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BENEFIT COVERAGE GUIDELINE – 7.01.533

Reconstructive Breast Surgery/Management of Breast Implants

BCBSA Ref. Policy: 7.01.22

Effective Date: **Jul. 2, 2026***	RELATED MEDICAL POLICIES:
Last Revised: Jun. 1, 2026	7.01.153 Adipose-Derived Stem Cells in Autologous Fat Grafting to the Breast
Replaces: N/A	7.01.503 Breast Reduction (Mammaplasty)
	7.01.582 Bioengineered Skin and Soft Tissue Substitutes
*Click here to view the current policy.	10.01.514 Cosmetic and Reconstructive Services
	11.01.525 Site of Service Ambulatory Service Center (ASC) Select Surgical Procedures

The Site of Service Medical Necessity criteria within this policy DOES NOT apply to Indian Health Services (IHS) facilities.
Please refer to the medical necessity criteria for the procedure only.

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Breast reconstruction is surgery done after an individual has had all or part of a breast removed. A breast can be removed for a number of reasons, including cancer, accident, or injury. The goal of breast reconstruction is to recreate a breast that matches the shape and size of the nonaffected breast. The most common reason for breast reconstruction is following the removal of a breast (mastectomy) as cancer treatment. This policy describes when breast reconstruction is covered to address a medical situation. Breast reconstruction to change the shape or size of breasts only for appearance is cosmetic surgery. The plan does not cover cosmetic surgery.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a

service may be covered.

Policy Coverage Criteria

We will review for medical necessity these elective surgical procedures.

The surgical procedure subject to medical necessity review for site of service addressed in this policy is limited to:

- **Reduction mammaplasty**

We also will review the site of service for medical necessity. Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

Site of Service for Elective Surgical Procedures	Medical Necessity
Medically necessary sites of service: • **Ambulatory Surgical Center**	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This is the preferred medically necessary site of service for certain elective surgical procedures**

• **Off campus-outpatient hospital/medical center**
• **On campus-outpatient**
	Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. An elective surgical procedure performed in a hospital outpatient department may be considered medically necessary if there is no access to an ambulatory surgical center due to one of the following criteria:
	• There is no qualifying ASC within 30 miles that can provide the necessary care due to one of the following:
	  ○ There is no geographically accessible ASC that has the necessary equipment to perform the procedure; or
	  ○ There is no geographically accessible ASC available at which the individual's physician has privileges; or
	  ○ An ASC's specific guideline prohibits the use of the ASC related to the individual's health condition or weight, or
	• The individual is aged 18 or younger, or

Site of Service for Elective Surgical Procedures	Medical Necessity
	• The service being performed is in conjunction with an additional service that requires the use of a hospital outpatient department, and the procedures are being performed in the same operative session **OR** • The individual has a clinical condition which puts them at increased risk for complications including any of the following (this list may not be all inclusive): ○ **Anesthesia Risk** ▪ ASA classification III or higher (see **definition**) ▪ Personal history of complication of anesthesia ▪ Documentation of alcohol dependence or history of cocaine use ▪ Prolonged surgery (greater than 3 hours) ○ **Cardiovascular Risk** ▪ Uncompensated chronic heart failure (**NYHA class** III or IV) ▪ Recent history of myocardial infarction (MI) (less than 3 months) ▪ Poorly controlled, resistant hypertension* ▪ Recent history of cerebrovascular accident (less than 3 months) ▪ Increased risk for cardiac ischemia (drug eluting stent placed less than 1 year or angioplasty less than 90 days) ▪ Symptomatic cardiac arrhythmia despite medication ▪ Significant valvular heart disease ○ **Liver Risk** ▪ Advanced liver disease (MELD Score greater than 8)** ○ **Pulmonary Risk** ▪ Chronic obstructive pulmonary disease (COPD) (FEV1 less than 50%) ▪ Poorly controlled asthma (FEV1 less than 80% despite treatment)

Site of Service for Elective Surgical Procedures	Medical Necessity
	▪ Moderate to severe obstructive sleep apnea (OSA)*** ○ **Renal Risk** ▪ End stage renal disease (on dialysis) ○ **Other** ▪ Morbid obesity (BMI greater than or equal to 50) ▪ Pregnancy ▪ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion]) ▪ Anticipated need for transfusion(s) **Note:** * 3 or more drugs to control blood pressure ** **https://reference.medscape.com/calculator/359/meld-score-age-above-12-years** . *** Moderate-AHI greater than or equal to 15 and less than or equal to 30, Severe-AHI greater than or equal to 30 ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)
• **Off campus-outpatient hospital/medical center** • **On campus-outpatient hospital/medical center**	**These sites of service are considered not medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.**
• **Inpatient hospital/medical center**	**This site of service is considered NOT medically necessary for this elective surgical procedure.**

Procedure	Medical Necessity
Reconstructive breast surgery	**Reconstructive breast surgery may be considered medically necessary in ANY of the following circumstances:** • A prior mastectomy or partial mastectomy was performed to: ○ Treat breast disease ▪ Breast cancer ▪ Severe fibrocystic breast disease unresponsive to medical therapy ▪ **Poland syndrome**, as determined by clinical exam or imaging, with ALL of the following present:

Procedure	Medical Necessity
	▫ Congenital absence or hypoplasia (under development) of the pectoralis major and/or minor muscles ▫ Breast hypoplasia ▫ Congenital partial absence of the upper costal cartilages of ribs ○ Treat breast injury or trauma ○ Reduce risk of breast cancer occurrence (prophylactic mastectomy) **OR** • Reconstruction is to restore symmetry between the unaffected breast and the affected breast. **Reconstructive breast surgery may include, but is not limited to, ANY of the following:** • Autologous reconstruction using autologous tissue (eg, latissimus dorsi flap, transverse rectus abdominis myocutaneous flap, or free flap) • Autologous fat grafting obtained by liposuction • Immediate or delayed insertion of breast implant(s) with or without associated tissue expansion • Mastopexy or reduction mammaplasty or augmentation on the contralateral breast to achieve symmetry • Nipple/areola reconstruction and nipple tattooing when the breast reconstruction is considered eligible for coverage • Revision of a reconstructed breast, including reconstruction after removal of a breast implant previously placed for medically necessary reconstructive purposes (noted **above**)
Explantation (removal) of breast implants	**Explantation (removal) of a silicone gel or saline-filled breast implant may be considered medically necessary if the original implant was placed for medically necessary reconstructive purposes (noted above) – and not for cosmetic purposes – when ONE or more of the following conditions are present:** • Baker Class III or IV contracture (see **Description** section) • Documented implant rupture placed after a medically necessary mastectomy or partial mastectomy due to illness, injury, or disease

Procedure	Medical Necessity
	• Extrusion • Infection • Surgical treatment of breast cancer or other malignancy involving the breast • Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) **The following indications for breast implant removal are considered not medically necessary:** • Baker class III contractures in individuals with implants placed for cosmetic purposes • Pain not related to contractures or rupture • Patient anxiety • Rupture of a saline implant in individuals with implants placed for cosmetic purposes • Systemic symptoms attributed to connective tissue diseases, autoimmune diseases, etc. **In the case that implants were placed for cosmetic purposes:** • Explantation is covered only if there has been interval development of breast cancer, BIA-ALCL, or other breast disease that requires mastectomy or partial mastectomy • In the absence of breast cancer, BIA-ALCL, or other breast disease that requires mastectomy or partial mastectomy, the subsequent removal of breast implants placed for cosmetic purposes is considered a complication of a non-covered service, and is contractually excluded in most cases **Note**: Please refer to the member contract for coverage associated with complications of non-covered procedures

Documentation Requirements
For reconstructive breast surgery, submit clinical documentation supporting the following conditions: • A prior mastectomy or partial mastectomy was done to: ○ Treat breast disease

Documentation Requirements

- Breast cancer
- Severe fibrocystic breast disease unresponsive to medical therapy
- **Poland syndrome**, as determined by clinical exam or imaging, with ALL of the following present:
  - Congenital absence or hypoplasia of the pectoralis major and/or minor muscles
  - Breast hypoplasia
  - Congenital partial absence of the upper costal cartilages of ribs
- Treat breast injury or trauma
- Reduce risk of breast cancer occurrence (prophylactic mastectomy)

OR

- Reconstruction is to restore symmetry between the unaffected breast and the affected breast.

For explantation (removal) of breast implants, submit clinical documentation supporting that the original implant had been placed for a medically necessary reason and not for cosmetic reasons, and one or more of the following conditions is present:

- Baker Class III or IV contracture
- Documented implant rupture of implants placed after a medically necessary mastectomy or partial mastectomy due to illness, injury, or disease
- Extrusion
- Infection
- Surgical treatment of breast cancer or other malignancy involving the breast
- Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)

Coding

Code	Description
CPT	
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq. cm or less
11921	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm
11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20.0 sq cm, or part thereof (List separately in addition to code for primary procedure)
11970	Replacement of tissue expander with permanent implant

Code	Description
11971	Removal of tissue expander without insertion of implant
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (list separately in addition to code for primary procedure)
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel) Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy, or in reconstruction
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19370	Open periprosthetic capsulotomy, breast
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
HCPCS	
C1789	Prosthesis, breast (implantable)
L8600	Implantable breast prosthesis, silicone or equal

Related Information

Definition of Terms

When specific definitions are not present in a member's plan, the following definition of terms will be applied:

American Society of Anesthesiologists (ASA) Physical Status Classification:

ASA PS Classification	Definition	Adult Examples including, but not limited to
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

DM-diabetes mellitus, HTN-hypertension, COPD-chronic obstructive pulmonary disease, ESRD-end stage renal disease, MI-myocardial infarction, CVA-cerebral vascular accident, TIA-transient ischemic attack, CAD-coronary artery disease, DIC-disseminated intravascular coagulation, ARD-acute respiratory distress.

Source: **Statement on ASA Physical Status Classification System**. Accessed January 26, 2026.

Cosmetic: Cosmetic services are those which are primarily intended to preserve or improve appearance. Cosmetic surgery is performed to reshape structures of the body in order to improve the patient's appearance or self-esteem.

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

Physical functional impairment: A limitation from normal (or baseline level) of physical functioning that may include, but is not limited to, problems with ambulation, mobilization, communication, respiration, eating, swallowing, vision, facial expression, skin integrity, distortion of nearby body parts or obstruction of an orifice. The physical functional impairment can be due to structure, congenital deformity, pain, or other causes. Physical functional impairment excludes social, emotional and psychological impairments or potential impairments.

Poland syndrome is a rare congenital disorder with associated depression of the ribs (concave appearance) on one or both sides of the sternum. The right side is more often affected than the left side and it occurs more commonly in males than females. The condition is characterized by absence or hypoplasia of the pectoralis major or minor muscles, absence of costal cartilages, hypoplasia of the breast and subcutaneous tissue, breast nipple abnmormalities, and hand and upper extremity abnormalities (e.g., short, webbed fingers). Surgical techniques to correct the disorder (typically performed later in childhood or adolescence) may include breast augmentation with tissue from the opposite breast, musculocutaneous flap to fill the hollow space on the exterior of the chest, prosthetic augmentation, and surgical repair of the chest wall.

Reconstructive surgery: Refers to surgeries performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function.

Application of the above policy regarding explantation of implants requires documentation of the original indication for implantation and the type of implant, either saline- or silicone gel-filled, and the current symptoms, either local or systemic.

Rupture of implants requires documentation with an imaging study, such as mammography, magnetic resonance imaging, or ultrasonography. Lack of imaging confirmation of rupture in association with persistent local symptoms is considered case by case

Pain as an isolated symptom is an inadequate indication for explantation. The pain should be related to the Baker classification or a diagnosis of rupture.

In 2023, The American Association of Plastic Surgeons published a consensus statement on BIA-ALCL.[1], The statement notes, "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." Plans might locally consider coverage of prophylactic explantation of textured breast implants to reduce remote risk of anaplastic large cell lymphoma based on this recommendation.

Benefit Application

Federal and State Mandates on Breast Reconstruction Surgery After Mastectomy

Women's Health and Cancer Rights Act of 1998, § 713 (a): "In general - a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a Mastectomy shall provide, in case of a participant or beneficiary who is receiving benefits in connection with a Mastectomy and who elects breast reconstruction in connection with such Mastectomy, coverage for (1) reconstruction of the breast on which the Mastectomy has been performed; (2) surgery and reconstruction of the other breast to produce symmetrical appearance; and (3) prostheses and physical complications all stages of Mastectomy, including lymphedemas in a manner determined in consultation with the attending physician and the patient."[37]

State of Alaska mandate for coverage for reconstructive surgery following mastectomy.
Source URL: **http://www.akleg.gov/basis/statutes.asp#21.42.400** Accessed January 26, 2026.

State of Washington mandate for coverage for reconstructive breast surgery
Source URL: **http://apps.leg.wa.gov/RCW/default.aspx?cite=48.46.280** Accessed January26, 2026.

Description

This policy describes different types of reconstructive breast surgery and establishes criteria for the explantation (removal) of breast implants based on whether the original implant was cosmetic or reconstructive in nature. Implants may be either silicone gel-filled or saline-filled.

Reconstructive breast surgery is defined as a surgical procedure that is designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. The most common indication for reconstructive breast surgery is a prior mastectomy. Benefits for reconstructive breast surgery in these individuals are mandated by federal law, and also in many states. In contrast, cosmetic breast surgery is defined as surgery designed to alter or enhance the appearance of a breast that has not undergone surgery, accidental injury, or trauma.

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

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 have been graded according to the Baker Classification as follows:

- 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

Background

Reconstructive Breast Surgery

Reconstructive breast surgery is defined as a surgical procedure that is designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. Breast reconstruction is distinguished from purely cosmetic procedures by the presence of a medical condition, e.g., breast cancer or trauma, which leads to the need for breast reconstruction.

The most common indication for reconstructive breast surgery is a prior mastectomy; in fact, benefits for reconstructive breast surgery in these individuals are a mandated benefit in many states. In contrast, cosmetic breast surgery is defined as surgery designed to alter or enhance the appearance of a breast that has not undergone surgery, accidental injury, or trauma. Reduction mammaplasty is a common example of cosmetic breast surgery, but surgery to alter the appearance of a congenital abnormality of the breasts, such as tubular breasts, would also be considered cosmetic in nature.

The following policy describes different types of reconstructive breast surgery and reviews the evidence on efficacy for the different approaches. It also establishes criteria for the explantation of breast implants based on indication, whether the original implant was cosmetic or reconstructive in nature, and whether the implant is silicone gel-filled or saline-filled.

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

BIA-ALCL is a rare T-cell lymphoma (designated as such by the World Health Organization in 2016) that can develop in the breast area around textured breast implants. It is not a breast cancer. The etiology is unknown at this time. Possible theories include implant particulate, chronic allergic inflammation, or a response to biofilm. It usually presents as a seroma or effusion with swelling of the breast surrounding the scar capsule. It has been found in cases of both saline and silicone breast implants, placed for both cosmetic or post malignancy reconstructive purposes. BIA-ALCL has not been found in individuals with smooth implants. Onset has been anywhere from 2 to 28 years post implantation, with the average being around 8 years. Diagnosis is made based on positive findings of CD30 large anaplastic T-cell lymphocytes by immunohistochemistry and flow cytometry via aspiration of the affected fluid collection, followed by histologic confirmation. Treatment is bilateral total capsulectomy and implant removal. NCCN has established standardized guidelines for this diagnosis. There is no recommended screening for individuals without symptoms.[41-48]

Currently, the FDA collects and evaluates information about BIA-ALCL in women with breast implants. In collaboration with the American Society of Plastic Surgeons and the Plastic Surgery Foundation (ASPS/PSF), the FDA developed a registry of BIA-ALCL cases, known as the PROFILE Registry (Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology) to track and collect scientific data on BIA-ALCL. According to the FDA there are 1380 confirmed cases worldwide with 64 known deaths as of June 30, 2024, the majority of which involved a textured implant. As of May 30, 2025, 458 suspected/confirmed US cases of BIA-ALCL have been reported to the PROFILE registry.

Sources: .**https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources .** Accessed January 26, 2026.

https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma. Accessed January 26, 2026.

Summary of Evidence

For individuals who have undergone breast surgery or who have experienced injury or trauma to the breast who receive breast reconstruction surgery, the evidence includes case series. Relevant outcomes are overall survival, disease-specific survival, morbid events, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity. The evidence supports the conclusion that breast reconstruction improves psychosocial outcomes, such as anxiety, social functioning, and perception of body image. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with breast implants and documented implant rupture, infection, extrusion, Baker contracture, or surgical treatment of breast cancer who receive breast implant explantation the evidence includes case series. Relevant outcomes are overall survival, disease-specific survival, morbid events, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity. 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. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For asymptomatic individuals with breast implants without documented implant rupture, infection, extrusion, Baker contracture, or surgical treatment of breast cancer who receive preventive breast implant explantation to reduce remote risk of anaplastic large cell lymphoma (ALCL), the evidence includes prospective and retrospective epidemiological cohort studies, case series, and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, morbid events, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity. Systematic reviews of epidemiological studies and government regulatory epidemiologic databases have evaluated the risk of breast implant-associated ALCL (BIA-ALCL). Estimates varied widely, with the highest incidence associated with textured implant products that are no longer marketed in the United States. The certainty of the evidence is limited by insufficient follow-up duration to assess risk and lack of standardization of

clinical outcome data collection. Additionally, there is no evidence evaluating whether removal of implants reduces ALCL risk, and there are known risks of explantation surgery. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04220970	Breast Implant-associated Anaplastic Large Cell Lymphoma (BIA-ALCL) Registry	150	Jun 2032
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)[33]	NA	NA
NCT06510205	Post-Market Clinical Follow-up for Mentor Breast Implants	5000	Dec 2034

NA: not applicable; NCT: national clinical trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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.[1] 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.[34] 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

The 2024 National Comprehensive Cancer Network (NCCN) guidelines (v.1.2026) included a section in their breast cancer guidelines that was titled "Principles of Breast Reconstruction Following Surgery" which included the following relevant statements:[35]

- 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.

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.[14]

Medicare National Coverage

There is no national coverage determination.

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 US Food and Drug Administration (FDA)."[2] 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.[3] 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 decision checklist, updated silicone gel-filled breast implant rupture screening recommendations, a device decription 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
- 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

FDA Labeling for Approved Breast Implants. Source URL:**https://www.fda.gov/medical-devices/breast-implants/labeling-approved-breast-implants**, Accessed January 26, 2026.

References

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History

Date	Comments
02/97	New Policy. Add to Surgery section.
06/25/98	Replace Policy. Reviewed with changes; discussion of reconstructive breast surgery, revised indications for removal of breast implants.
12/07/99	Replace Policy. Policy description revised.
12/10/02	Replace Policy. Policy reviewed without literature review; new review date only
10/16/03	Replace Policy. Policy reviewed by consensus without literature review; new review date only.
02/06/06	Disclaimer and Scope Update
06/09/06	Codes updated. No other changes.
07/10/07	Policy renumbered. Replaces BC.7.01.22. Policy updated with literature review; references added. Policy statement revised to indicate medical necessity for reconstructive surgery as a result of mastectomy or trauma, and explantation of implants as medically necessary if the original surgery met medically necessary criteria; explantation as not medically necessary under indicated circumstances; and as a contract exclusion based upon cosmetic purposes. Benefit Application section updated with definitions for cosmetic, physical functional impairment and reconstructive surgery.
08/24/07	Cross Reference Update. No other changes.
11/13/07	Cross Reference Update. No other changes.
05/13/08	Cross Reference Update. No other changes.
08/12/08	Policy updated with literature search. Policy statement updated to include "or other malignancies involving the breast" under the reconstructive and cosmetic purposes criteria. Under Cosmetic Purposes "irrespective of the existence of any medical necessity criteria described in the section devoted to explantation of implants placed for reconstructive purposes above" was added to the last statement. Codes added, effective 10/1/08.
06/09/09	Replace Policy. Replace Policy. Policy updated with literature search. No change to policy statements. Codes added.
05/11/10	Replace Policy. Policy updated with literature search. No change to policy statements.
11/09/10	Replace Policy. Policy statement revised to allow lumpectomies, previously not addressed, as a medically necessary indication for reconstructive breast surgery.
09/15/11	Replace Policy. Policy updated with literature search. Reference added. No change to the policy statement. Related Policies updated; 10.01.514 added.

Date	Comments
03/23/12	Replace Policy – Policy updated with literature search. No change to the policy statement.
04/16/12	Related Policies updated: 7.01.09 removed as this policy has been archived.
03/08/13	Replace policy. Policy updated with literature search. No change to the policy statement. Reference 15 added.
05/02/14	Annual review. Moved definition of terms from Benefit Application to Policy Guidelines section. Added links to AK & WA state laws on breast reconstruction. A literature search through March 2014 did not prompt any changes to the rationale section. No new references added. Minor edits for readability. Policy statement unchanged.
10/13/14	Interim Review. Added clarifying policy statements to indicate the services are considered cosmetic when medical necessity criteria are not met.
06/17/15	Annual Review. Policy statements unchanged. Informational codes removed (not reviewed); ICD-9 diagnosis codes and procedure codes also removed as they are not used in adjudication.
12/15/15	Update Related Policies. Remove 7.01.129 as it is archived.
02/09/16	Annual Review. Policy updated with literature search; references 5, 17-18 added. Policy statement unchanged.
03/01/17	Annual Review, approved February 14, 2017. Policy updated with literature search. Policy moved into new format; no change to policy statements.
03/24/17	Minor formatting update.
06/01/17	Interim Review, approved May 23, 2017. Policy section updated; procedures in this policy are considered not medically necessary when criteria in this policy are not met. Clarification and simplification of coverage statements made. Change from a medical policy to a benefit coverage guideline.
08/18/17	Coding update, added CPT code 11921.
11/01/17	Interim Review, approved October 19, 2017. Added indications to medical necessity criteria: reduce risk of breast cancer occurrence, and treat disease (severe fibrocystic disease unresponsive to medical therapy).
06/01/18	Annual Review, approved May 3, 2018. Policy reviewed with literature search. No references added. Policy statement unchanged. Added HCPCS codes S2067 and S2068.
06/19/18	Added Site of Service information to the policy.
09/07/18	Coding update, added CPT codes 11922, 11960, 11970, 11971, 19303, 19304, 19324, and 19325.
05/01/19	Minor update, clarified Site of Service requirements.
07/01/19	Annual Review, approved June 11, 2019. References 5, 13-14, 17, 19-21, and 28-30 added. Added medically necessary indication of breast implant-associated anaplastic

Date	Comments
	large cell lymphoma for explanation of breast implant. Other minor edits for clarity only.
10/01/19	Coding update, removed CPT codes 19303 and 19304.
01/03/20	Coding update, removed CPT code 11960.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated and will no longer be deleted or replaced with InterQual criteria on July 2, 2020. Added BIA-ALCL as an indication for removal of implants placed for cosmetic purposes. Added codes 15771 and 15772.
01/01/21	Annual Review, approved December 1, 2020. Policy updated with literature review. References added. Policy statements unchanged. Coding update to CPT 19324 and 19366 codes terminated 1/1/2021.
11/01/21	Annual Review, approved October 5, 2021. Policy updated with literature review. References added and updated. Policy statements unchanged.
09/01/22	Annual Review, approved August 8, 2022. Policy updated with literature review through May 23, 2022. Policy statements unchanged except for minor edit. Removed CPT codes 19324 and 19366 that were termed 1/1/2021.
03/01/23	Coding update. Updated CPT code 19380 description.
04/01/23	Coding update. Removed HCPC codes S2067 and S2068.
09/01/23	Annual Review, approved August 7, 2023. Policy updated with literature review through May 1, 2023; reference added. Changed the wording from "patient" to "individual" throughout the policy for standardization; otherwise, policy statement unchanged.
09/01/24	Annual Review, approved August 12, 2024. Policy updated with literature review through April 30, 2024; references added. Clarified that Baker class III contractures and rupture of a saline implant in individuals with implants for cosmetic purposes are considered not medically necessary. Policy intent unchanged. Policy statements otherwise unchanged.
11/01/24	Minor update made to the BCBSA Reference policy section. Policy 7.01.09 was removed as a reference policy.
07/03/25	Minor update made to Related Policy section. Policy 7.01.113 Bioengineered Skin and Soft Tissue Substitutes is deleted and replaced with 7.01.582 Bioengineered Skin and Soft Tissue Substitutes.
08/01/25	Interim update, approved July 8, 2025. Removed Related Policy 11.01.524 Site of Service: Select Surgical Procedures. Added related policy 11.01.525 Site of Service Ambulatory Service Center (ASC) Select Surgical Procedures. Added Site of Service

Date	Comments
	Ambulatory Service Center (ASC) Select Surgical Procedures criteria, effective November 7, 2025, following 90-day provider notification.
09/01/25	Annual Review, approved August 12, 2025. Policy updated with literature review through April 11, 2025; References added. Policy statements unchanged.
04/01/26	Annual Review, approved March 10, 2026. Policy reviewed. References added and updated. Added Poland syndrome to the list of breast diseases for which reconstructive breast surgery may be considered medically necessary when criteria are met. Effective July 2, 2026 after a 90-day notification. Added CPT 15769 and HCPCS C1789. Added 7.01.153 Adipose-Derived Stem Cells in Autologous Fat Grafting to the Breas to Related Medical Policies.
06/01/26	Minor update. Removed hospital medical center from the medically necessary sites of service for elective surgical procedures. It should only state "Ambulatory Surgical Center" with the initial leader statement. This was an inadvertent error that was missed. Added header to indicate that site of service review does not apply to Indian Health Services (IHS) facilities.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.