Medical Policy:
Breast Implants and Reconstruction (Commercial)

<table>
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<tr>
<th>POLICY NUMBER</th>
<th>EFFECTIVE DATE</th>
<th>APPROVED BY</th>
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<tbody>
<tr>
<td>MG.MM.SU.14gC2</td>
<td>11/11/2019</td>
<td>MPC (Medical Policy Committee)</td>
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**IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:**

Property of ConnectiCare, Inc. All rights reserved. The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. 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. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare 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). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. 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. Each benefit plan 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 ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies (LMRP). All coding and web site links are accurate at time of publication.

**Definitions**

<table>
<thead>
<tr>
<th><strong>Breast Augmentation</strong></th>
<th>A surgical procedure that increases the size and proportions of a woman’s breast.</th>
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<tr>
<td><strong>Breast implants</strong></td>
<td>Prosthetic devices (saline- or silicone gel-filled or biluminal) that are surgically inserted in the chest.</td>
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<tr>
<td><strong>Breast reconstruction</strong></td>
<td>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).</td>
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<tr>
<td><strong>Capsular contracture</strong></td>
<td>A tightening of the capsule (scar tissue) surrounding an implant, resulting in firmness or hardening of the breast.</td>
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<tr>
<td><strong>Capsulectomy</strong></td>
<td>Surgical removal of the capsule.</td>
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<tr>
<td><strong>Capsulotomy (open)</strong></td>
<td>Incision or opening in the capsule made by an open surgical approach.</td>
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Breast medical guidelines include:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Description</th>
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<tr>
<td>Cosmetic surgery</td>
<td>Reshaping normal structures of the body to improve the patient’s appearance and self-esteem.</td>
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<tr>
<td>Mastopexy</td>
<td>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.</td>
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<tr>
<td>Reconstructive surgery</td>
<td>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).</td>
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<tr>
<td>Tissue expander</td>
<td>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.</td>
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### Related Guidelines

**Cosmetic Surgery Procedures**

**Gender Reassignment Surgery**

**Surgical Correction of Chest Wall Deformities**

**Mastectomy/Risk-Reduction Mastectomy; MCG #s:**

- ORG: S-860 (ISC)
- ORG: S-862 (ISC)
- ORG: S-864 (ISC)
- RRG: S-860-RRG (ISC)
- RRG: S-862-RRG (ISC)
- RRG: S-864-RRG (ISC)

### 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.

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 Surgical Correction of Chest Wall Deformities)

### 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: 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* (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

<table>
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<tr>
<th>Class</th>
<th>Description</th>
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<tr>
<td>Class I</td>
<td>Augmented breast feels soft as a normal breast.</td>
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<tr>
<td>Class II</td>
<td>Augmented breast is less soft and the implant can be palpated but is not visible.</td>
</tr>
<tr>
<td>Class III</td>
<td>Augmented breast is firm and palpable and the implant (or distortion) is visible.</td>
</tr>
<tr>
<td>Class IV</td>
<td>Augmented breast is hard, painful, cold, tender and distorted.</td>
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**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**

- **Breast reconstruction**: Fat grafting as a method for total breast reconstruction is not considered medically necessary due to insufficient evidence of therapeutic value.
- **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

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medically necessary since the potential adverse medical consequences of
implant rupture are related to silicone gel implants only.

- 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.

Applicable Coding

*To access the codes, please download the policy to your computer, and click on the paperclip icon within the policy*

| Applicable CPT and Diagnosis Codes |

References

American Society of Plastic Surgeons. ASPS Recommended Insurance Coverage Criteria for
Third-Party Payers Breast Reconstruction Following Diagnosis and Treatment for Breast


Specialty-matched clinical peer review.
Revision history

<table>
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<th>DATE</th>
<th>REVISION</th>
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| 11/15/2019 | • Connecticare has adopted the clinical criteria of its parent corporation, EmblemHealth  \\
|            | • Reformatted and reorganized policy, transferred content to new template |
| 08/22/2019 | • Added language that defines incidental services pertaining to implant removal. |
| 10/09/2015 | • Amended Limitations/Exclusions section to communicate that removal of ruptured saline implants is not medically necessary. |

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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).