Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Reconstructive Breast Surgery and Management of Breast Implants

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Description/Background

Reconstructive breast surgery is defined as a surgical procedure designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. The most common indication for reconstructive breast surgery is 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 free tissue transfer, 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 filled with either saline or silicone gel that are inserted either between the breast tissue and the underlying pectoral muscle or under the 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. Whether removal of a breast implant may be considered medically necessary depends 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.[1]
Class IV	Breast is hard, painful, cold, tender and distorted.

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 and systemic.

Local Complications

Local complications include implant contracture, rupture, extrusion, infection, breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), or other cancers, including squamous cell carcinoma (SCC) and various lymphomas, that develop in the scar tissue (capsule) that forms around the breast implants. 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 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, reconstruction with or without 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 with textured surfaces than in 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 undergo removal of the implant and surrounding scar capsule. In rare cases, BIA-ALCL may metastasize; treatment may include chemotherapy, radiotherapy, and lymph node dissection.

Rarely, other histological types of lymphoma are reported in association with breast implants. There have been anecdotal cases of extranodal NK/T-cell lymphoma, nasal type, and 6 cases of B-cell lymphoma including follicular lymphoma, intravascular large-cell lymphoma, diffuse large B-cell lymphoma, marginal zone lymphoma, and plasmablastic lymphoma.[1] Evans et al (2020), in an effort to expand understanding of the rare B-cell lymphoma presentation, described clinical and pathological features in 3 additional individuals. Two individuals developed extranodal marginal zone lymphoma in the peri-implant capsule; and, 1 had concurrent ALCL within the superficial lining of the capsule. The third individual presented with diffuse large B-cell lymphoma inside the breast parenchyma surrounding the implant. The authors stated that determining the etiology and risk factors for B-cell lymphomas associated with breast implants is highly challenging, given the limited number of reported cases.[1]

The U.S. Food and Drug Administration (FDA) provided an update on March 22, 2023 on reports of squamous cell carcinoma (SCC) in the scar tissue (capsule) that forms around breast implants. Previously, on September 8, 2022, the FDA released a safety communication informing the public of reports of cancers, including SCC and various lymphomas, in the capsule that forms around breast implants. The various lymphomas are not the same as the lymphomas described previously by the FDA as Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). The FDA is aware of 19 cases of SCC in the capsule around the breast implant from published literature. There have been reports in the literature of deaths from progression of the disease. While the FDA continues to believe that occurrences of SCC in the capsule around the breast implant may be rare, the cause, incidence and risk factors remain unknown.[2]

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 can 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.

Regulatory Status

In July 2019, Allergan voluntarily recalled Natrelle Biocell textured breast implants and tissue expanders from the market. The recall notice stated, "Allergan is taking this action as a precaution following notification of recently updated global safety information concerning the uncommon incidence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) provided by the U.S. Food and Drug Administration (FDA)."[3] Smooth surfaced implants are not affected by this recall. FDA and other health authorities have not recommended removal or replacement of textured breast implants or tissue expanders in asymptomatic individuals.

In October 2021, FDA issued additional orders restricting the sale and distribution of breast implants.[4] The orders required new labeling including a boxed warning, a patient decision checklist, updated silicone gel-filled breast implant rupture screening recommendations, a device description with a list of specific materials used in the device, and a patient device card. FDA recommended that the boxed warning include the following components:

- Breast implants are not considered lifetime devices;
- The chance of developing complications increases over time;
- Some complications will require more surgery;
- Breast implants have been associated with the development of a cancer of the immune system called BIA-ALCL;
- BIA-ALCL occurs more commonly in patients with textured breast implants than smooth implants, and deaths have occurred from BIA-ALCL; and
- Breast implants have been associated with systemic symptoms.

The orders apply to the following devices:

- IDEAL IMPLANT Structured Saline Breast Implants (company ended operations on 5/30/23)
- Mentor Saline-Filled and Spectrum Breast Implants
- Inamed (now Allergan) Natrelle Saline Filled Breast Implants
- Inamed (now Allergan) Natrelle Silicone Filled Breast Implants
- Mentor MemoryShape Silicone Gel-Filled Breast Implants
- Mentor MemoryGel Silicone Gel-Filled Breast Implants
- Sientra OPUS Silicone Gel Breast Implants

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

Breast Reconstruction

Capsular Reconstruction ONLY (not including implant removal) Inclusions:

- Repair of Capsular contracture
    - Baker Class III contracture (only if the initial implant was for reconstructive purposes)
    - Baker Class IV contracture

Exclusions:

- All other conditions

Whole breast reconstruction Inclusions:

Breast reconstruction on the affected breast and/or contralateral breast to achieve symmetry for any **one** of the conditions listed below:

- Congenital defects, such as breast agenesis or with surgical correction of chest wall deformity causing functional deficit in Poland Syndrome
- Mastectomy (including radical, modified radical, subcutaneous, simple and partial) due to current diagnosis of breast cancer
- Medically necessary Mastectomy secondary to family or personal history of cancer of the breast
- Accidental injury/trauma to the breast(s)
- For implant removal when:
    - The implant is removed for cancer or suspected cancer associated with the implant as indicated in the chart below.

    OR
    - The implant removal meets "Implant Removal" criteria below and the original implant was placed for reconstructive purposes

Note: The procedures needed to reconstruct the breast(s) are only allowed once per each underlying diagnosis.

Exclusions:

- Breast reconstruction that does not meet the above criteria

Implant Removal (only on the affected breast unless the individual was diagnosed with BIA-ALCL/suspected BIA/ALCL or other cancers associated with the breast implant capsule)

Inclusions:

Documentation of one of the following:

- Baker Class III contractures (only if the initial implant was for reconstructive purposes)
- Baker Class IV contracture
- Recurrent infection
- Extrusion
- Silicone implant rupture
- Saline implant rupture (only if the initial implant was for reconstructive purposes)

- Surgery or radiation therapy for a new diagnosis of breast cancer
- Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Bilateral removal is covered if requested.
- 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.
- B-cell lymphoma associated with the breast implant capsule. Bilateral removal is covered if requested.
- Squamous Cell Carcinoma associated with the breast implant capsule. 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:

- See chart below for indications where removal of breast implants are considered not medically necessary.
- Prophylactic removal not associated with textured surface implants

The following chart should facilitate determination of the medical necessity of implant removal. Yes, indicates that the implant removal would be considered medically necessary, given the symptoms, type of implant, and original indication for implantation.:

Indication for Removal	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 –				
• 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				
• Implant Rupture*	Yes	Yes	Yes	No
• Due to Baker Class IV contracture	Yes	Yes	Yes	Yes
• Recurrent infection	Yes	Yes	Yes	Yes
• BIA-ALCL Diagnosis	Yes	Yes	Yes	Yes
• Suspected BIA-ALCL based on symptoms	Yes	Yes	Yes	Yes
• B-cell lymphoma associated with the	Yes	Yes	Yes	Yes

breast implant capsule				
• Squamous Cell Carcinoma associated with the breast implant capsule	Yes	Yes	Yes	Yes
• Extruded implant	Yes	Yes	Yes	Yes
• Surgery or radiation therapy for breast cancer	Yes	Yes	Yes	Yes
• Other Indications				
• 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

*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: Codes 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 Surgery

Clinical Context and Therapy Purpose

The purpose of breast reconstruction surgery in individuals who have undergone breast surgery or who have experienced injury or trauma to the breast is to provide a treatment option that is an alternative to usual treatment without reconstructive breast surgery.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who have undergone breast surgery or who have experienced injury or trauma to the breast.

Interventions

The therapy being considered is reconstructive breast surgery.

There is a broadening array of surgical approaches to breast reconstruction. The most common is insertion of a breast implant, either a silicone gel-filled or saline-filled prosthesis. The implant is either inserted immediately at the time of mastectomy or sometime afterward in conjunction with the previous use of a tissue expander (19342, 19357).

The breast may also be reconstructed using autologous tissues, such as a free flap, a latissimus dorsi flap, or more commonly, using a transverse rectus abdominis flap. Nipple areola reconstruction or nipple tattooing may also be considered reconstructive breast surgery. Since the purpose of reconstructive breast surgery is to restore the normal appearance of the breast, on some occasions procedures are performed on the contralateral, normal breast to achieve symmetry, such as mastopexy and reduction mammaplasty. These procedures fall into the category of reconstructive breast surgery only when performed in conjunction with a contralateral mastectomy for cancer with associated reconstruction. Except for medically necessary reduction mammaplasty, these procedures are considered cosmetic in other circumstances.

Comparators

The comparator of interest is usual care without breast reconstructive surgery.

Outcomes

The general outcomes of interest are overall survival, disease-specific survival, morbid events, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Complications of breast implants are common and may require explantation.[5] Determining the medical necessity of explantation requires documentation of the type of implant and its original indication, i.e., whether reconstructive or cosmetic. The basic 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. Since the purpose of reconstructive implants is the restoration of normal breast appearance, in a small subset of patients explantation may be warranted in cases of unsatisfactory aesthetic outcome.

Complications can be subdivided into local or systemic complications. Local complications include implant contracture, rupture, extrusion, or infection. Extrusion or infection are considered absolute medical indications for explantation in all cases, whether the implant was originally cosmetic or not. Documented rupture of a silicone gel-filled implant is considered an absolute indication for explantation in all cases. However, 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.

However, a ruptured saline implant compromises the aesthetic outcome and thus explantation may be considered appropriate in cases of reconstructive implants.

Rupture of the breast implant may be difficult to document, but physical exam, mammography, ultrasonography, or magnetic resonance imaging has been used. There is no consensus on which method affords the best sensitivity and specificity.[6,7,8] Although it has been suggested that older implants are associated with a higher incidence of rupture, there is no consensus that screening implants for rupture is warranted. Specifically, in the hearings on breast implants by the U.S. Food and Drug Administration (FDA), held in 1992, the FDA did not recommend screening for asymptomatic ruptures.

Instead, workup for a potential rupture is typically initiated at the onset of local symptoms, such as sudden change in the size or consistency of an implant, or the development of local pain.

Section Summary: Breast Reconstruction Surgery

Breast reconstruction is intended for patients undergoing mastectomy for breast cancer, or who have an injury or trauma to the breasts. For the general population of women undergoing mastectomy, the evidence supports the conclusion that breast reconstruction improves psychosocial outcomes, such as anxiety, social functioning, and perception of body image.

Breast Implant Explantation in Individuals with Implant Rupture, Infection, Extrusion, Baker Contracture, or Surgical Treatment of Breast Cancer

Clinical Context and Therapy Purpose

The purpose of breast explantation in individuals with implant rupture, infection, extrusion, Baker contracture, or surgical treatment of breast cancer is to provide a treatment option that is an alternative to usual treatment without expantation.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with breast implants and documented implant rupture, infection, extrusion, Baker contracture, or surgical treatment of breast cancer.

Interventions

The therapy being considered is breast implant explantation.

Comparators

The comparator of interest is usual care without breast implant explantation.

Outcomes

The general outcomes of interest are overall survival, disease-specific survival, morbid events, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Local complications of breast implants are frequent and may require removal of the implant. Contracture is the most common local complication of breast implants. Contractures are somewhat subjective findings, and can be graded according to the Baker classification as follows:[9]

Grade I: Augmented breast feels as soft as a normal breast

Grade II: Breast is less soft and the implant can be palpated but is not visible

Grade III: Breast is firm, palpable, and the implant (or its distortion) is visible

Grade IV: Breast is hard, painful, cold, tender, and distorted

Grade IV contractures interfere with adequate mammography screening and are the cause of local symptoms, and thus their presence constitutes a health risk.[10] Therefore, explantation may be considered medically necessary in all cases, regardless of whether the implant was originally inserted for cosmetic or reconstructive purposes. Grade III contractures, which describe firm, palpable implants, do not interfere with mammography; therefore, explantation of these implants is not considered an absolute indication for explantation. However, since Grade III contractures have an impact on the normal appearance of the breast, explantation may be appropriate in implants inserted for reconstructive purposes, since the goal of restoration of the normal appearance of the breast is not achieved.

Potential systemic complications of implants, most prominently various connective tissue diseases or chronic fatigue syndrome, have been controversial in the past. In particular, it had been hypothesized that leakage of silicone, due either to an implant rupture or to “bleeding” of silicone through an intact capsule, may incite an autoimmune response with the development of systemic symptoms. However, large epidemiologic studies have not demonstrated that women with breast implants are overrepresented among all those with connective tissue disease.[11,12,13] In addition, there are inadequate empiric 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. However, explantation is not necessary in patients who are undergoing chemotherapy or radiation therapy for breast cancer.

Once an implant has been removed, patients who have originally undergone reconstructive implantation are candidates for additional reconstructive breast surgery, either insertion of

another breast implant, or for autologous reconstruction of the breast, as described here. Patients who have originally undergone implantation of a cosmetic breast implant are not candidates for additional reconstructive breast surgery after explantation.

Section Summary: Breast Implant Explantation in Individuals with Implant Rupture, Infection, Extrusion, Baker Contracture, or Surgical Treatment of Breast Cancer

Local complications of breast implants are common and may require explantation. The medical necessity of implant explantation is dependent on the type of implant, the indication for removal, and the original indication for implantation.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Plastic Surgeons
In 2023, The American Association of Plastic Surgeons published a consensus statement on BIA-ALCL.[14] Recommendations were based on a systematic review of the literature and focused on textured-surface breast implants. Recommendations relevant to this evidence opinion included the following:

- "Use of macrotextured breast implants should be discontinued and surveillance of patients who received breast implants, smooth and textured surface, should be employed."
- "Implant manufacturers should disclose publicly or for independent academic analysis, their internal surveillance data, detailing both the number of BIA-ALCL cases reported to them and their country-specific and global sales and implantation figures for their respective breast implants."
- "No change in the use of smooth-surface breast implants is warranted at this time based upon BIA-ALCL."
- "Currently available evidence is sufficient to determine that the association of textured breast implants to BIA-ALCL does meet the definition of causation based on the Bradford Hill criteria."
- "An en bloc capsulectomy with explantation, resection of associated masses and excision of involved lymph nodes is recommended for patients with BIA-ALCL, when deemed appropriate as part of a multidisciplinary evaluation."
- "Based on the potential for risk reduction, prophylactic explantation of macrotextured surface implants can be deemed reasonable. Furthermore, after implementing a risk stratification and surveillance plan, coupled with an informed discussion about the benefits of surgery, it may also be considered reasonable for explantation of any type of textured implant...It’s important to differentiate between the notion of a procedure being reasonable—referring to the potential to mitigate risk—and it being advisable. While we acknowledge the reasonableness of these procedures, the determination of their advisability rests solely with the discretion of the surgeon in consultation with the patient." The panel further noted, "The final decision for explantation with or without

capsulectomy should be shared between patient and surgeon following an evaluation of the patient's goals balanced against the perceived benefits of the surgery and an individual surgical risk assessment. Importantly, this was based on a consensus recommendation as evidence remains limited on risk reduction. Different textured implants carry very different risks for BIA-ALCL, and patients differ in their comorbidities and risk tolerance. The final decision for explantation with or without capsulectomy should be shared between patient and surgeon following an evaluation of the patient's goals balanced against the perceived benefits of the surgery and an individual surgical risk assessment."

- "Prophylactic explantation of the contralateral textured breast implant is recommended in patients with a confirmed BIA-ALCL diagnosis due to the risk of unrecognized or occult bilateral disease."
- "Preemptive notification of the risk of developing BIA-ALCL is recommended for all patients with textured breast implants."

American College of Radiology

In 2023, the American College of Radiology published Appropriateness Criteria for initial imaging in asymptomatic and symptomatic individuals with breast implants.[15] The document includes the following statements:

- "For asymptomatic patients with saline implants, no imaging is recommended. If concern for rupture exists, ultrasound is usually appropriate though saline rupture is often clinically evident."
- "There is no relevant literature to support the role of [breast ultrasound] in the evaluation of an asymptomatic patient with silicone implants that have been in place less than 5 years. Note that in the updated FDA recommendations for asymptomatic patients with silicone implants, the first US or MRI should be performed at 5 to 6 years postoperatively, then every 2 to 3 years thereafter."
- "In a patient with unexplained axillary adenopathy with current or prior silicone breast implants, ultrasound and/or mammography are usually appropriate, depending on age."
- "In a patient with concern for silicone implant rupture, ultrasound or MRI without contrast is usually appropriate."
- "In the setting of a patient with breast implants and possible implant-associated anaplastic large cell lymphoma, ultrasound is usually appropriate as the initial imaging.

National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2024 Breast Cancer March 11, 2024 included a section in their breast cancer guidelines that was titled "Principles of Breast Reconstruction Following Surgery" which included the following relevant statements: [16]

- Breast reconstruction is elective and patients may choose to not have breast reconstruction. Individual patients present preoperatively with a variety of factors that may impact the choice of reconstruction, the risk of complications, donor site morbidity, and aesthetic result. Each of these factors must be taken into account, along with patient desire, to choose the optimal method of reconstruction.
- Selection of reconstruction option is based on an assessment of cancer treatment, patient body habits, obesity, smoking history, comorbidities, and patient concerns.
- The patient may have a strong feeling towards one form of reconstruction after being given the options. Breast reconstruction should be a shared decision.

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) There exists an association between certain types of textured breast implants and BIA-ALCL. The risk appears to vary based on the method of texturing. Patients with a past or current history of textured implants should follow up with their reconstructive surgeon.[16]

In 2019, NCCN published consensus guidelines on the diagnosis and treatment of breast implant-associated ALCL but these guidelines did not address preventive explantation of implants to reduce risk. [16]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) T-Cell Lymphomas Version 4.2024 — May 28, 2024
Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL):[17]

Definition:

- BIA-ALCL is an uncommon and emerging PTCL most frequently arising around a textured surface breast implant or in a patient with a history of a textured surface device.
- BIA-ALCL commonly presents with delayed periprosthetic effusion and breast asymmetry occurring greater than 1 year (average, 7–9 years) after implantation. Rarely, BIA-ALCL can present with a mass, regional lymphadenopathy, overlying skin rash, and/or capsular contracture.
- The majority of patients with BIA-ALCL exhibit an indolent clinical course with slow progression of disease and an excellent prognosis.
- Regional lymph node metastasis and more rarely distant organ and bone marrow metastasis may be seen in advanced stages.

GENERAL PRINCIPLES OF BIA-ALCL
Goals of therapy should be individualized but often include the following:

- Generally, complete surgical resection alone of the implant, capsule, and associated mass is used in earlier stage disease confined to the periprosthetic scar capsule.
- May consider immediate or delayed breast reconstruction with autologous tissue or smooth surface breast implants.
- Local disease relapse may be amenable to re-excision surgery alone without requiring systemic therapies

U.S. Preventive Services Task Force Recommendations
Not applicable

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04220970	Breast Implant-associated Anaplastic Large	150	June 2032

	Cell Lymphoma (BIA-ALCL) Registry		
NCT05017337	A Translational Study of Breast-implant associated anaplastIc Large Cell Lymphoma and Capsular Contracture	100	Jul 2024
NA	Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE) [18]	NA	NA

NA: not applicable; NCT: national clinical trial.

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 (L39051)
Original effective date: For services performed on or after 11/30/2023
Revision effective date: N/A

[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:

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.
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 breast reduction 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,
- To improve or correct asymmetry following cancer surgery on one breast.

Note: either the involved breast or contralateral breast may be treated to achieve symmetry.
Note: For coverage indications for contralateral reconstruction of an unaffected breast following a medically necessary mastectomy, refer to the CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §140.2.

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

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 6/12/24, 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.

9/1/22	6/21/22		Routine maintenance. LCD was retired 11/13/21.
3/1/23	12/20/22		LCD L39051 added (jf)
9/1/23	6/13/23		Routine maintenance (jf) Vendor Managed NA
11/1/23	8/23/23		Routine maintenance (jf) Vendor Managed: NA Inclusions: added post removal procedures (previously addressed in table only). Added “B-cell lymphoma within the capsular tissue of the implant” Added ref 1 and 15
3/1/24	12/19/23		• Edits to the description section and inclusions added about capsular contracture (jf). • Vendor Managed: NA • Edit title: add “and” remove / • Title Change: From Reconstructive Breast Surgery/ Management of Implants changed to Reconstructive Breast Surgery and Management of Implants.
11/1/24	8/26/24		Routine maintenance (jf) Vendor Managed: NA Ref Added: 2,13, 14 -Addition of Squamous Cell Carcinoma to the policy background under local complications. -Addition of Squamous Cell Carcinoma (SCC) to the policy background, inclusions and chart POST JUMP-edits to inclusions and exclusions of breast cancer reconstruction and diagnosis of suspicious of cancer. -Added suspected BIA-ALCL under Implant Removal

			-Pg. 7 Indication for removal chart edited Post-Removal Procedure removed

Next Review Date: 3rd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: RECONSTRUCTIVE BREAST SURGERY AND 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.