

## Medical Policy:

### Breast Implants and Reconstruction

POLICY NUMBER	LAST REVIEW
MG.MM.SU.14i	October 8, 2021

**Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.**

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Breast augmentation	A surgical procedure that increases the size and proportions of a woman's breast.
Breast implants	Prosthetic devices (saline- or silicone gel-filled or biluminal) that are surgically inserted in the chest.
Breast reconstruction	A surgical procedure that restores the natural breast contour and mass following mastectomy, trauma, injury or congenital deformity (the latter indication is excluded from coverage; see <i>Note</i> , p. 2 and <a href="#">Cosmetic Surgery Procedures</a> ).
Capsular contracture	A tightening of the capsule (scar tissue) surrounding an implant, resulting in firmness or hardening of the breast.
Capsulectomy	Surgical removal of the capsule.
Capsulotomy (open)	Incision or opening in the capsule made by an open surgical approach.
Cosmetic surgery	Reshaping normal structures of the body to improve the patient's appearance and self-esteem.
Mastopexy	Plastic surgery to move sagging breasts into a more elevated position. It involves the repositioning of the nipple and areola and is sometimes performed in conjunction with implant insertion.

Reconstructive surgery	Performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance (e.g., post mastectomy for breast cancer; see <i>Note</i> , p. 2 and <a href="#">Cosmetic Surgery Procedures</a> ).
Tissue expander	An adjustable implant that can be inflated with salt water to stretch the tissue at the mastectomy site to create a new tissue flap for implantation of the breast implant.

## Guideline

**Note:**

1. The Plan abides by the federal Women’s Health and Cancer Rights Act, which provides protections to those patients who choose to have breast reconstruction following a mastectomy.<sup>i</sup>
2. Requests for congenital deformity indications will be reviewed on a case by case basis. To facilitate coverage determination, please refer to the member's benefit package. If there is a discrepancy between this policy and a member’s plan of benefits, then the provision of the benefits will govern and rule. (See also [ConnectiCare/EmblemHealth Surgical Correction of Chest Wall Deformities policies](#))

A. **Breast reconstruction procedures:** Members are eligible for all of the following procedures (which may be performed concurrently with a mastectomy/lumpectomy or at any time postoperatively):

- Reconstruction of postmastectomy or traumatically injured breast
- Reconstruction of the nondiseased (contralateral) breast for symmetry
- Tissue expansion or implant insertion only following:
  - Mastectomy secondary to breast disease
  - Traumatic injury

*When implant insertion is solely for breast size enlargement, the procedure is deemed cosmetic.*

B. **Breast implant removal:**<sup>ii</sup> Members are eligible for coverage of implant removal (regardless of the etiology of initial implant) when any of the following conditions exist:

- Implant extrusion
- Implant rupture<sup>iii</sup> (endnote is specific to silicone implants; for information specific to the removal of saline implants, see [Limitations/Exclusions](#))
- Infection.
- Baker IV capsular contracture (Table 1)
- Objective evidence of implant rupture, such as mammogram, MRI or ultrasound must be submitted for review. To confirm the presence of Baker IV classification, photos must be also provided.

**Table 1: The Baker Classification System for Capsular Contracture**

<b>Class I</b>	Augmented breast feels soft as a normal breast.
<b>Class II</b>	Augmented breast is less soft and the implant can be palpated but is not visible.

<b>Class III</b>	Augmented breast is firm and palpable and the implant (or distortion) is visible.
<b>Class IV</b>	Augmented breast is hard, painful, cold, tender and distorted.

## Documentation

The following documentation must be supplied to the Plan for authorization consideration:

- Original indication for implantation and current symptoms.
- Imaging study, i.e., mammography, MRI or ultrasonography (for demonstration of rupture).

## Limitations and Exclusions

- **Breast reconstruction:** Fat grafting — the plan considers harvesting (via of lipectomy or liposuction) and grafting of autologous fat as a replacement for implants for breast reconstruction, or to fill defects after breast conservation surgery or other reconstructive techniques medically necessary.
- **Autoimmune disease:** The plan does not cover silicone implant removal if autoimmune disease was diagnosed in the presence of silicone implant, as no causal relationship has been established between silicone implants and the development of the disease.
- **Implant removal:**
  - Implant removal in the presence of documented medical necessity (as indicated above) is a covered benefit; however, the plan does not cover any subsequent implant procedure unless the original insertion was a component of a medically necessary reconstruction.
  - Removal of a ruptured saline-filled or "Alternative" implant is considered not medically necessary since the potential adverse medical consequences of implant rupture are related to silicone gel implants only.
  - "Breast implant illness" or "silicone implant illness" are not medically necessary indications for breast implant removal, as there are no evidence-based studies or peer-reviewed data concerning the formation of a new syndrome.
  - Removal of textured implants due to fear of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is not a medically necessary indication for breast implant removal.
  - Certain procedures are commonly performed in conjunction with other procedures as a component of the overall service provided. An incidental procedure is one that is performed at the same time as a more complex primary procedure and is clinically integral to the successful outcome of the primary procedure. An assumption of same anatomic site is made during the auditing process. Site specific modifiers may be used to denote the performance of these procedures at different anatomic sites. Therefore, intact mammary implant removal (CPT code 19328) and mammary implant material removal (CPT code 19330) will be considered incidental services performed under capsulotomy (CPT code 19370) and capsulectomy (CPT code 19371) procedures within the same operative session.
- **Implant reinsertion:** The plan does not cover reinsertion unless the original placement was part of a reconstruction. If the implant was originally placed for a condition not listed in the Guideline section above, then the reinsertion is cosmetic and not considered medically necessary.
- **Capsulectomy:** A capsulectomy is not medically necessary for saline implant removal.
- **Mastopexy:** Mastopexy is covered when associated with a reconstructive procedure.

## Procedure Codes

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)
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk) (List separately in addition to code for primary procedure)
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation; with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
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 (eg, fTRAM, DIEP, SIEA, GAP flap)
19366	Breast reconstruction with other technique
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 (eg, 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
L8600	Implantable breast prosthesis, silicone or equal
L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
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

## ICD-10 Diagnoses

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
C50.111	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
C50.211	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
C50.311	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
C50.411	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
C50.511	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
C50.611	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
C50.811	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
C50.911	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
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
N64.89	Other specified disorders of breast
N65.0	Deformity of reconstructed breast
N65.1	Disproportion of reconstructed breast
T85.41xA	Breakdown (mechanical) of breast prosthesis and implant, initial encounter
T85.42xA	Displacement of breast prosthesis and implant, initial encounter
T85.43xA	Leakage of breast prosthesis and implant, initial encounter
T85.44xA	Capsular contracture of breast implant, initial encounter
T85.49xA	Other mechanical complication of breast prosthesis and implant, initial encounter
T85.79xA	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts, initial encounter
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
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

## References

American Society of Plastic Surgeons. ASPS Recommended Insurance Coverage Criteria for Third-Party Payers Breast Reconstruction Following Diagnosis and Treatment for Breast Cancer. Sept. 2018. <https://www.plasticsurgery.org/for-medical-professionals/health-policy/recommended-insurance-coverage-criteria>. Accessed November 18, 2020.

FDA. Breast Implants. September 2020. <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/default.htm>. Accessed November 18, 2020.

Rohrich RJ, Kaplan J, Dayan E. Silicone Implant Illness: Science versus Myth? *Plast Reconstr Surg*. 2019 Jul;144(1):98-109.

Kaplan J, Rohrich R. Breast implant illness: a topic in review. *Gland Surg*. 2021 Jan;10(1):430-443.

Keane G, Chi D, Ha AY, Myckatyn TM. En Bloc Capsulectomy for Breast Implant Illness: A Social Media Phenomenon? *Aesthet Surg J*. 2021 Mar 12;41(4):448-459

National Comprehensive Care Network (NCCN) Clinical Practice Guidelines in Oncology. T-cell Lymphomas. Version 1.2021. <https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1483>. Accessed October 5, 2021.

FDA. Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Jul. 2019. <https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl>. Accessed October 5, 2021.

Specialty-matched clinical peer review.

## Revision History

Oct. 8, 2021	Added to Limitations Exclusions: <ul style="list-style-type: none"><li>– “Breast implant illness” or “silicone implant illness” are not medically necessary indications for breast implant removal, as there are no evidence-based studies or peer-reviewed data concerning the formation of a new syndrome.</li><li>– Removal of textured implants due to fear of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is not a medically necessary indication for breast implant removal.</li></ul>
Nov. 11, 2020	Added positive-coverage language for fat grafting (removing investigational designation).
Aug. 22, 2019	Added language that defines incidental services pertaining to implant removal.
Nov. 11, 2016	Added link to EmblemHealth Medical Guideline Surgical Correction of Chest Wall Deformities.
Oct. 9, 2015	Amended Limitations/Exclusions section to communicate that removal of ruptured saline implants is not medically necessary.

- 
- <sup>i</sup> The Women’s Health and Cancer Rights Acts of 1998 is a federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy. The law stipulates that coverage must be provided for reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prosthesis (e.g., breast implant) and treatment for physical complications of the mastectomy, including lymphedema.
- <sup>ii</sup> According to the American Society of Plastic Surgeons (ASPS), capsulectomy (removal of the scar capsule surrounding the implant) and the removal of trouble-free implants are not generally recommended, as the FDA has stated that removal carries a potentially greater risk than leaving these devices in place. Additionally, removal of the prosthesis may result in additional scarring.
- <sup>iii</sup> Rupture is defined as a physical disruption of the solid silicone elastomer shell of a silicone gel implant which results in the migration of silicone gel out of the implant on a macroscopic level (not to be confused with gel bleed). It is also recommended that the medical record specify how the implant rupture is documented (e.g., obvious distortion or deformity on physical examination or a history of change in size and shape of the implant associated with confirmation by noninvasive testing of implant rupture, either intra- or extracapsular; the best noninvasive test for silicone gel implant rupture is MRI).