



Breast Implants and Reconstruction

Last Review Date: June 15, 2011

Number: MG.MM.SU.d

Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. 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. 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 Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. 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 *Note*, p. 2 and [Cosmetic Surgery Procedures](#)).

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 *Note*, p. 2 and [Cosmetic Surgery Procedures](#)).

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.¹
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.

Breast reconstruction procedures: Members are eligible for all of the following procedures, which may be performed concurrently with a mastectomy 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.

Breast implant removal:² 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.³
- 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

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

¹ 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.

² 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.

³ 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).

Class III	Augmented breast is firm and palpable and the implant (or distortion) is visible.
Class IV	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/EXCLUSIONS

- **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.
- **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.

APPLICABLE PROCEDURE CODES

19324	Mammaplasty, augmentation; without prosthetic implant
19325	Mammaplasty, augmentation; with prosthetic implant
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	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
19366	Breast reconstruction with other technique
19367	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site
19368	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle,

	including closure of donor site; with microvascular anastomosis (supercharging)
19369	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast
19380	Revision of reconstructed breast (only after a mastectomy)
19396	Preparation of moulage for custom breast implant
C1789	Prosthesis, breast (implantable)
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

REFERENCES

American Society of Plastic Surgeons. ASPS Recommended Insurance Coverage Criteria for Third-Party Payers Breast Reconstruction for Deformities Unrelated to Cancer Treatment. 2004. Available at: <http://www.plasticsurgery.org/for-medical-professionals/legislation-and-advocacy/health-policy-resources/recommended-insurance-coverage-criteria.html> . Accessed June 20, 2011.

American Society of Plastic Surgeons. ASPS Recommended Insurance Coverage Criteria for Third-Party Payers Breast Reconstruction Following Diagnosis and Treatment for Breast Cancer. 2004. Available at: <http://www.plasticsurgery.org/for-medical-professionals/legislation-and-advocacy/health-policy-resources/recommended-insurance-coverage-criteria.html> . 2004. Accessed June 20, 2011.

FDA, Center for Devices and Radiological Health. Saline-filled Breast Implant Surgery: Making an Informed Decision (Mentor Corporation). 2004. Available at; <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064457.pdf>. Accessed June 20, 2011.

Specialty-matched clinical peer review.