 2021 Release, CP: Procedures:

- **Breast Reconstruction**
- **Reduction Mammoplasty, Female**
- **Reduction Mammoplasty, Female (Adolescent)**

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 dermal matrix including but not limited to Alloderm, Cortiva® [AlloMax™], DermACELL, or FlexHD**

~~**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~~

~~**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.~~

~~**Removal, replacement, or revision of an implant may be considered reconstructive in certain circumstances:**~~

- ~~When the original implant or reconstructive surgery was considered reconstructive surgery under the terms of the member's benefit plan, coverage may exist for removal, replacement, and/or reconstruction.~~
- ~~When the original implant or reconstructive surgery was considered reconstructive surgery under the terms of the member's benefit plan, then removal of a ruptured prosthesis is treating a "complication arising from a medical or surgical intervention".~~
- ~~Removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for the following:~~
  ~~o Treatment of Anaplastic Lymphoma of the breast when there is pathologic confirmation of the diagnosis by cytology or biopsy; or~~
  ~~o Individuals with an increased risk of implant-associated Anaplastic Lymphoma of the breast due to use of Allergan BIOCELL textured breast implants and tissue expanders~~
- ~~Revision of a reconstructed breast (CPT code 19380) when the original reconstruction was performed following mastectomy or for another covered health service (see Applicable Codes section below for a list of codes that meet the criteria for a reconstructed breast).~~

~~**The breast reconstruction benefit does not include coverage for any of the following:**~~

- ~~Aspirations~~
- ~~Biopsy (open or core)~~
- ~~Excision of cysts~~
- ~~Fibroadenomas or other benign or malignant tumors~~
- ~~Aberrant breast tissue~~
- ~~Duct lesions~~
- ~~Nipple or areolar lesions~~
- ~~Treatment of gynecomastia~~

Treatments for Complications Post Mastectomy

- Treatment of lymphedema post Mastectomy is considered Medically Necessary and may include 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
- Treatment of a post-operative infection(s)

Breast Implant Removal

Removal of breast implants with or without capsulectomy/capsulotomy is medically necessary in certain circumstances. For medical necessity clinical coverage criteria refer to InterQual® 2021, Apr. 2021 Release, CP: Procedures: Breast Implant Removal.

Removal or replacement of an implant is not considered reconstructive and medically necessary for the following:

- An implant that is not ruptured and unassociated with local breast complications

Removal of a ruptured saline implant not placed post mastectomy

Breast Repair/-Reconstruction not Post Mastectomy

Breast repair and reconstruction procedures not post Mastectomy are considered Reconstructive and Medically Necessary for the following:

- 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.
- Removal of a breast implant and capsulectomy for Anaplastic Lymphoma, regardless of the indication for the initial implant placement, when:
  - There is pathologic confirmation of the diagnosis by cytology or biopsy; or
  - Individuals has an increased risk of implant-associated Anaplastic Lymphoma of the breast due to use of Allergan BIOCELL textured breast implants and tissue expanders.

Breast reconstruction is not considered medically necessary for any of the following:

- 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.

~~The following procedures may be utilized during breast reconstruction:~~

- A woman's own muscle, fat and skin are repositioned to create a breast mound by one of the following methods:
  - Transverse Rectus Abdominus Myocutaneous (TRAM) Flap – The muscle, fat and skin from the lower abdomen is used to reconstruct the breast
  - Deep Inferior Epigastric Perforator (DIEP) or Superior Gluteal Artery Perforator SGAP Flap – The fat and skin but not muscle is used from the lower abdomen or buttocks to reconstruct the breast
  - Latissimus Dorsi (LD) Flap – The muscle, fat and skin from the back are used to reconstruct the breast – may also need a breast implant
  - Other methods may also be used to move muscle, fat and skin to reconstruct a breast
- Tissue expansion is used to stretch the skin and tissue to provide coverage for a breast implant to create a breast mound. The procedure can be done with or without a dermal matrix including but not limited to Alloderm, Allomax, DermACELL, or FlexHD which are a covered benefit. **Note:** Reconstruction alone may be done with an implant, but a tissue expander may be needed.
  - Tissue expansion requires several office visits over 4-6 months to fill the device through an internal valve to expand the skin.
- After the tissue expansion is completed, surgical placement of an FDA approved breast implant (either silicone or saline) is performed. The breast implant may be used with a flap or alone following tissue expansion.
- After the breast implant is completed, creation of a nipple (by various techniques) and areola (tattooing) may be performed.
- Mastopexy or breast reduction when required prior to mastectomy to preserve the viability of the nipple.

Treatments for Complications Post Mastectomy

- Lymphedema:
  - Complex decongestive physiotherapy (CDP) is covered for the complication of lymphedema post Mastectomy
  - Lymphedema pumps when required are covered (when covered, these pumps are covered as Durable Medical Equipment)
  - Compression lymphedema sleeves are covered (when covered, these sleeves are covered as a prosthetic device)
  - Elastic bandages and wraps associated with covered treatments for the complications of lymphedema
- Treatment of a post-operative infection(s)
- Removal of a ruptured breast implant (either silicone or saline) is reconstructive for implants done post Mastectomy; placement of a new breast implant will be covered if the original implantation was done post Mastectomy or for a covered reconstructive health service

Note: A gap exception may be granted if there is not an in-network provider able to provide the requested Reconstructive Procedure. Check the federal, state or contractual requirements for benefit coverage.

Coverage Limitations and Exclusions

UnitedHealthcare excludes Cosmetic Procedures from coverage including but not limited to the following:

- Breast reconstruction has been successfully completed post Mastectomy and the member chooses to enlarge their breasts for cosmetic reasons.

- ~~Breast reconstruction or scar revision after breast biopsy or removal of a cyst with or without a biopsy.~~
- ~~Insertion of breast implants or reinsertion of breast implants for the purpose of improving appearance unless covered under a state or federal mandate.~~
- ~~Liposuction other than to achieve breast symmetry during post Mastectomy.~~
- ~~Procedures that correct an anatomical congenital anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a covered person may suffer psychological consequences or socially avoidant behavior as a result of an injury, sickness or congenital anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure.~~
- ~~Removal or replacement of an implant that is not ruptured and unassociated with local breast complications.~~
- ~~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.~~
- ~~Revision of a prior reconstructed breast due to normal aging.~~

Definitions

Check the definitions within the federal, state, and contractual requirements that supersede the definitions below.~~Check the definitions within the member benefit plan document that supersede the definitions below~~.

Anaplastic Lymphoma: Breast implant-associated (BIA) anaplastic large cell lymphoma (ALCL) is a rare T-cell lymphoma that can present as a delayed fluid collection around a textured implant or surrounding scar capsule.

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.

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

~~**Deep Inferior Epigastric Perforator (DIEP) Flap:** DIEP stands for the deep inferior epigastric perforator artery, which runs through the abdomen. In a DIEP flap reconstruction, fat, skin, and blood vessels are cut from the wall of the lower belly and moved up to the chest to rebuild the breast. The surgeon reattaches the blood vessels of the flap to blood vessels in the chest using microsurgery. DIEP is often referred to as a muscle-sparing or muscle-preserving type of flap, which means that no muscle is taken from the abdomen.~~

~~**Gluteal Artery Perforator (GAP) Free Flap:**~~

- ~~An SGAP flap (superior gluteal artery perforator), or gluteal perforator hip flap, uses this blood vessel to transfer a section of skin and fat from the upper buttocks/hip to reconstruct the breast.~~
- ~~The IGAP flap (inferior gluteal artery perforator) uses this blood vessel to transfer a section of skin and fat from the bottom of the buttocks, near the buttock crease to reconstruct the breast.~~

~~**Latissimus Dorsi (LD) Flap:** The LD flap moves muscle (and skin if required) from the back to reconstruct the breast. It may be transferred as a free tissue transfer or rotated into place as a pedicle flap to reconstruct the breast. In a latissimus dorsi flap procedure, an oval flap of skin, fat, muscle, and blood vessels from the upper back is used to reconstruct the breast. This flap is tunneled to the chest to rebuild the breast.~~

Mastectomy: Mastectomy is the removal of the whole breast. There are five different types of Mastectomy: "simple" or "total" Mastectomy, modified radical Mastectomy, radical Mastectomy, partial Mastectomy, and subcutaneous (nipple-sparing) Mastectomy.

- Simple or Total Mastectomy: Removes the entire breast and no axillary lymph node dissection
- Modified radical Mastectomy: Modified radical Mastectomy involves the removal of both breast tissue and axillary lymph nodes
- Radical Mastectomy: Removes the entire breast, axillary lymph nodes, and the chest wall muscles
- Partial Mastectomy (lumpectomy, tylectomy, quadrantectomy, and segmentectomy): Partial Mastectomy is the removal of the cancerous part of the breast tissue and some normal tissue around it. While lumpectomy is technically a form of partial Mastectomy, more tissue is removed in partial Mastectomy than in lumpectomy.
- Nipple-Sparing Mastectomy: During nipple-sparing Mastectomy, all of the breast tissue is removed; however, the nipple is not removed.

Poland Syndrome: Poland syndrome is a congenital absence of the pectoralis major muscle, usually the sternal component, as well as breast and areolar hypoplasia. This condition can also be associated with absence of the latissimus dorsi and serratus anterior muscles, hand symbrachydactyly, and other extremity deformities.

Reconstructive Procedures: Reconstructive Procedures when the primary purpose of the procedure is either of the following:

- Treatment of a medical condition
- Improvement or restoration of physiologic function

Reconstructive Procedures include 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.

Procedures that correct an anatomical congenital anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an injury, sickness or congenital anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a Reconstructive Procedure.

~~**Transverse Rectus Abdominus Myocutaneous (TRAM) Flap:** The surgeon takes muscle and overlying lower abdominal tissue and moves it to the chest area. TRAM flap may be done as either a pedicle flap or a free flap.~~

~~**Women's Health and Cancer Rights Act of 1998, § 713 (a):** "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."~~

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.

Note: CPT code 19364 should be reported for free flap breast reconstruction. [This encompasses the services described in HCPCS codes S2066, S2067, and S2068]. (American Society of Plastic Surgeons, CPT Corner, December 2020)

CPT Code	Description
Mastectomy	
19301	Mastectomy, partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19302	Mastectomy, partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy
19303	Mastectomy, simple, complete
19305	Mastectomy, radical, including pectoral muscles, axillary lymph nodes
19306	Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (urban type operation)
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle
Breast Reconstruction Post Mastectomy and Poland Syndrome	
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 ~~prosthesis~~implant
11971	Removal of tissue expander(s) without insertion of ~~prosthesis~~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

CPT Code	Description
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
~~19324~~	~~Mammaplasty, augmentation; without prosthetic implant~~
19325	**Breast** ~~Mammaplasty,~~ augmentation; with ~~prosthetic~~ implant
*****19330	Removal of **ruptured breast implant, including implant contents (e.g., saline, silicone gel)**~~mammary implant material~~
19340	~~Immediate i~~Insertion of breast **implant on same day of mastectomy (i.e., immediate)**~~prosthesis following mastopexy, mastectomy or in reconstruction~~
19342	**Insertion or replacement of breast implant on separate day from mastectomy**~~Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction~~
19350	Nipple/areola reconstruction
*****19355	Correction of inverted nipples
19357	**Tissue expander placement in breast reconstruction, including subsequent expansion(s)**~~Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion~~
19361	Breast reconstruction**;** with latissimus dorsi flap, ~~without prosthetic implant~~
19364	Breast reconstruction**;** with free flap **(e.g., fTRAM, DIEP, SIEA, GAP flap)**
~~19366~~	~~Breast reconstruction with other technique~~
19367	**Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap**~~Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site~~
19368	**Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)**~~Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)~~
19369	**Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap**~~Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site~~

CPT Code	Description
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)** ~~Revision of reconstructed breast~~
19396	Preparation of moulage for custom breast implant
19499	Unlisted procedure, breast
~~Covered t~~**To Achieve Symmetry of the Contralateral Breast Post Mastectomy Only**	
19318	~~Reduction mammaplasty~~ **Breast reduction**
Breast Repair/Reconstruction not Post Mastectomy	
19328	**Removal of intact breast implant**
***19330**	**Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)**
***19355**	**Correction of inverted nipples**
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)**

Codes labeled with an asterisk(*) are not on the state of Louisiana Fee Schedule and therefore not covered by the State of Louisiana Medicaid Program.

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

Diagnosis Code	Description
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	**Malignant neoplasm of central portion of right male breast**
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
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

Diagnosis Code	Description
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
T85.43XS	Leakage of breast prosthesis and implant, sequela

Diagnosis Code	Description
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 medically necessary lumpectomy or mastectomy for treatment of breast cancer which resulted in a significant deformity to restore the breast to normal appearance. This may include mastopexy to the contra-lateral breast and may involve a variety of surgical procedures.

Breast reconstruction surgery may also be unrelated to breast cancer such as treatment for Poland's Syndrome, removal of breast implants with or without a capsulectomy/capsulotomy, and inverted nipples.

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. This is a cancer of the immune system and BIA-ALCL most commonly affects breast implants that have textured surfaces. The current lifetime risk of BIA-ALCL is estimated to be 1:2,207 – 1:86,029 for women with textured implants. BIA-ALCL has been found with both silicone and saline implants and both breast cancer reconstruction and cosmetic individuals.

On July 24, 2019 the U.S. Food and Drug Administration (FDA) took significant action to protect women from breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) by requesting that Allergan, the manufacturer of a specific type of textured implant, recall specific models of its textured breast implants from the U.S. market due to the risk of BIA-ALCL. Following the FDA's request, Allergan has notified the FDA that it is moving forward with a worldwide recall of their BIOCELL textured breast implant products, including: 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. The recall helps ensure that unused products are removed from suppliers and doctors' offices. The agency also issued a safety communication today for patients with breast implants, patients considering breast implants and their health care professionals outlining the known risks and what steps patients should consider when monitoring for symptoms of BIA-ALCL, including swelling and pain in their breasts. The safety communication also lists information about all models and style numbers included in the recall.

In 2019 NCCN published consensus standard of care guidelines on the diagnosis and treatment of BIA-ALCL. Recommendations focus on parameters for achieving reliable diagnosis and disease management and emphasize the critical role for complete surgical ablation. Suggestions for adjunct treatments and chemotherapy regimens are included for advanced BIA-ALCL with lymph node involvement. BIA-ALCL recurrence and management of unresectable disease, and organ metastasis are addressed.

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 explantation.

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 ML et al. (2020) performed a literature search to provide a comprehensive review of the literature about surgical treatment for inverted nipples. Their search included PubMed, Google Scholar, and Cochrane database using the following MeSH terms: "inverted nipple," "inverted nipple surgery," "inverted nipple treatment," and "inverted nipple management" (period: 1999–2020; last search on 22 March 2020). 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. which included 3369 inverted nipple cases. Eight studies described techniques with lactiferous ducts damaging, while 25 studies described techniques with lactiferous duct preservation using dermal flaps, sutures, or distractor systems. The average follow-up was 23.9 months. Overall, a satisfactory correction was reached in 88.6% of cases, and the recurrence rate was 3.89%. The authors reported that heterogeneity and subjectivity of outcomes presentation make it more complicated to state which is the best surgical strategy to obtain satisfactory and stable results with minimal morbidity. This study highlights the need of a standardized method to evaluate outcomes, including aesthetic, functional, and psychological results using objective and subjective measurement instruments. 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. See the following website for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 10, 2022)

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Policy History/Revision Information

Date	Summary of Changes
Xx/01/202Y	**Title Change/Template Update** • Reorganized and renamed policy; combined content previously included in the Coverage Determination Guidelines titled: ○ *Breast Reconstruction Post Mastectomy (for Louisiana Only)* ○ *Breast Repair/Reconstruction Not Following Mastectomy (for Louisiana Only)* • Changed policy type classification from "Coverage Determination Guideline" to "Medical Policy" **Coverage Rationale** • Revised language to indicate: ○ Breast reconstruction post a medically necessary mastectomy and breast reconstruction 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 ▪ Reduction Mammoplasty, Female ▪ Reduction Mammoplasty, Female (Adolescent) ○ 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 of lymphedema post Mastectomy is considered Medically Necessary and may include 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 ○ Treatment of a post-operative infection(s) [is considered Medically Necessary] ○ Removal of breast implants with or without capsulectomy/capsulotomy is medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: Breast Implant Removal

- Removal or replacement of an implant is not considered reconstructive and medically necessary for the following:
  - An implant that is not ruptured and unassociated with local breast complications
  - Removal of a ruptured saline implant not placed post mastectomy
- Breast repair and reconstruction procedures not post Mastectomy are considered Reconstructive and Medically Necessary for the following:
  - 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
  - Removal of a breast implant and capsulectomy for Anaplastic Lymphoma, regardless of the indication for the initial implant placement, when:
    - There is pathologic confirmation of the diagnosis by cytology or biopsy; or
    - Individuals has an increased risk of implant-associated Anaplastic Lymphoma of the breast due to use of Allergan BIOCELL textured breast implants and tissue expanders
- Breast reconstruction is not considered medically necessary for any of the following:
  - 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

Definitions

- Removed definition of:
  - Deep Inferior Epigastric Perforator (DIEP) Flap
  - Functional or Physical Impairment
  - Gluteal Artery Perforator (GAP) Free Flap
  - Latissimus Dorsi (LD) Flap
  - Sickness
  - Transverse Rectus Abdominus Myocutaneous (TRAM) Flap
  - Women's Health and Cancer Rights Act of 1998, §713(a)

Applicable Codes

- Added CPT codes 15771 and 15772
- Removed CPT/HCPCS codes 19324, 19366, S2066, S2067, and S2068

	• Revised description for CPT codes 11970, 11971, 19318, 19325, 19330, 19340, 19342, 19357, 19361, 19364, 19367, 19368, 19369, and 19380 • Added notation to indicate: ○ CPT codes 11922, 15777, 19330, and19355 are not on the State of Louisiana Fee Schedule and therefore not covered by the State of Louisiana Medicaid Program ○ CPT code 19364 should be reported for free flap breast reconstruction; this encompasses the services described in HCPCS codes S2066, S2067, and S2068 • Added ICD-10 diagnosis code Q79.8 **Supporting Information** • Added *Description of Services*, *Clinical Evidence*, and *FDA* sections • Updated *References* section to reflect the most current information **Archived previous policy versions CS011LA.M and CS013LA.J**

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.