7.01.22	Reconstructive Breast Surgery/Management of Breast Implants		
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Section:	7.0 Surgery	**Page:**	Page 1 of 20

Policy Statement

Coverage eligibility of breast implants for the purposes of augmentation may depend on contract language. After reconstructive breast surgery on one side, insertion of an implant on the contralateral, normal side is rarely necessary to achieve symmetry.

I. Reconstructive breast surgery may be considered **medically necessary** after a medically necessary mastectomy, accidental injury, or trauma. Medically necessary mastectomies are most typically done as treatment for cancer. Reconstruction may be performed by an implant-based approach or through the use of autologous tissue.

II. Explantation of a *silicone* gel-filled breast implant may be considered **medically necessary** in all cases for a documented implant rupture, infection, extrusion, Baker class IV contracture, or as an adjunct to current surgical treatment of breast cancer.

III. Explantation of a ruptured *saline*-filled breast implant may be considered **medically necessary** only in those individuals who had originally undergone breast implantation for reconstructive purposes. Otherwise, indications for the explantation of a saline-filled implant are similar to those of a silicone-filled implant.

IV. Explantation of a breast implant associated with a Baker class III contracture may be considered **medically necessary** only in those individuals who had originally undergone breast implantation for reconstructive purposes.

V. Reconstructive breast surgery after explantation of an implant is considered **medically necessary** only in those individuals who had originally undergone breast implantation for reconstructive purposes.

VI. The following indications for explantation of implants are considered **investigational**:
   A. Systemic symptoms, attributed to connective tissue diseases, autoimmune diseases
   B. Anxiety
   C. Baker class III (or lower) contractures in individuals with implants for cosmetic purposes
   D. Rupture of a saline implant in individuals with implants for cosmetic purposes
   E. Pain not related to contractures
   F. Preventive explantation in asymptomatic individuals to reduce remote risk of anaplastic large cell lymphoma (see Policy Guidelines)
   G. Preventive explantation in asymptomatic individuals to reduce remote risk of B cell lymphoma.

In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions:

A. The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery
B. The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem (see Policy Guidelines and Documentation for Clinical Review sections)
C. There is alternative approved medical or surgical intervention with equal or superior clinical outcomes

D. The procedure is for cosmetic purposes only

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

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

Indication/Type of Implant

Indication for Explantation	Reconstruction/ Silicone	Reconstruction/ Saline	Cosmetic/ Silicone	Cosmetic/ Saline
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
Anxiety	no	no	no	no
Absolute Medical Indications				
Rupture*	yes	yes	yes	no
Baker class IV contracture	yes	yes	yes	yes
Recurrent infection	yes	yes	yes	yes
Extruded implant	yes	yes	yes	yes
Surgery for breast cancer	yes	yes	yes	yes
Other Indications				
Baker class III contractures	yes	yes	no	no
Pain**	no	no	no	no
To reduce remote risk of anaplastic large cell lymphoma	no	no	no	no
To reduce remote risk of B cell lymphoma	no	no	no	no
Post-Explantation Procedures				
reimplantation of implants	yes	yes	no	no
autologous reconstruction	yes	yes	no	no

*Rupture of implants requires documentation with an imaging study, such as mammography, 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.

For the purpose of this policy, the qualified reviewer will differentiate a normal structure from an abnormal one based on **any** of the following elements:

- The availability of published normative data for specific anatomic measurements (e.g., cephalometric data for orthognathic surgery)

- The normal structures wide range of accepted variations in diverse populations (e.g., nasal size and shape)
- The presence of a cosmetic implant, in the absence of adjacent native tissue structural pathology, does not constitute an abnormal structure (e.g., cosmetic unilateral, bilateral or asymmetrical saline breast implants)

In determining whether or not a procedure is likely to result in more than minimal improvement in appearance, the qualified reviewer will consider both the size and location of the structural abnormality.

"Cosmetic surgery" means surgery that is performed to alter or reshape normal structures of the body in order to improve appearance. Under existing California statutes, medically necessary services to treat complications from a non-covered service (e.g., cosmetic surgery) are a covered benefit as addressed below.

Coding
See the Codes table for details.

Description

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.

Related Policies

- Bioengineered Skin and Soft Tissue Substitutes

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

FDA:
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)."[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 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

State:
The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines "reconstructive surgery" as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do **either** of the following (see also Blue Shield of California Medical Policy: Reconstructive Services):

A. Create a normal appearance to the extent possible
B. Improve function

Rationale

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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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.[4,] 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.[5,6,7,] 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:[8,]

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.[9,] 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.[10,11,12,13,] 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.

Preventive Breast Implant Explantation to Reduce Remote Risk of Anaplastic Large Cell Lymphoma

Clinical Context and Therapy Purpose

The purpose of breast implant explantation in asymptomatic individuals is to reduce remote risk of anaplastic large cell lymphoma (ALCL).

Anaplastic large cell lymphoma is a form of T-cell, non-Hodgkin lymphoma. According to National Comprehensive Cancer Network (NCCN) Consensus Guidelines published in 2019, breast implant-associated ALCL (BIA-ALCL) is commonly indolent and slow-growing, with an excellent prognosis (overall survival rate 94% and 91% at 3 and 5 years, respectively), especially when treated with surgery.[14,] The most common presentation is a large spontaneous periprosthetic fluid collection occurring at least 1 year and on average 7 to 10 years following implantation.

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

Populations
The relevant population of interest is asymptomatic individuals with breast implants without 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.

NCCN consensus guidelines recommend that symptomatic effusions greater than 1 year after implantation should be tested for BIA-ALCL, but do not address screening in asymptomatic individuals.[14,]

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.

Specific outcomes include the incidence of ALCL and complications of explantation surgery.

Follow-up of 8 to 12 years following implantation is preferred.

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
Systematic Reviews
Lynch et al (2021) conducted a systematic review of epidemiological studies of the risk of BIA-ALCL.[15,] In addition to published literature, the study authors collected regulatory agency epidemiologic data, including from the FDA's Manufacturer User Facility Device Experience (MAUDE) database and the American Society of Plastic Surgeons (ASPS) Patient Registry and Outcomes For breast Implants and Anaplastic large cell lymphoma (ALCL) etiology and Epidemiology (PROFILE) registry.

Eight studies met inclusion criteria (Table 1). The heterogeneity of reported data prevented meta-analysis and limited the calculation of combined risk estimates. The authors presented estimates by geographic location and by device. Two studies conducted in the US provided data to calculate the incidence rate, with estimates ranging from 1.46 per 100,000 person-years to 0.203 per 100,000 person-years (2.03 per million). The patient-specific cumulative risk within the US market ranged from 1.79 per 1,000 to 2.82 per 1,000. In the US, FDA estimates ranged from 1 in 3,817 to 1 in 30,000.

The authors concluded that population-based cohort studies and government databases consistently revealed an association between textured-surface breast implants and the incidence of BIA-ALCL. There was significant global geographic and manufacturer-specific variation in the risk of disease, but the data confirmed that Allergan textured devices carry substantially higher risk profiles than other devices regardless of population studied. No cases occurred solely in the context of a smooth surface breast implant. The evidence was limited by incomplete clinical data and a lack of long-term follow-up. The authors recommended greater standardization of reporting outcomes, and improving long-term follow-up to help establish more robust data.

Table 1. Epidemiological Studies Included in Lynch et al (2021)[15,]

Study	Location	Study Design	Years	ALCL Cases	Sample Size
Largent et al (2011)[16,]	US	Retrospective cohort	1994-2007	3	NR
McGuire et al (2016)[17,]	US	Prospective cohort	-2014	8	17,656
Cordeiro et al (2020)[18,]	US	Retrospective cohort	1992-2019	10	3,456
Nelson et al (2020)[19,]	US	Retrospective cohort	1991-2017	11	9373
De Boer et al (2018)[20,]	The Netherlands	Retrospective cohort	1990-2016	43	3000
Campanale et al (2018)[21,]	Italy	Retrospective cohort	2015-2017	22	10,000,000
Loch-Wilkinson et al (2019)[22,]	Australia	Retrospective cohort	2015-2019	104	NR
Doren et al (2018)[23,]	US	Case Series	1996-2015	100	3,000,000

ALCL: anaplastic large cell lymphoma; NR: not reported.

Additional systematic reviews have similarly concluded that while rare, the incidence of BIA-ALCL is increasing, but limitations in the evidence base preclude an accurate estimation of its incidence.[24,25,26,]

Regulatory Epidemiologic Database

In 2023, McCarthy et al published an updated report from the PROFILE registry.[27,] From August 2012 to August 2020, a total of 330 suspected or confirmed cases of BIA-ALCL were reported to the registry, including 144 cases newly reported since the 2018 publication included in the systematic reviews discussed above. All cases occurred in individuals with a history of a textured device; there were no cases reported in an individuals with a confirmed smooth-only device history.

Section Summary: Preventive Breast Implant Explantation to Reduce Remote Risk of Anaplastic Large Cell Lymphoma

Systematic reviews of epidemiological studies and government regulatory epidemiologic databases have evaluated the risk of BIA-ALCL. Estimates varied widely, with the highest incidence associated with textured implant products that are no longer marketed in the US. 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.

Preventive Breast Implant Explantation to Reduce Remote Risk of B Cell Lymphoma

Clinical Context and Therapy Purpose

The purpose of breast implant explantation in asymptomatic individuals is to reduce the remote risk of B cell lymphoma.

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

Populations
The relevant population of interest is asymptomatic individuals with breast implants without 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.

Specific outcomes include the incidence of B cell lymphoma and complications of explantation surgery.

Follow-up of 8 to 12 years following implantation is preferred.

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
Case Reports
Recent case reports and small case series (N=3 to 8 cases) have described B cell lymphomas occurring in individuals with breast implants.[28,29,30,] More data are needed to determine if breast implants are associated with an increased risk of B cell lymphoma.

Section Summary: Preventive Breast Implant Explantation to Reduce Remote Risk of B Cell Lymphoma
The evidence is limited to case reports and small case series describing occurrences of B cell lymphoma in individuals with breast implants.

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

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.[1,] Recommendations were based on a systematic review of the literature and focused on textured-surface breast implants. Recommendations releveant 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.[31,] 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.2.2024) included a section in their breast cancer guidelines that was titled "Principles of Breast Reconstruction Following Surgery" which included the following relevant statements:[32,]

- 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,]

U.S. Preventive Services Task Force Recommendations

Not applicable

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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 Cell Lymphoma (BIA-ALCL) Registry	150	Jun 2032
NCT05017337	A Translational Study of Breast-implant associated anaplastlc 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

NA: not applicable; NCT: national clinical trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical indication for removal including Baker class if applicable
  - Reason for original insertion of the breast implant
  - Type of implant being removed
- Operative report(s) (if applicable)
- Radiological reports (if applicable)

Post Service (in addition to the above, please include the following):

- Breast implant related operative report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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)
	19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
	19342	Insertion or replacement of breast implant on separate day from mastectomy
	19361	Breast reconstruction; with latissimus dorsi flap
	19364	Breast reconstruction; with free flap (e.g., fTRAM, DIEP, SIEA, GAP flap)
	19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap
	19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)
	19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap
	19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
	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)
	L8030	Breast prosthesis, silicone or equal, without integral adhesive
	L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
	L8039	Breast prosthesis, not otherwise specified
	L8600	Implantable breast prosthesis, silicone or equal
	S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
	S2067	Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator

Type	Code	Description
		(GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
	S2068	Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
09/01/2022	New policy.
08/01/2023	Annual review. No change to policy statement. Policy guidelines and literature updated.
08/01/2024	Annual review. Policy statement, guidelines and literature updated. Coding update.
10/01/2024	Administrative update.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
Reconstructive Breast Surgery/Management of Breast Implants 7.01.22 **Policy Statement:** Coverage eligibility of breast implants for the purposes of augmentation may depend on contract language. After reconstructive breast surgery on one side, insertion of an implant on the contralateral, normal side is rarely necessary to achieve symmetry. I. Reconstructive breast surgery may be considered **medically necessary** after a medically necessary mastectomy, accidental injury, or trauma. Medically necessary mastectomies are most typically done as treatment for cancer. Reconstruction may be performed by an implant-based approach or through the use of autologous tissue. II. Explantation of a *silicone* gel-filled breast implant may be considered **medically necessary** in all cases for a documented implant rupture, infection, extrusion, Baker class IV contracture, or as an adjunct to current surgical treatment of breast cancer. III. Explantation of a ruptured *saline*-filled breast implant may be considered **medically necessary** only in those individuals who had originally undergone breast implantation for reconstructive purposes. Otherwise, indications for the explantation of a saline-filled implant are similar to those of a silicone-filled implant. IV. Explantation of a breast implant associated with a Baker class III contracture may be considered **medically necessary** only in those individuals who had originally undergone breast implantation for reconstructive purposes. V. Reconstructive breast surgery after explantation of an implant is considered **medically necessary** only in those individuals who had	**Reconstructive Breast Surgery/Management of Breast Implants 7.01.22** **Policy Statement:** Coverage eligibility of breast implants for the purposes of augmentation may depend on contract language. After reconstructive breast surgery on one side, insertion of an implant on the contralateral, normal side is rarely necessary to achieve symmetry. I. Reconstructive breast surgery may be considered **medically necessary** after a medically necessary mastectomy, accidental injury, or trauma. Medically necessary mastectomies are most typically done as treatment for cancer. Reconstruction may be performed by an implant-based approach or through the use of autologous tissue. II. Explantation of a *silicone* gel-filled breast implant may be considered **medically necessary** in all cases for a documented implant rupture, infection, extrusion, Baker class IV contracture, or as an adjunct to current surgical treatment of breast cancer. III. Explantation of a ruptured *saline*-filled breast implant may be considered **medically necessary** only in those individuals who had originally undergone breast implantation for reconstructive purposes. Otherwise, indications for the explantation of a saline-filled implant are similar to those of a silicone-filled implant. IV. Explantation of a breast implant associated with a Baker class III contracture may be considered **medically necessary** only in those individuals who had originally undergone breast implantation for reconstructive purposes. V. Reconstructive breast surgery after explantation of an implant is considered **medically necessary** only in those individuals who had

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
originally undergone breast implantation for reconstructive purposes. VI. The following indications for explantation of implants are considered **investigational**: A. Systemic symptoms, attributed to connective tissue diseases, autoimmune diseases B. Anxiety C. Baker class III contractures in individuals with implants for cosmetic purposes D. Rupture of a saline implant in individuals with implants for cosmetic purposes E. Pain not related to contractures F. Preventive explantation in asymptomatic individuals to reduce remote risk of anaplastic large cell lymphoma (see Policy Guidelines) G. Preventive explantation in asymptomatic individuals to reduce remote risk of B cell lymphoma. In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions: A. The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery B. The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem (see Policy Guidelines and Documentation for Clinical Review sections) C. There is alternative approved medical or surgical intervention with equal or superior clinical outcomes D. The procedure is for cosmetic purposes only	originally undergone breast implantation for reconstructive purposes. VI. The following indications for explantation of implants are considered **investigational**: A. Systemic symptoms, attributed to connective tissue diseases, autoimmune diseases B. Anxiety C. Baker class III (or lower) contractures in individuals with implants for cosmetic purposes D. Rupture of a saline implant in individuals with implants for cosmetic purposes E. Pain not related to contractures F. Preventive explantation in asymptomatic individuals to reduce remote risk of anaplastic large cell lymphoma (see Policy Guidelines) G. Preventive explantation in asymptomatic individuals to reduce remote risk of B cell lymphoma. In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions: A. The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery B. The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem (see Policy Guidelines and Documentation for Clinical Review sections) C. There is alternative approved medical or surgical intervention with equal or superior clinical outcomes D. The procedure is for cosmetic purposes only