Policy Number	**SUR716.009**
Policy Effective Date	**01/01/2026**

Reconstructive Breast Surgery/Management of Breast Implants

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Related Policies (if applicable)
SUR717.001 Gender Assignment Surgery and Gender Reassignment Surgery with Related Services
SUR716.001 Cosmetic and Reconstructive Procedures
SUR716.011 Reconstructive Breast Surgery

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0123 (IL HB 1384) Coverage for Reconstructive Services requires the following policies amended, delivered, issued, or renewed on or after January 1, 2025 (Individual and family PPO/HMO/POS; Student; Group [Small Group; Mid-Market; Large Group Fully Insured PPO/HMO/POS] or Medicaid), to provide coverage for medically necessary services that are intended to restore physical appearance on structures of the body damaged by trauma.

EXCEPTION: For members residing in the state of Arkansas, § 23-99-405 related to coverage of mastectomy and reconstruction services, should an enrollee elect reconstruction after a mastectomy, requires coverage for surgery and reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, and protheses and coverage for physical complications at all stages of a mastectomy, including lymphedema. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

EXCEPTION: For members residing in the state of Arkansas: AR 23-79-2902-03 SB 83 requires a health benefit plan to provide coverage for all modalities, types, and techniques of a healthcare service provided for a breast reconstruction surgery and shall cover any surgery determined as the best course of treatment by a healthcare professional, consistent with prevailing medical standards, and in consultation with the patient. Breast reconstruction surgery is defined as: 1) augmentation, reduction, and mastectomy and all procedures for a contralateral breast necessary for symmetry, 2) all breast reconstruction modalities, including implant-based breast reconstruction, tissue-based reconstruction, and any other modalities recognized within Level I of the Healthcare Common Procedure Coding System codes, 3) chest wall reconstruction, including without limitation an aesthetic flat closure, 4) custom fabricated breast prostheses, including without limitation replacement of such breast prostheses, and 5) coverage for the mechanical, medical, and surgical treatment of physical complications of a mastectomy, breast reconstruction surgery, chest wall reconstruction, radiation, and lymph node surgery. This applies to the following: Fully Insured Group, Student, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

Coverage

This medical policy does NOT address Gender Reassignment Services (Transgender Services). This medical policy IS NOT TO BE USED for Gender Reassignment Services. Refer to SUR717.001, Gender Assignment Surgery and Gender Reassignment Surgery with Related Services

Breast implant services **may be subject to the member's contract benefit coverage and/or exclusions**, including complications related to the breast implant itself, whether saline-filled or silicone gel-filled, and/or the related procedure services (removal/insertion/reinsertion).

For example, none of the services listed below would be covered for a cosmetic breast implant augmentation (unilateral or bilateral) which is **unrelated** to post-mastectomy reconstruction with contralateral breast surgery, post-accidental injury or trauma:

- Diagnostic evaluation, OR
- Preparation for surgery, OR
- Services or supplies provided in conjunction with treatment, OR
- Removal of implant, OR
- Replacement of implant.

Table 1
To **determine coverage** for removal of a breast implant (either silicone gel-filled OR saline-filled product), with or without replacement of a breast implant (either silicone gel-filled OR saline-filled product), **compare the individual's presenting clinical condition(s) and the individual's breast implant history** below:

Clinical Conditions	**Post Reconstructive Implant**	**Post Reconstructive Implant Reinsertion or**	**Post Cosmetic Implant Removal (see NOTE 2)**	**Post Cosmetic Implant Reinsertion or**

	Removal (see NOTE 1)	**Replacement (see NOTE 1)**		**Replacement (see NOTE 2)**
Documented surgical treatment of breast cancer whether a silicone gel-filled **or** saline-filled implant(s)	**Mandated Benefit**	**Mandated Benefit**	**Mandated Benefit**	**Mandated Benefit**
Documented breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL), associated with components of implant envelope (sleeve or covering) or contents of the implant whether silicone gel-filled **or** saline-filled implant	**Medically Necessary**	**Medically Necessary**	**Medically Necessary**	**Check Member's Contract Prior to Requiring Medical Review**
Recurrent breast infection related only to contracture from **or** rupture of silicone gel-filled **or** saline-filled implant	**Mandated Benefit**	**Mandated Benefit**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**
Imaging evidence of silicone gel-filled **or** saline-filled implant rupture	**Mandated Benefit**	**Mandated Benefit**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**
Imaging evidence of extrusion of silicone gel-filled **or** saline-filled contents into the subcutaneous tissue	**Mandated Benefit**	**Mandated Benefit**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**
Baker Class III **or** IV contracture as a result of a silicone gel-filled **or** saline-filled implant	**Mandated Benefit**	**Mandated Benefit**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**

Baker Class II contracture as a result of a silicone gel-filled **or** saline-filled implant	**Not Medically Necessary**	**Not Medically Necessary**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**
Baker Class I augmented breast feels as soft as a normal breast whether a silicone gel-filled **or** saline-filled implant	**Not Medically Necessary**	**Not Medically Necessary**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**
Chronic breast pain related **ONLY** to recurrent breast infection, contracture from, or rupture of a silicone gel-filled **or** saline-filled implant	**May be Medically Necessary**	**May be Medically Necessary**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**
Breast **or** chest wall pain unrelated to contractures or rupture	**Not Medically Necessary**	**Not Medically Necessary**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**
Individual anxiety or fear of silicone gel-filled **or** saline-filled implant(s) rupture and/or contracture	**Not Medically Necessary**	**Not Medically Necessary**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**
Individual anxiety or fear of cancer risk, including but not limited to breast implant associated – anaplastic large-cell lymphoma (BIA-ALCL), associated with components of implant envelope (sleeve or covering) **or** contents of the implant whether	**Not Medically Necessary**	**Not Medically Necessary**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**

silicone gel-filled **or** saline-filled implant				
Individual anxiety or fear of potential systemic conditions from silicone gel-filled **or** saline-filled implant, such as: • Connective tissue disease, OR • Autoimmune disease, OR • Rheumatic conditions, OR • Neurologic symptoms, OR • Fibromyalgia, OR • Chronic fatigue syndrome	**Not Medically Necessary**	**Not Medically Necessary**	**Check Member's Contract Prior to Requiring Medical Review**	**Check Member's Contract Prior to Requiring Medical Review**

NOTE 1: Reconstructive Removal: With or without replacement or reinsertion of silicone gel-filled or saline-filled implant(s), when the initial surgery was due to cancer or an approved prophylactic mastectomy for a benign disease (e.g., cancer risk) or other condition (e.g., a result of trauma or accident). There are some instances where reconstructive use of a breast implant has been done following trauma or accident. Refer to Medical Policy SUR716.011 Reconstructive Breast Surgery for explanation of coverage regarding breast implants following breast surgery for cancer on the affected and unaffected breast.

NOTE 2: Cosmetic Removal: With or without replacement or reinsertion of silicone gel-filled or saline-filled implant, unrelated to cancer or cancer risk, trauma, or accident, are intended primarily to improve physical appearance, performed primarily for psychological purposes and/or to restore form that does not correct or materially improve a bodily function. Refer to Medical Policy SUR716.001 Cosmetic and Reconstructive Procedures for explanation of coverage.

NOTE 3: Documentation Requirements: Documentation may be required to review requests or claims for breast implant(s) surgery, including, but not limited to, indications such as breast implant rupture or extrusion. Examples of documentation include but are not limited to a minimum of 2 of the following:

- Photographs, or
- Imaging using mammography, magnetic resonance imaging, or ultrasonography, or
- Consultations, or

- Operative reports and/or other applicable hospital records, such as, laboratory or pathology report(s), history and physical, and/or
- Treating provider's office records.

Policy Guidelines

None.

Description

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.

Regulatory Status

In July 2019, Allergan voluntarily recalled Natrelle Biocell textured breast implants and tissue expanders from the market. The recall notice stated, "Allergan is taking this action as a precaution following notification of recently updated global safety information concerning the uncommon incidence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) provided by the U.S. Food and Drug Administration (FDA)." (1) Smooth surfaced implants are not affected by this recall. The FDA and other health authorities have not recommended removal or replacement of textured breast implants or tissue expanders in asymptomatic individuals.

In October 2021, the FDA issued additional orders restricting the sale and distribution of breast implants. (2) 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. The 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 (FDA-approved in 2009);
- Inamed (now Allergan) Natrelle Saline Filled Breast Implants (FDA-approved in 2004 and again in 2005);
- Inamed (now Allergan) Natrelle Silicone Filled Breast Implants (FDA-approved in 2009 and again in 2013 for the Natrelle 410® Highly Cohesive Anatomically Shaped Silicone-Gel Filled Breast Implant);
- Mentor MemoryShape Silicone Gel-Filled Breast Implants;
- Mentor MemoryGel Silicone Gel-Filled Breast Implants (FDA-approved in 2009 and again in 2013 for the Mentor® MemoryShape Breast Implant); and
- Sientra OPUS Silicone Gel Breast Implants.

See <https://www.fda.gov> for the most recent updated list of implants.

Rationale

Medical policies 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.

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 policy.

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.

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.

Complications of breast implants are common and may require explantation. (3) 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.

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. (4-6) 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 explantation.

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

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: (7)
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 V: Contractures interfere with adequate mammography screening and are the cause of local symptoms, and thus their presence constitutes a health risk. (8) 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. (9-12) 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.

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

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. (13) 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 policy.

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. (13)

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. (14) 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 2). 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 United States 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 U.S., the 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 2. Epidemiological Studies Included in Lynch et al. (2021) (14)

Study	Location	Study Design	Years	ALCL Cases	Sample Size
Largent et al. (2011) (15)	U.S.	Retrospective cohort	1994-2007	3	NR

McGuire et al. (2016) (16)	U.S.	Prospective cohort	-2014	8	17,656
Cordeiro et al. (2020) (17)	U.S.	Retrospective cohort	1992-2019	10	3,456
Nelson et al. (2020) (18)	U.S.	Retrospective cohort	1991-2017	11	9373
De Boer et al. (2018) (19)	The Netherlands	Retrospective cohort	1990-2016	43	3000
Campanale et al. (2018) (20)	Italy	Retrospective cohort	2015-2017	22	10,000,000
Loch-Wilkinson et al. (2019) (21)	Australia	Retrospective cohort	2015-2019	104	NR
Doren et al. (2018) (22)	U.S.	Case Series	1996-2015	100	3,000,000

ALCL: anaplastic large cell lymphoma; NR: not reported; U.S.: United States.

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. (23-25)

Regulatory Epidemiologic Database

In 2023, McCarthy et al. published an updated report from the PROFILE registry. (26) 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 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 policy.

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. (27-29) 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.

Preventive Breast Implant Explantation to Reduce Remote Risk of Squamous Cell Carcinoma

Clinical Context and Therapy Purpose

The purpose of breast implant explantation in asymptomatic individuals is to reduce the remote risk of squamous cell carcinoma **(SCC)**.

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

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 squamous cell carcinoma 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

Niraula et al. (2023) conducted a systematic review of published cases of BIA-SCC to describe the relevant clinical data and outcomes. (30) The review included 14 articles with 18 known cases of BIA-SCC with symptoms typically emerging around 21 years after breast implantation. The estimated 6-month mortality rate was 11.1%, while the 12-month mortality rate was 23.8%. However, the authors note that the 6-month mortality rate should be interpreted cautiously due to the limited sample size. Additionally, they state that the rate is lower than what the American Society of Plastic Surgeons has reported without a clear rationale for this discrepancy.

Santanelli et al. (2024) conducted a systematic review of epidemiological studies and case series of the risk of BIA-SCC to estimate prevalence, incidence rate (IR), and risk. (31) The authors reported that the U.S. BIA-SCC prevalence is estimated as 0.61 per 100,000 (95% confidence interval (CI), 0.2:100,000 to 1.3:100,000), with a lifetime risk of 1:164,884 (95% CI, 0.2:100,000 to 5.6:100,000), and an IR of 0.002 per 100,000 person-years.

Regulatory Epidemiologic Database

As of March 22, 2023, the FDA recommends that any suspected or confirmed cases of BIA-SCC, lymphomas, or any other cancers around the breast implant be reported to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database and the device manufacturer 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. (32)

Section Summary: Preventive Breast Implant Explantation to Reduce Remote Risk of Squamous Cell Carcinoma

The evidence is limited to case reports and small case series describing occurrences of BIA-SCC in individuals with breast implants.

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 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 BIA-ALCL. Estimates varied widely, with the highest incidence associated with textured implant products that are no longer marketed in the U.S. 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.

For 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 B cell lymphoma, the evidence includes case reports. 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. Recent case reports and small case series (N=3 to 8 cases) have described B cell lymphomas occurring in individuals with breast implants. More data are needed to determine if breast implants are associated with an increased risk of B cell lymphoma. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For 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 BIA-SCC, the evidence includes 2 systematic reviews of a few case reports. 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. Recent case reports and small case series have described BIA-SCC occurring in individuals with breast implants, albeit it is a very rare occurrence. More data are needed to determine if breast implants are associated with an increased risk of squamous cell carcinoma. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements
American Society for Aesthetic Plastic Surgeons

In 2023, the American Society for Aesthetic Plastic Surgeons published a consensus statement on BIA-ALCL. (33) 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."

<u>American College of Radiology</u>

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 ultrasound (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 2025 National Comprehensive Cancer Network (NCCN) guidelines (v.3.2025) 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 1 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. (13)

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT Number	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) (36)	NA	NA
NCT06510205	Post-Market Clinical Follow-up for Mentor Breast Implants	5000	Dec 2034

NA: not applicable, NCT: National Clinical Trial

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	11970, 19328, 19330, 19325, 19340, 19342, 19371, 19380, 19396
HCPCS Codes	L8600

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

1. Allergan. Biocell Product Safety Alert. 2019. Available at: <https://www.biocellinformation.com> (accessed April 14, 2025).
2. Food and Drug Administration. 2021. FDA Strengthens Safety Requirements and Updates Study Results for Breast Implants. Available at: <https://www.fda.gov> (accessed April 14, 2025).
3. Gabriel SE, Woods JE, O'Fallon WM, et al. Complications leading to surgery after breast implantation. N Engl J Med. Mar 6 1997; 336(10):677-682. PMID 9041097
4. Chung KC, Wilkins EG, Beil RJ, et al. Diagnosis of silicone gel breast implant rupture by ultrasonography. Plast Reconstr Surg. Jan 1996; 97(1):104-109. PMID 8532766
5. Netscher DT, Weizer G, Malone RS, et al. Diagnostic value of clinical examination and various imaging techniques for breast implant rupture as determined in 81 patients having implant removal. South Med J. Apr 1996; 89(4):397-404. PMID 8614880

6. Samuels JB, Rohrich RJ, Weatherall PT, et al. Radiographic diagnosis of breast implant rupture: current status and comparison of techniques. Plast Reconstr Surg. Sep 1995; 96(4):865-877. PMID 7652061
7. Baker JL. Augmentation mammoplasty. In: Owsley JQ, Jr., Peterson RA, eds. Symposium on aesthetic surgery of the breast. St. Louis: CV Mosby; 1978.
8. American Society of Plastic and Reconstructive Surgeons. American Society of Plastic and Reconstructive Surgeons Citizens' Petition to the Food and Drug Administration which requests that silicone gel-filled implants remain available because the device is necessary for the public health. Arlington Heights, IL. November 29 1991.
9. Gabriel SE, O'Fallon WM, Kurland LT, et al. Risk of connective-tissue diseases and other disorders after breast implantation. N Engl J Med. Jun 16 1994; 330(24):1697-1702. PMID 8190133
10. Hennekens CH, Lee IM, Cook NR, et al. Self-reported breast implants and connective-tissue diseases in female health professionals. A retrospective cohort study. JAMA. Feb 28 1996; 275(8):616-621. PMID 8594243
11. Sanchez-Guerrero J, Colditz GA, Karlson EW, et al. Silicone breast implants and the risk of connective-tissue diseases and symptoms. N Engl J Med. Jun 22 1995; 332(25):1666-1670. PMID 7760867
12. Silverman BG, Brown SL, Bright RA, et al. Reported complications of silicone gel breast implants: an epidemiologic review. Ann Intern Med. Apr 15 1996; 124(8):744-756. PMID 8633836
13. Clemens MW, Jacobsen ED, Horwitz SM. 2019 NCCN Consensus Guidelines on the Diagnosis and Treatment of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Aesthet Surg J. Jan 31 2019; 39(Suppl_1):S3-S13. PMID 30715173
14. Lynch EB, DeCoster RC, Vyas KS, et al. Current risk of breast implant-associated anaplastic large cell lymphoma: a systematic review of epidemiological studies. Ann Breast Surg. 2021; 5:30. PMID 35415602
15. Largent J, Oefelein M, Kaplan HM, et al. Risk of lymphoma in women with breast implants: analysis of clinical studies. Eur J Cancer Prev. May 2012; 21(3):274-280. PMID 22456426
16. McGuire P, Reisman NR, Murphy DK. Risk Factor Analysis for Capsular Contracture, Malposition, and Late Seroma in Subjects Receiving Natrelle 410 Form-Stable Silicone Breast Implants. Plast Reconstr Surg. Jan 2017; 139(1):1-9. PMID 27627058
17. Cordeiro PG, Ghione P, Ni A, et al. Risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in a cohort of 3546 women prospectively followed long term after reconstruction with textured breast implants. J Plast Reconstr Aesthet Surg. May 2020; 73(5):841-846. PMID 32008941
18. Nelson JA, Dabic S, Mehrara BJ, et al. Breast Implant-associated Anaplastic Large Cell Lymphoma Incidence: Determining an Accurate Risk. Ann Surg. Sep 01 2020; 272(3):403-409. PMID 32694446
19. de Boer M, van Leeuwen FE, Hauptmann M, et al. Breast Implants and the Risk of Anaplastic Large-Cell Lymphoma in the Breast. JAMA Oncol. Mar 01 2018; 4(3):335-341. PMID 29302687
20. Campanale A, Boldrini R, Marletta M. 22 Cases of Breast Implant-Associated ALCL: Awareness and Outcome Tracking from the Italian Ministry of Health. Plast Reconstr Surg. Jan 2018; 141(1):11e-19e. PMID 29280858

21. Lock-Wilinson A, Beath KJ, Magnusson MR, et al. Breast Implant-Associated Anaplastic Large Cell Lymphoma in Australia: A Longitudinal Study of Implant and Other Related Risk Factors. Aesthet Surg J. Jul 13 2020; 40(8):838-846. PMID 31738381
22. Doren EL, Miranda RN, Selber JC, et al. U.S. Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma. Plast Reconstr Surg. May 2017; 139(5):1042-1050. PMID 28157769
23. Ebner PJ, Liu A, Gould DJ, et al. Breast implant-associated anaplastic large cell lymphoma, a systematic review and in-depth evaluation of the current understanding. J Surg Oncol. Sep 2019; 120(4):573-577. PMID 31373010
24. Collett DJ, Rakhorst H, Lennox P, et al. Current Risk Estimate of Breast Implant-Associated Anaplastic Large Cell Lymphoma in Textured Breast Implants. Plast Reconstr Surg. Mar 2019; 143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma):30S-40S. PMID 30817554
25. Leberfinger AN, Behar BJ, Williams NC, et al. Breast Implant-Associated Anaplastic Large Cell Lymphoma: A Systematic Review. JAMA Surg. Dec 01 2017; 152(12):1161-1168. PMID 29049466
26. McCarthy CM, Roberts J, Mullen E, et al. Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE): Updated Report 2012-2020. Plast Reconstr Surg. Oct 01 2023; 152(4S):16S-24S. PMID 36995215
27. Medeiros LJ, Marques-Piubelli ML, Sangiorgio VFI, et al. Epstein-Barr-virus-positive large B-cell lymphoma associated with breast implants: an analysis of eight patients suggestions a possible pathogenetic relationship. Mod Pathol. Dec 2021; 34(12):2154-2167. PMID 34226673
28. Evans MG, Miranda RN, Young PA, et al. B-cell lymphomas associated with breast implants: Report of three cases and review of the literature. Ann Diagn Pathol. Jun 2020; 46:151512. PMID 32315816
29. Morgan S, Tremblay-LeMay R, Lipa JE, et al. Breast implant-associated EBV-positive diffuse large B-cell lymphoma: Two case reports and literature review. Pathol Res Pract. Oct 2021; 226:153589. PMID 34455365
30. Niraula S, Katel A, Barua A, et al. A Systematic Review of Breast Implant-Associated Squamous Cell Carcinoma. Cancers (Basel). Sep 12 2023; 15(18). PMID 37760485
31. Santanelli di Pompeo F, Firmani G, Stanzani E, et al. Breast Implants and the Risk of Squamous Cell Carcinoma of the Breast: A Systematic Literature Review and Epidemiologic Study. Aesthet Surg J. Jun 14 2024; 44(7):757-768. PMID 38307034
32. The U.S. Food and Drug Administration. Medical Device Safety. <Available at: https://www.fda.gov> (accessed April 14, 2025).
33. Clemens MW, Myckatyn TM, Di Napoli A, et al. American Association of Plastic Surgeons Consensus on Breast Implant-Associated Anaplastic Large-Cell Lymphoma. Plast Reconstr Surg. Sep 01 2024; 154(3):473-483. PMID 38412359
34. Chelton A, Niell BL, Brown A, et al. ACR Appropriateness Criteria® Breast Implant Evaluation: 2023 Update. J Am Coll Radiol. Nov 2023; 20(11S):S329-S350. PMID 38040459
35. NCCN. National Comprehensive Cancer Network. Breast Cancer. (Version 3.2025). Available at: <https://www.nccn.org> (accessed April 14, 2025).

36. Plastic Surgery Foundation. Patient Registry and Outcomes For Breast Implants and Anaplastic Large Cell Lymphoma (ALCL) Edtiology and Epidemiology (PROFILE). Available at: <https://www.thepsf.org> (accessed April 14, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. Coverage relating to Chronic breast pain related ONLY to recurrent breast infection, contracture from, or rupture of a silicone gel-filled or saline-filled implant-changed from not medically necessary to may be medically necessary. References 1-2, 8, and 13-36 added; others removed. Title changed from Breast Implant, Removal and/or Insertion
05/15/2024	Reviewed. No changes.
05/01/2023	Document updated with literature review. Coverage unchanged. Reference 19 added, others removed.
12/01/2022	Reviewed. No changes.
01/01/2022	Document updated with literature review. The following change was made to Coverage: Statement on post reconstructive implant reinsertion or replacement for documented breast implant-associated anaplastic large-cell lymphoma changed from not medically necessary to conditionally medically necessary. Reference 4, 5, 23 and 27 added, others removed.
10/15/2020	Reviewed. No changes.
02/15/2019	Document updated with literature review. Coverage unchanged. No references added; several removed.
12/01/2017	Document updated with literature review. The following was added to the coverage section, Table 1, clinical condition: Documented breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), associated with components of implant envelope (sleeve or covering) or contents of the implant whether silicone gel-filled or saline-filled implant: 1) For Post Reconstructive Implant Removal – Medically Necessary; 2) For Post Reconstructive Implant Reinsertion or Replacement – Not Medically Necessary; 3) For Post Cosmetic Implant Removal – Medically Necessary; and

	4) For Post Cosmetic Implant Reinsertion or Replacement – Check Member's Contract Prior to Requiring Medical Review.
08/15/2017	Reviewed. No changes.
09/15/2016	Document updated with literature review. The following was added to coverage section: 1) In general, "Breast implant services may be subject to the member's contract benefit coverage and/or exclusions, including complications related to the breast implant itself, whether saline-filled or silicone gel-filled, and/or the related procedure services (removal/insertion/reinsertion)"; 2) Within Table 1 to determine coverage, "compare the patient's presenting clinical condition(s) and the patient's breast implant history below"; and 3) Within Table 1 under post cosmetic implant removal and post cosmetic implant reinsertion or replacement, "Check Member's Contract Prior to Requiring Medical Review" and "Mandate Benefit" if the patient has breast cancer diagnosis only.
10/01/2015	Reviewed. No changes.
04/01/2014	Document updated with literature review. The following additions AND changes were made to the post reconstruction and post cosmetic grid: 1) Documented surgical treatment of breast cancer whether a silicone gel-filled or saline-filled implant(s) – covered as a mandated benefit for post reconstruction and cosmetic exclusion for post cosmetic services; 2) Imaging evidence of extrusion of silicone gel-filled or saline-filled implant(s) – covered as a mandated benefit for post reconstruction and cosmetic exclusion for post cosmetic services; 3) Baker Class I augmented breast feels as soft as a normal breast whether a silicone gel-filled or saline-filled implant – not medically necessary for post reconstruction and cosmetic exclusion for post cosmetic services; 4) Chronic breast pain related ONLY to recurrent breast infection, contracture from, or rupture of a silicone gel-filled or saline-filled implant – not medically necessary for post reconstruction and cosmetic exclusion for post cosmetic services; 5) Patient anxiety or fear of cancer risk, including but not limited to anaplastic large cell lymphoma (ALCL), associated with components of implant envelope (sleeve or covering) or contents of the implant whether silicone gel-filled or saline-filled implant – not medically necessary for post reconstruction and cosmetic exclusion for post cosmetic services; 6) Breast or chest wall pain unrelated to contractures or rupture – not medically necessary for post reconstruction and cosmetic exclusion for post cosmetic services; and, 7) Patient anxiety or fear of potential systemic conditions from silicone gel-filled or saline-filled implant – not medically necessary for post reconstruction and cosmetic exclusion for post cosmetic services. Description and Rationale significantly revised.
12/01/2005	Document updated with literature review.
05/01/1996	Document number changed.
01/01/1996	Document updated with literature review.

07/01/1992	New medical document.