**Medical Policy:**
**Breast Implants and Reconstruction**
(Commercial)

<table>
<thead>
<tr>
<th>POLICY NUMBER</th>
<th>LAST REVIEW DATE</th>
<th>APPROVED BY</th>
</tr>
</thead>
<tbody>
<tr>
<td>MG.MM.SU.14i</td>
<td>10/8/2021</td>
<td>MPC (Medical Policy Committee)</td>
</tr>
</tbody>
</table>

**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 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>Term</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Breast Augmentation</td>
<td>A surgical procedure that increases the size and proportions of a woman’s breast.</td>
</tr>
<tr>
<td>Breast implants</td>
<td>Prosthetic devices (saline- or silicone gel-filled or biluminal) that are surgically inserted in the chest.</td>
</tr>
<tr>
<td>Breast reconstruction</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>
</tr>
<tr>
<td>Capsular contracture</td>
<td>A tightening of the capsule (scar tissue) surrounding an implant, resulting in firmness or hardening of the breast.</td>
</tr>
<tr>
<td>Capsulectomy</td>
<td>Surgical removal of the capsule.</td>
</tr>
<tr>
<td>Capsulotomy (open)</td>
<td>Incision or opening in the capsule made by an open surgical approach.</td>
</tr>
<tr>
<td>Cosmetic surgery</td>
<td>Reshaping normal structures of the body to improve the patient’s appearance and self-esteem.</td>
</tr>
<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>
</tr>
<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>
</tr>
</tbody>
</table>
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### Tissue expander

| 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. |

### 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
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also provided.

Table 1: The Baker Classification System for Capsular Contracture

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
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<tbody>
<tr>
<td>Class I</td>
<td>Augmented breast feels soft as a normal breast.</td>
</tr>
<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>
</tr>
</tbody>
</table>

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 — 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.
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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 Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>11920</td>
<td>Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less</td>
</tr>
<tr>
<td>11921</td>
<td>Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm</td>
</tr>
<tr>
<td>11922</td>
<td>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)</td>
</tr>
<tr>
<td>15777</td>
<td>Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15769</td>
<td>Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)</td>
</tr>
<tr>
<td>19316</td>
<td>Mastopexy</td>
</tr>
<tr>
<td>19318</td>
<td>Breast reduction</td>
</tr>
<tr>
<td>19325</td>
<td>Mammaplasty, Breast augmentation; with prosthetic implant (Revised. 01/01/2021)</td>
</tr>
<tr>
<td>19328</td>
<td>Removal of intact mammary breast implant (Revised. 01/01/2021)</td>
</tr>
<tr>
<td>19330</td>
<td>Removal of mammary implant material Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel) (Revised. 01/01/2021)</td>
</tr>
<tr>
<td>19340</td>
<td>Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel) (Revised. 01/01/2021)</td>
</tr>
<tr>
<td>19342</td>
<td>Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction Insertion or replacement of breast implant on separate day from mastectomy (Revised. 01/01/2021)</td>
</tr>
<tr>
<td>19350</td>
<td>Nipple/areola reconstruction</td>
</tr>
<tr>
<td>19355</td>
<td>Correction of inverted nipples</td>
</tr>
<tr>
<td>19357</td>
<td>Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion Tissue expander placement in breast reconstruction, including subsequent expansion(s) (Revised. 01/01/2021)</td>
</tr>
<tr>
<td>19361</td>
<td>Breast reconstruction with latissimus dorsi flap, without prosthetic implant (Revised. 01/01/2021)</td>
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</tbody>
</table>
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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Revised</th>
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<tbody>
<tr>
<td>19364</td>
<td>Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)</td>
<td>01/01/2021</td>
</tr>
<tr>
<td>19366</td>
<td>Breast reconstruction with other technique</td>
<td></td>
</tr>
<tr>
<td>19367</td>
<td>Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous flap (TRAM) flap single pedicle, including closure of donor site;</td>
<td>Revised: 01/01/2021</td>
</tr>
<tr>
<td>19368</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging) Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)</td>
<td>Revised: 01/01/2021</td>
</tr>
<tr>
<td>19369</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap</td>
<td>Revised: 01/01/2021</td>
</tr>
<tr>
<td>19370</td>
<td>Open periprosthetic capsulotomy, breast Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy</td>
<td>Revised: 01/01/2021</td>
</tr>
<tr>
<td>19371</td>
<td>Periprosthetic capsulectomy, breast Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents</td>
<td>Revised: 01/01/2021</td>
</tr>
<tr>
<td>19380</td>
<td>Revision of reconstructed breast Revision of reconstructed breast (eg, significant removal of tissue, readvancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)</td>
<td>Revised: 01/01/2021</td>
</tr>
<tr>
<td>19396</td>
<td>Preparation of moulage for custom breast implant</td>
<td></td>
</tr>
<tr>
<td>L8600</td>
<td>Implantable breast prosthesis, silicone or equal</td>
<td></td>
</tr>
<tr>
<td>L8033</td>
<td>Nipple prosthesis, custom fabricated, reusable, any material, any type, each</td>
<td></td>
</tr>
<tr>
<td>S2066</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>S2067</td>
<td>Breast reconstruction of a single breast with &quot;stacked&quot; 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</td>
<td></td>
</tr>
<tr>
<td>S2068</td>
<td>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</td>
<td></td>
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</tbody>
</table>

## ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C50.011</td>
<td>Malignant neoplasm of nipple and areola, right female breast</td>
</tr>
<tr>
<td>C50.012</td>
<td>Malignant neoplasm of nipple and areola, left female breast</td>
</tr>
<tr>
<td>C50.019</td>
<td>Malignant neoplasm of nipple and areola, unspecified female breast</td>
</tr>
<tr>
<td>C50.111</td>
<td>Malignant neoplasm of central portion of right female breast</td>
</tr>
<tr>
<td>C50.112</td>
<td>Malignant neoplasm of central portion of left female breast</td>
</tr>
<tr>
<td>C50.119</td>
<td>Malignant neoplasm of central portion of unspecified female breast</td>
</tr>
<tr>
<td>C50.211</td>
<td>Malignant neoplasm of upper-inner quadrant of right female breast</td>
</tr>
<tr>
<td>C50.212</td>
<td>Malignant neoplasm of upper-inner quadrant of left female breast</td>
</tr>
<tr>
<td>C50.219</td>
<td>Malignant neoplasm of upper-inner quadrant of unspecified female breast</td>
</tr>
<tr>
<td>C50.311</td>
<td>Malignant neoplasm of lower-inner quadrant of right female breast</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>C50.312</td>
<td>Malignant neoplasm of lower-inner quadrant of left female breast</td>
</tr>
<tr>
<td>C50.319</td>
<td>Malignant neoplasm of lower-inner quadrant of unspecified female breast</td>
</tr>
<tr>
<td>C50.411</td>
<td>Malignant neoplasm of upper-outter quadrant of right female breast</td>
</tr>
<tr>
<td>C50.412</td>
<td>Malignant neoplasm of upper-outter quadrant of left female breast</td>
</tr>
<tr>
<td>C50.419</td>
<td>Malignant neoplasm of upper-outter quadrant of unspecified female breast</td>
</tr>
<tr>
<td>C50.511</td>
<td>Malignant neoplasm of lower-outter quadrant of right female breast</td>
</tr>
<tr>
<td>C50.512</td>
<td>Malignant neoplasm of lower-outter quadrant of left female breast</td>
</tr>
<tr>
<td>C50.519</td>
<td>Malignant neoplasm of lower-outter quadrant of unspecified female breast</td>
</tr>
<tr>
<td>C50.611</td>
<td>Malignant neoplasm of axillary tail of right female breast</td>
</tr>
<tr>
<td>C50.612</td>
<td>Malignant neoplasm of axillary tail of left female breast</td>
</tr>
<tr>
<td>C50.619</td>
<td>Malignant neoplasm of axillary tail of unspecified female breast</td>
</tr>
<tr>
<td>C50.811</td>
<td>Malignant neoplasm of overlapping sites of right female breast</td>
</tr>
<tr>
<td>C50.812</td>
<td>Malignant neoplasm of overlapping sites of left female breast</td>
</tr>
<tr>
<td>C50.819</td>
<td>Malignant neoplasm of overlapping sites of unspecified female breast</td>
</tr>
<tr>
<td>C50.911</td>
<td>Malignant neoplasm of unspecified site of right female breast</td>
</tr>
<tr>
<td>C50.912</td>
<td>Malignant neoplasm of unspecified site of left female breast</td>
</tr>
<tr>
<td>C50.919</td>
<td>Malignant neoplasm of unspecified site of unspecified female breast</td>
</tr>
<tr>
<td>D05.00</td>
<td>Lobular carcinoma in situ of unspecified breast</td>
</tr>
<tr>
<td>D05.01</td>
<td>Lobular carcinoma in situ of right breast</td>
</tr>
<tr>
<td>D05.02</td>
<td>Lobular carcinoma in situ of left breast</td>
</tr>
<tr>
<td>D05.10</td>
<td>Intraductal carcinoma in situ of unspecified breast</td>
</tr>
<tr>
<td>D05.11</td>
<td>Intraductal carcinoma in situ of right breast</td>
</tr>
<tr>
<td>D05.12</td>
<td>Intraductal carcinoma in situ of left breast</td>
</tr>
<tr>
<td>D05.80</td>
<td>Other specified type of carcinoma in situ of unspecified breast</td>
</tr>
<tr>
<td>D05.81</td>
<td>Other specified type of carcinoma in situ of right breast</td>
</tr>
<tr>
<td>D05.82</td>
<td>Other specified type of carcinoma in situ of left breast</td>
</tr>
<tr>
<td>D05.90</td>
<td>Unspecified type of carcinoma in situ of unspecified breast</td>
</tr>
<tr>
<td>D05.91</td>
<td>Unspecified type of carcinoma in situ of right breast</td>
</tr>
<tr>
<td>D05.92</td>
<td>Unspecified type of carcinoma in situ of left breast</td>
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<tr>
<td>N64.89</td>
<td>Other specified disorders of breast</td>
</tr>
<tr>
<td>N65.0</td>
<td>Deformity of reconstructed breast</td>
</tr>
<tr>
<td>N65.1</td>
<td>Disproportion of reconstructed breast</td>
</tr>
<tr>
<td>T85.41xA</td>
<td>Breakdown (mechanical) of breast prosthesis and implant, initial encounter</td>
</tr>
<tr>
<td>T85.42xA</td>
<td>Displacement of breast prosthesis and implant, initial encounter</td>
</tr>
<tr>
<td>T85.43xA</td>
<td>Leakage of breast prosthesis and implant, initial encounter</td>
</tr>
<tr>
<td>T85.44xA</td>
<td>Capsular contracture of breast implant, initial encounter</td>
</tr>
<tr>
<td>T85.49xA</td>
<td>Other mechanical complication of breast prosthesis and implant, initial encounter</td>
</tr>
<tr>
<td>T85.79xA</td>
<td>Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts, initial encounter</td>
</tr>
<tr>
<td>Z45.811</td>
<td>Encounter for adjustment or removal of right breast implant</td>
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<tr>
<td>Z45.812</td>
<td>Encounter for adjustment or removal of left breast implant</td>
</tr>
<tr>
<td>Z45.819</td>
<td>Encounter for adjustment or removal of unspecified breast implant</td>
</tr>
<tr>
<td>Z90.10</td>
<td>Acquired absence of unspecified breast and nipple</td>
</tr>
<tr>
<td>Z90.11</td>
<td>Acquired absence of right breast and nipple</td>
</tr>
<tr>
<td>Z90.12</td>
<td>Acquired absence of left breast and nipple</td>
</tr>
<tr>
<td>Z90.13</td>
<td>Acquired absence of bilateral breasts and nipples</td>
</tr>
</tbody>
</table>

### References
American Society of Plastic Surgeons. ASPS Recommended Insurance Coverage Criteria for Third-Party Payers Breast Reconstruction Following Diagnosis and Treatment for Breast
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Specialty-matched clinical peer review.

Revision history

<table>
<thead>
<tr>
<th>DATE</th>
<th>REVISION</th>
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<tbody>
<tr>
<td>10/8/2021</td>
<td>• Added to Limitations Exclusions:</td>
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<tr>
<td></td>
<td>• &quot;Breast implant illness&quot; or &quot;silicone implant illness” are not</td>
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<td>medically necessary indications for breast implant removal, as</td>
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<td></td>
<td>there are no evidence-based studies or peer-reviewed data</td>
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<td>concerning the formation of a new syndrome.</td>
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<td></td>
<td>• Removal of textured implants due to fear of breast implant-</td>
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<td>associated anaplastic large cell lymphoma (BIA-ALCL) is not a</td>
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<td></td>
<td>medically necessary indication for breast implant removal.</td>
</tr>
<tr>
<td>11/11/2020</td>
<td>• Added positive-coverage language for fat grafting (removing</td>
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<td></td>
<td>investigational designation).</td>
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<tr>
<td>11/15/2019</td>
<td>• Connecticare has adopted the clinical criteria of its parent</td>
</tr>
<tr>
<td></td>
<td>corporation, EmblemHealth</td>
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<tr>
<td></td>
<td>• Reformatted and reorganized policy, transferred content to new</td>
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<td>template</td>
</tr>
<tr>
<td>08/22/2019</td>
<td>• Added language that defines incidental services pertaining to implant</td>
</tr>
<tr>
<td></td>
<td>removal.</td>
</tr>
<tr>
<td>10/09/2015</td>
<td>• Amended Limitations/Exclusions section to communicate that removal</td>
</tr>
<tr>
<td></td>
<td>of ruptured saline implants is not medically necessary.</td>
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</tbody>
</table>
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(Commercial) 

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).