Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 9/1/21**
(See policy history boxes for previous effective dates)

Title: Reconstructive Breast Surgery/Management of Breast Implants

Description/Background

Reconstructive breast surgery is 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 performed to correct 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 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 used in breast reconstruction are devices with an outer silicone shell which are 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 considered 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:

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.

Regulatory Status

In May 2000, the U.S. Food and Drug Administration (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."

On July 24, 2019 the FDA requested Allergan to recall all BIOCELL® textured breast implants and tissue expanders. The recall was based on data reported increased incidences of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and BIA-ALCL-related deaths associated with BIOCELL® devices. On June 1, 2020, Allergan launched a dedicated multi-channel campaign to contact patients who might not have been aware of the recall.

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.

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

Breast Reconstruction

Inclusions:
Breast reconstruction on the 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 the initial implant was for reconstructive purposes)
- Baker Class IV contracture
- Recurrent infection
- Extrusion
- Silicone implant rupture
- Surgery or radiation therapy for a new diagnosis of breast cancer
- 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.
- Textured-surface breast implant, when the surgeon determines it is in the best interest of the patient.
- Implants or tissue expanders that have been withdrawn from the market at the request of the FDA (ie, Allergan BIOCELL®)

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:

	Original surgery was for reconstructive purposes using silicone implant	Original surgery was for reconstructive purposes using saline implant	Original surgery was for cosmetic purposes using silicone implant	Original surgery was for cosmetic purposes using saline implant
Systemic Illness – indication for implant removal				
• Connective tissue disease	No	No	No	No
• Autoimmune disease	No	No	No	No
• Rheumatic conditions	No	No	No	No
• Neurologic symptoms	No	No	No	No
• Fibromyalgia	No	No	No	No
• Chronic fatigue syndrome	No	No	No	No
• Patient anxiety	No	No	No	No
Absolute Medical Indications for implant removal				
• Implant Rupture*	Yes	Yes	Yes	No
• Due to Baker Class IV contracture	Yes	Yes	Yes	Yes
• Recurrent infection	Yes	Yes	Yes	Yes
• BIA-ALCL	Yes	Yes	Yes	Yes
• Suspected BIA-ALCL based on symptoms	Yes	Yes	Yes	Yes
• Extruded implant	Yes	Yes	Yes	Yes
• Surgery or radiation therapy for breast cancer	Yes	Yes	Yes	Yes
• Other Indications for implant removal				
• Due to Baker Class III contracture	Yes	Yes	No	No
• Due to Pain**	No	No	No	No
• Textured-surface breast implants, when the surgeon determines it is in the best interest of the patient	Yes	Yes	Yes	Yes
Post-Removal Procedures				
• Reimplantation of implants	Yes	Yes	No	No
• Autologous reconstruction	Yes	Yes	No	No

*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:

L8600**	C1789**	S2066	S2067	S2068	
11920	11921	11922			
19301	19302	19303	19305	19306	19307
19316	19318	19325	19328	19330	
19340	19342	19350	19355	19357	
19361	19364	19367	19368	19369	
19370	19371	19380	19396		

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.

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 (BIA-ALCL). Extrusion, rupture of a silicone implant, recurrent infection or BIA-ALCL are considered absolute medical indications for explantation in all cases. 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 explantation would not be considered medically necessary in patients with cosmetic implants.

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.)

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 January 5, 2020, the FDA has received a total of 773 U.S. and global medical device reports (MDRs) of BIA-ALCL, including 36 deaths. As of 2020, the FDA has determined that: all patients who have breast implants or are considering breast implants should be aware of the risk of BIA-ALCL, the risk of BIA-ALCL is higher for textured surface implants versus smooth surface implants, certain textured tissue expanders [Allergan BIOCELL] should not be used, and there is insufficient data to determine whether the implant fill is a risk factor for BIA-ALCL. Patients with confirmed BIA-ALCL should undergoremoval of the implant and surrounding scar capsule. In rare cases, BIA-ALCL may metastasize; treatment may include chemotherapy, radiotherapy, and lymph node dissection.

Systemic Complications
Potential systemic complications of implants, most prominently, various connective tissue diseases or chronic fatigue syndrome, remain 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 may be requested in patients who are undergoing radiation therapy for breast cancer.

SUPPLEMENTAL INFORMATION

National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2021
T-Cell Lymphomas, October 5, 2020

Breast Implant-Associated ALCL:
Clinical Presentation: Physical signs (effusion, enlargement, mass, ulceration) > 1 year post implantation (Average 7-9 years post implantation)
Initial workup: Ultrasound of breast and axilla 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 (140.2)
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 §l862(a)(l0) 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)

Local:

Wisconsin Physicians Service Insurance Corporation
Local Coverage Determination (LCD): Cosmetic and Reconstructive Surgery (L34698)
Original effective date: For services performed on or after 10/01/2015
Revision effective date: For services performed on or after 01/01/2021

[Note: This LCD is not quoted in full. The information quoted is related to the topic of this medical policy. Please refer to the LCD for complete information.]

A. 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.

   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 Mammaplasty for Breast-Related Symptoms
- Mastectomy for Male Gynecomastia
- Prophylactic Mastectomy (Retired)
- Skin and Tissue Substitutes

References

1. Centers for Medicare & Medicaid Services (CMS). The Women's Health and Cancer Rights Act of 1998 (WHCRA). https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet.html Accessed 4/28/21.
2. 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.
3. Chen C, et al. Nipple sparing mastectomy and intermediate tissue expander/implant breast reconstruction. Plastic and Reconstructive Surgery. 2009, Vol. 124, No. 6, pp. 1772-1780.
4. Djohan R, et al. Patient satisfaction following nipple sparing mastectomy and immediate breast reconstruction: An eight year outcome. Plastic and Reconstructive Surgery. 2010, Vol. 125, No. 3, pp.818-829.
5. U.S. Food and Drug Administration, Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm Accessed 4/28/21.
6. U.S. Food and Drug Administration. The FDA requests Allergan voluntarity recall Natrelle BIOCELL textured breast implants and tissue expanders from the market to protect patients: FDA safety communication. https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue Accessed 4/28/21
7. U.S. Food and Drug Administration. Medical device reports of breast implant-associated anaplastic large cell lymphoma. Content current as of 08/20/2020 https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma Accessed 4/28/21
8. Hu E and Alderman AK.Breast Reconstruction.Surgical Clinics of North America, Vol. 87, 2007, pp. 453-467.
9. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). T-Cell Lymphomas. Version 1.2021.J October 5, 2020. https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf Accessed 4/28/21.
10. Vendemia N, et al. Nipple-areola reconstruction. Cancer Journal. 2008, Vol. 14, No. 4, pp. 253-257.
11. Whelan T. Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery. The Journal of the American Medical Association. Vol.292, No. 4, July 2004, pp. 435-441.
12. Wisconsin Physicians Service (WPS) Insurance Corporation. Cosmetic Surgery and Reconstructive Surgery. Local Coverage Determination, L34698. Revision effective date 01/01/2021.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/28/21, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/07	5/10/07	7/1/07	This policy combines the policies Breast Implant and Breast Reconstruction Surgery policies.
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
9/1/18	7/9/18	6/25/18	Routine maintenance. Added BIA-ALCL indications for implant removal; rationale updated.
9/1/19	7/25/19		Routine maintenance. Added “removal of textured-surface implants if recommended by surgeon”; rationale updated.
9/1/20	6/16/20		Routine maintenance. CPT code 19304 was deleted 1/1/20. New indications for removal: radiation therapy, BIOCELL products. New indication for replacement: reconstruction following BIA-ALCL treatment.
9/1/21	6/15/21		Routine maintenance Code update: 19324 and 19366 deleted; other codes with nomenclature changes.

Next Review Date: 2nd Qtr, 2022

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: RECONSTRUCTIVE BREAST SURGERY/MANAGEMENT OF BREAST IMPLANTS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy guidelines apply
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

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.