Title: Reconstructive Breast Surgery/Management of BreastImplants

Description/Background

Reconstructive breast surgery is defined as a surgery performed to restore the normal appearance of the breast after surgery, accidental injury or trauma. The most common indication for reconstructive breast surgery is a history of a prior mastectomy. Breast reconstruction may include surgery on the non-affected breast (including breast reduction or augmentation) for achieving symmetry of both the affected and the contralateral breast. Breast reconstruction may also be medically necessary, not cosmetic, when done for the correction of congenital defects such as the complete absence of breast tissue (Poland’s syndrome), developmental abnormalities, trauma, infection or following other therapeutic surgeries, such as breast reduction procedures. The goal of reconstructive breast surgery is to return the breast(s) to a condition that closely mimics the original anatomical situation prior to the ablative surgical procedure. Surgical reconstruction of the affected breast after mastectomy also includes the treatment of complications from the original procedure, if indicated.

Other types of breast reconstruction services include nipple/areola reconstruction, nipple tattooing and/or the use of autologous tissue, such as transverse rectus abdominis myocutaneous flap (TRAM procedure) or a latissimus dorsi flap. In addition, mastopexy or reduction mammoplasty on the contralateral breast may be performed to achieve symmetry with the reconstructed breast.

Prosthetic breast implants are silicone or saline-filled sacs that may be used for breast reconstruction or cosmetic breast augmentation. These devices are made of an outer silicone shell and filled with either saline or silicone gel. They are inserted either between the breast tissue and the underlying chest muscle or under the chest muscle.

Breast implants are not lifetime devices. Eventually, most patients will need to undergo at least one or more surgical procedures for routine implant replacement. This may be necessary for...
reasons ranging from breast implant deflation to medical complications including implant hardening or encapsulation, as well as leaking or frank rupture. Removal of a breast implant may be medically necessary depending on the significance of the complication. Capsular contracture is the most common local complication of breast implantation.

Breast contractures are typically graded according to the Baker Classification system as follows:
- **Class I**: Augmented breast feels as soft as a normal breast.
- **Class II**: Breast is less soft and the implant can be palpated, but is not visible.
- **Class III**: Breast is firm, the implant is palpable and the implant (or its distortion) is visible.
- **Class IV**: Breast is hard, painful, cold, tender and distorted.

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**Regulatory Status**

In May 2000, the FDA approved the first premarket approvals for saline-filled breast implants. The manufacturers were Allergan and Mentor. In November 2006 the FDA approved Allergan and Mentor’s PMAs for silicone gel-filled breast implants.

In March 2012, the FDA approved Sientra Inc.’s PMA for a silicone gel-filled breast implant.

On 3/21/18 the FDA issued the following information:

“Individuals with breast implants have a risk of developing breast implant-associated anaplastic large cell lymphoma, or BIA-ALCL. BIA-ALCL is not breast cancer—it is a type of non-Hodgkin’s lymphoma (cancer of the immune system) … Precise risks are difficult to determine due to lack of information about how many patients have received breast implants in the US and worldwide.”

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**Medical Policy Statement**

The safety and effectiveness of breast implant and breast reconstruction procedures have been established. Insertion, removal and reinsertion of silicone gel or saline filled breast implants are established procedures for breast reconstruction and implant surgery when specific clinical criteria are met.

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**Inclusionary and Exclusionary Guidelines** *(Clinically based guidelines that may support individual consideration and pre-authorization decisions)*

**Breast Reconstruction**

**Inclusions:**

Breast reconstruction on affected breast and/or contralateral breast to achieve symmetry (reconstruction may include insertion or re-insertion of implants {silicone or saline}, free flap, autologous tissue, latissimus dorsi flap or transverse rectus abdominis myocutaneous flap, nipple tattooing or nipple reconstruction) for any of the conditions listed below:
- Congenital defects, such as breast agenesis
- Mastectomy (including radical, modified radical, subcutaneous, simple and partial) due to current diagnosis of breast cancer
- Mastectomy secondary to family or personal history of cancer of the breast
- Accidental injury/trauma to the breast(s)

**Exclusions:**
All other conditions.

**Implants**

**Inclusions:**
Implant removal for documented:
- Baker Class III contractures (only if initial implant was for reconstructive purposes)
- Baker Class IV contracture
- Recurrent Infection
- Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)
- Suspected BIA-ALCL (symptoms of pain, swelling, redness or lump in the area of the implant; seroma; asymmetry of the breast). Bilateral removal is covered if requested.
- Extrusion
- Silicone implant rupture
- Surgery for a new diagnosis of breast cancer
- Textured-surface breast implant, when the surgeon determines it is in the best interest of the patient. Reinsertion of an implant will not be covered.

**Exclusions:**
The following indications for removal of breast implant are considered not medically necessary:
- Patient anxiety
- Pain not related to contractures or rupture
- Baker Class III contractures in patients with implants for cosmetic purposes
- Removal of a ruptured saline breast implant(s) when the original insertion was for a cosmetic purpose
- Systemic symptoms, attributed to connective tissue diseases, autoimmune diseases, etc.

*Please reference the following table for detailed information regarding medical necessity:*

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<thead>
<tr>
<th></th>
<th>Original surgery done for reconstructive purposes using silicone implant</th>
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<th>Original surgery done for cosmetic purposes using silicone implant</th>
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<tr>
<td>Systemic Illness – indication for implant removal</td>
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<td>Connective tissue disease</td>
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<tr>
<td>Implant Rupture*</td>
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<td>Due to Baker Class IV contracture</td>
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<td>Recurrent infection</td>
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<td>Suspected BIA-ALCL based on symptoms</td>
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<td>Extruded implant</td>
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<td>Surgery for breast cancer</td>
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<td>Other Indications for implant removal</td>
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<td>Due to Baker Class III contracture</td>
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<td>Due to Pain**</td>
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<td>Textured-surface breast implants, when the surgeon determines it is in the best interest of the patient</td>
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**Post-Removal Procedures**

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<td>Reimplantation of implants</td>
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<td>Reimplantation of implants following removal of textured-surface implants</td>
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<td>Autologous reconstruction</td>
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</table>

*Rupture of implants requires documentation with an imaging study, such as mammography, MRI or ultrasonography. Lack of imaging confirmation of rupture in association with persistent local symptoms requires a case-by-case consideration.

**Pain as an isolated symptom is an inadequate indication of implant removal. The pain should be related to the Baker Classification or a diagnosis of rupture.
CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

**Established codes:**

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**Note: Code L8600 may not be considered a medical benefit but may be considered a facility benefit. Claims should be submitted with a revenue code.**

**Note: Code C1789 may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.**

**Other codes (investigational, not medically necessary, etc.):**

N/A

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

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**Rationale**

Breast reconstruction services, which may include the insertion of breast implants, are established as safe and effective procedures to improve or restore bodily appearance or to correct an anatomic impairment caused by an accidental injury, a prior medically necessary surgical procedure or disease. The insertion of breast implants may be considered an integral part of breast reconstruction.

Complications of breast implants are common and may require explantation. Determining the medical necessity of explantation requires documentation of the type of implant and its original indication, whether reconstructive or cosmetic. The underlying principle is that cosmetic implants require explantation only for absolute medical indications that pose significant health consequences, while the criteria for explantation of reconstructive implants are broader. Complications can be subdivided into local or systemic complications.

**Local Complications**

Local complications include implant contracture, rupture, extrusion, infection or breast implant-associated anaplastic large cell lymphoma. Extrusion, rupture of a silicone implant, recurrent infection or BIA-ALCL are considered absolute medical indications for explantation in all cases, whether the implant was originally cosmetic or not. Explantation of a ruptured saline implant is considered medically necessary only in the setting of prior reconstruction. Since normal saline...
is physiologic, rupture poses no health threat, and thus explantation would not be considered medically necessary in patients with cosmetic implants.

In 2016, the World Health Organization designated BIA-ALCL as a rare T-cell lymphoma that can develop following breast implants. In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant. Data suggest that BIA-ALCL occurs more frequently with breast implants that have textured surfaces rather than those with smooth surfaces. BIA-ALCL patients most commonly present with a peri-prosthetic fluid collection or capsular mass at an average of eight to ten years following implantation. Other symptoms include breast enlargement or swelling, change in breast shape or change in the look or feel of the area around the implant. As of September 30, 2018, the FDA has received a total of 660 medical device reports (MDRs) of BIA-ALCL, including 9 deaths. After careful review, including the identification of duplicate and follow-up reports, the resulting data reflected a total of 457 unique MDRs. The FDA reports that current literature offers varying estimates on the incidence of BIA-ALCL, ranging from a high of one per 3,817 patients to a low of one in 30,000. Although most patients who develop BIA-ALCL have had textured implants, there have been reported cases of BIA-ALCL in patients with smooth-surfaced implants. Many of the reports to the FDA have not included surface texture of the implant at the time of diagnosis. Australia, which has better methods to track medical problems from implants, estimates that BIA-ALCL affects one woman per 1,000 with breast implants. Treatment involves removal of the implant and surrounding capsule. In rare cases, BIA-ALCL may metastasize; treatment may include chemotherapy, radiotherapy, and lymph node dissection.

Contracture is the most common local complication of breast implants. Contractures are somewhat subjective findings, and can be graded according to the Baker classification. Class IV contractures interfere with adequate mammography screening and are the cause of local symptoms, and thus their presence constitutes a health risk. Therefore, explantation may be considered medically necessary in all cases, regardless of whether the implant was originally inserted for cosmetic or reconstructive purposes. (See inclusionary/exclusionary guidelines.)

**Systemic Complications**
Potential systemic complications of implants, most prominently various connective tissue diseases or chronic fatigue syndrome, remains a controversial topic. To date, large epidemiologic studies have not demonstrated that women with breast implants are overrepresented among all those with connective tissue disease. In addition, there are inadequate studies to demonstrate that removal of breast implants is associated with resolution of systemic symptoms. As a result of this evidence, there is not considered to be a relationship between silicone breast implants and systemic disease, particularly connective tissue disease.

Patients with cosmetic implants may develop breast cancer. While lumpectomy can be accomplished without removal of the implant, in general, explantation as an adjunct to surgical treatment for breast cancer would be considered medically necessary. Explantation is not necessary in patients who are undergoing chemotherapy or radiation therapy for breast cancer.
Peripheral T-Cell Lymphomas

Breast implant associated ALCL:
Clinical Presentation: Physical signs (effusion, enlargement, mass, ulceration) > 1 year post implantation (Average 8-10 years post implantation)
Initial workup: Ultrasound of breast or breast MRI in selected cases or PET/CT scan in selected cases
Treatment: Total capsulectomy and excision of associated mass with biopsy of suspicious node(s), explantation. Consider removal of contralateral implant

**Government Regulations**

**National:**
National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy, Publication Number 100-3, Manual Section Number 140.2
Effective Date of this Version: 1/1/1997

**Indications and Limitations of Coverage**
Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason. Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage under §1862(a)(10) of the Act.)

CMS: The Women’s Health and Cancer Rights ACT of 1998. Applies when individual is receiving benefits in connection with a mastectomy and individual requests breast reconstruction, 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)
- Treatment for physical complications of the mastectomy, including lymphedema. ([https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet.html](https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet.html))

**Local:**
WPS Medicare L34698, “Cosmetic Surgery and Reconstructive Surgery,” Original effective date: For services performed on or after 10/01/2015
Revision effective date: For services performed on or after 12/01/2018

A. Coverage Indications, Limitations, and/or Medical Necessity According to the American Society of Plastic and Reconstructive Surgeons, the specialty of plastic surgery includes reconstructive and cosmetic procedures:
1. Reconstructive surgery is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors, involutional defects, or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance.

2. Cosmetic surgery is performed to reshape normal structures of the body in order to improve the patient’s appearance and self-esteem.

Per the Medicare Benefit Policy Manual cosmetic surgery or expenses incurred in connection with such surgery, for the sole purpose of improving one’s appearance, is not covered.

B. Indications for specific surgical procedures:

1. Breast reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is covered.

2. Removal or revision of a breast implant is considered medically necessary when it is removed for one of the following reasons:
   a. Mechanical complication of breast prosthesis; including rupture or failed implant, and/or implant extrusion.
   b. Infection or inflammatory reaction due to a breast prosthesis; including infected breast implant, or rejection of breast implants.
   c. Other complication of internal breast implant; including siliconoma, granuloma, interference with diagnosis of breast cancer, and/or painful capsular contracture with disfigurement.

3. Reduction Mammoplasty is the surgical reshaping of the breasts to reduce or lift enlarged or sagging breasts. Cosmetic surgery to reshape the breasts to improve appearance is not a Medicare benefit.

Macromastia (breast hypertrophy) is an increase in the volume and weight of breast tissue relative to the general body habitus. Breast hypertrophy may adversely affect other body systems: musculoskeletal, respiratory, and integumentary. Unilateral hypertrophy may result in symptoms following contralateral mastectomy.

Medical necessity for a reduction mammoplasty is limited to circumstances in which:
There are signs and/or symptoms resulting from the enlarged breasts (macromastia) that have not responded adequately to non-surgical interventions, and
To reduce the size of a normal breast to bring it into symmetry with a breast reconstructed after cancer surgery.

Tattooing to correct color defects of the skin may be considered reconstructive when performed in connection with a payable post-mastectomy reconstruction, or for reconstruction following trauma or removal of cancer from an eyelid, eyebrow or lip(s).

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)
Related Policies

• Cosmetic and Reconstructive Surgery
• Reduction Mammoplasty for Breast-Related Symptoms
• Mastectomy for Male Gynecomastia
• Prophylactic Mastectomy (Retired)
• Skin and Tissue Substitutes

References

3. Centers for Medicare & Medicaid Services (CMS), National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy, Publication Number 100-3, Manual Section Number 140.2, Effective Date 1/1/1997.


The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/3/19, the date the research was completed.
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<th>BCBSM Signature Date</th>
<th>BCN Signature Date</th>
<th>Comments</th>
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<td>5/10/07</td>
<td>7/1/07</td>
<td>This policy combines the policies Breast Implant and Breast Reconstruction Surgery policies.</td>
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| 9/1/08                | 07/28/08             | 7/3/08             | Maintenance  
CPT Codes deleted: L8000, L8001, L8002, L8010, L8015, L8020, L8030, L8035, L8039  
CPT Codes added: C1789, S2066, S2067, S2068 |
| 9/1/09                | 6/16/09              | 6/16/09            | Routine maintenance |
| 7/1/11                | 4/19/11              | 5/3/11             | Routine maintenance |
| 3/1/14                | 12/10/13             | 1/6/14             | Routine maintenance |
| 11/1/14               | 8/21/14              | 8/25/14            | Routine maintenance; added procedure code 11921 |
| 3/1/16                | 12/10/15             | 12/10/15           | Routine maintenance |
| 3/1/17                | 12/13/16             | 12/13/16           | Routine maintenance |
| 3/1/18                | 12/12/17             | 12/12/17           | Routine maintenance |
| 9/1/19                | 7/25/19              |                    | Routine maintenance. Added removal of textured-surface implants if recommended by surgeon; rationale updated. |

Next Review Date: 2nd Qtr, 2020
I. Coverage Determination:

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<tr>
<th>Coverage Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>Commercial HMO (includes Self-Funded groups unless otherwise specified)</td>
<td>Covered, policy guidelines apply</td>
</tr>
<tr>
<td>BCNA (Medicare Advantage)</td>
<td>See Government Regulations section. If there is no NCD or LCD, medical policy criteria apply.</td>
</tr>
<tr>
<td>BCN65 (Medicare Complementary)</td>
<td>Coinsurance covered if primary Medicare covers the service.</td>
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II. Administrative Guidelines:

- The member’s contract must be active at the time the service is rendered.
- Coverage is based on each member’s certificate and is not guaranteed. Please consult the individual member’s certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.