Medical Coverage Policy

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Breast Implant Removal

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health

benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses removal of silicone gel-filled or saline-filled breast implants and subsequent surgical implantation of a new U.S. Food and Drug Administration (FDA)-approved breast implant. For reconstructive breast surgery following mastectomy or lumpectomy, see Medical Coverage Policy 0178 Breast Reconstruction Following Mastectomy or Lumpectomy.

Coverage Policy

Coverage for breast implant removal varies across plans and may be governed by federal and/or state mandates. Please refer to the federal mandate on breast reconstruction and the customer's benefit plan document for coverage details.

Removal of EITHER a saline-filled OR silicone gel-filled breast implant and/or surgical management of the implant capsule (including capsulotomy, capsulorrhaphy, partial or complete capsulectomy) when associated with breast reconstruction following mastectomy or lumpectomy is considered medically necessary for ANY indication, including for the purpose of producing a symmetrical appearance of the nondiseased breast.

The removal of a silicone gel-filled breast implant with or without capsular revision (partial or complete capsulectomy), is considered medically necessary when rupture of the implant and/or extrusion of the implant contents have been confirmed on imaging studies (i.e., mammography, ultrasound, or magnetic resonance imaging [MRI]).

The removal of EITHER a silicone gel-filled OR saline-filled breast implant, with or without capsular revision (partial or complete capsulectomy), is considered medically necessary for at least ONE of the following indications:

- **The implant is interfering with EITHER of the following:**
  - diagnostic evaluation of a suspected breast cancer
  - adequate treatment of known breast cancer (e.g., obstructing radiation therapy)
- **ANY of the following:**
  - acute, persistent or recurrent local or systemic infection secondary to a breast implant when there is failure, contraindication, or intolerance to medical management, including antibiotics
  - current exposure of a breast implant
  - Baker Grade IV capsular contracture
  - tissue necrosis secondary to the implant
  - confirmed diagnosis of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)
  - current use of Allergan BIOCELL textured breast implants and tissue expanders
  - confirmed diagnosis of breast implant-associated squamous cell carcinoma (BIA-SCC)

Removal of an intact silicone gel-filled breast implant when performed solely for suspected autoimmune disease or connective tissue disease, breast implant illness, or breast cancer prevention is considered not medically necessary.

Following removal of a breast implant, the subsequent surgical implantation of a new U.S. Food and Drug Administration (FDA)-approved breast implant is considered medically necessary for EITHER of the following:

- breast reconstruction of a diseased or affected breast following mastectomy or lumpectomy
- creation of a symmetrical appearance in the contralateral/nondiseased breast following mastectomy or lumpectomy in the opposite breast

The following are considered not medically necessary and/or cosmetic unless associated with breast reconstruction following mastectomy or lumpectomy:

- removal of a ruptured saline-filled implant in the absence of one of the indications listed above
- removal of any type of breast implant when performed for ANY of the following:
  - solely to treat psychological symptomatology or psychosocial complaints
  - solely to improve appearance
  - solely because of shifting or migration of the implant
  - removal of the implant in the opposite/contralateral breast, unless criteria are otherwise met for that breast implant
  - for any other indication not otherwise mentioned above as covered
- replacement of an implant following removal
- mastopexy following implant removal

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Implant Removal Associated with Breast Reconstruction Following Mastectomy or Lumpectomy

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
19328†	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
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

†**Note: Considered Not Medically Necessary when removal of an intact silicone gel-filled breast implant is performed solely for suspected autoimmune disease, connective tissue disease or for breast implant illness.**

Implant Removal Associated with Rupture of Gel-Filled Implant

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
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

Implant Removal Associated with Interference with Diagnostic Evaluation or Treatment

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
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

Implant Removal Associated with Infection, Implant Exposure, Contracture, Tissue Necrosis, BIOCELL Implants, or Implant-Associated Anaplastic Large Cell Lymphoma/Squamous Cell Carcinoma

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
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

Breast Implant Replacement

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
19325	Breast augmentation with implant
19342	Insertion or replacement of breast implant on separate day from mastectomy

Considered Not Medically Necessary and/or cosmetic unless associated with breast reconstruction following mastectomy or lumpectomy:

CPT®* Codes	Description
19316	Mastopexy
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19342	Insertion or replacement of breast implant on separate day from mastectomy

General Background

Breast implants vary in shell surface (e.g., smooth versus textured), shape (e.g., round or shaped), profile (i.e., how far it protrudes), volume (i.e., size) and shell thickness. The primary components of most breast implants are a shell, otherwise known as the envelope or lumen, filler (e.g., saline, silicone gel or alternative) and a patch to cover the manufacturing hole.

While most breast implants are single lumen (i.e., shell only), some breast implants are double lumen (i.e., one shell inside the other). Some breast implants are manufactured with a fixed volume or filler; some are filled during surgery; and some allow for adjustments of the filler volume after implantation.

Breast implants are typically inserted under local or general anesthesia in an outpatient setting. If the procedure is done for cosmetic reasons, the incision is most commonly made along the lower edge of the areola, in the axilla or in the inframammary fold. For postmastectomy reconstruction, the surgical incision is used, and the implant is placed either deep in the breast on the pectoral fascia (i.e., submammary) or beneath the pectoralis major.

Surgical complications associated with breast implantation are similar to those encountered with other breast surgeries: infection, bleeding, change in nipple sensation (e.g., hypersensitivity or hyposensitivity), malposition, delayed healing, and anesthetic accidents.

Although breast implants may be inserted for either reconstructive or cosmetic reasons, clinically significant post-implant complications may occur, necessitating removal of the implants. Local complications associated with breast implants include capsular contracture, acute or persistent infection, silicone implant extrusion, tissue necrosis and silicone implant rupture. These conditions, when they become clinically significant, may require removal of the implant. Additionally, the presence of an implant may interfere with the diagnosis or treatment of breast cancer. Infections that may occur in or around an implant include wound infections, as well as infections within a capsular contracture or as a result of a ruptured implant. Toxic shock syndrome is a rare

complication with multiple systemic symptoms but usually does not have inflammation or purulence at the surgical site (Lalani and Zenn, 2022; Kim et al., 2021). Removal of the implant may be necessary when the infection does not respond to antibiotics. Unstable or weakened tissue and/or interruption in wound healing may result in the implant breaking through the skin (exposing it) or extrusion. Necrotic tissue may form around the implant, requiring implant removal. Silicone gel-filled implant rupture may cause the contents to leak into the surrounding tissues.

U.S. Food and Drug Administration (FDA): Saline-Filled Implants and Silicone Gel-filled implants

Saline-filled breast implants and silicone-gel filled implants are considered class III medical devices and are regulated by the FDA via the Premarket Approval (PMA)process. These devices are indicated for breast augmentation in women age 18 or older (22 years old for some silicone gel-filled implants) and for breast reconstruction in women of any age. These devices are also used in revision surgeries, which correct or improve the result of an original breast surgery.

Saline-Filled Implants

Device or Product	Identifier	Manufacturer
Natrelle Saline Breast Implants** (Smooth surfaced implants)	P990074	Allergan™
Puregraft Serene Breast Implant	P120011	Bimini Health Tech
Mentor Saline-Filled and Spectrum® Breast Implants	P990075	Mentor Worldwide, LLC.

*FDA product codes: FWM

** Allergan (formerly Inamed) Natrelle Saline Breast Implants (P990074)

- In July 2019, Allergan voluntarily recalled Natrelle BIOCELL textured breast implants and tissue expanders from the market to protect patients from breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Smooth surfaced implants are not affected by this recall (FDA, 2021).

Silicone Gel-Filled Implants

Device or Product	Identifier	Manufacturer
Natrelle® Silicone Gel-Filled Breast Implants ** (Smooth surfaced implants)	P020056	Allergan™
Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant**	P040046	Allergan™
MemoryGel®Silicone Gel-Filled Breast Implants	P030053	Mentor Worldwide, LLC.
MemoryShape® Silicone Gel-Filled Breast Implant	P060028	Mentor Worldwide, LLC.
Sientra Silicone Gel Breast Implant	P070004	Tiger Aesthetics Medical, LLC

*FDA product codes: FTR

** Allergan Natrelle® Silicone Gel-Filled Breast Implants (P990074 and P020056)

- In July 2019, Allergan voluntarily recalled Natrelle BIOCELL textured breast implants and tissue expanders from the market to protect patients from BIA-ALCL. Smooth surfaced implants are not affected by this recall (FDA, 2021).

** Allergan Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant (P040046)

- In July 2019, Allergan voluntarily recalled Natrelle BIOCELL textured breast implants and tissue expanders from the market to protect patients from BIA-ALCL. Smooth surfaced implants are not affected by this recall (FDA, 2021).

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

The FDA - for silicone and saline breast implantation states breast implant surgery should not be performed in women with an active infection, existing cancer or precancer of a breast that has not been adequately treated, or who are pregnant or nursing.

On September 8, 2022, updated Mar 8, 2023, the FDA issued a safety communication about reports of cancers, including squamous cell carcinoma (SCC) and various lymphomas, in the scar tissue (capsule) that forms around breast implants. The various lymphomas are different than the previously reported Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). The safety communication states that the FDA believes the occurrence of SCC or various lymphomas in the capsule are rare, however the incidence rate and risk factors for are unknown. Reported signs and symptoms included swelling, pain, lumps or skin changes. As outlined in this communication, the FDA does not recommend prophylactic removal of breast implants in asymptomatic patients solely due to concerns regarding the potential risk of developing squamous cell carcinoma (SCC) or various lymphomas.

On October 27, 2021, the FDA issued new labeling requirements for all legally marketed breast implants due to ongoing concerns about the possible risk of systemic illness or anaplastic large cell lymphoma in patients with silicone gel-filled breast implants. Additionally, the sale and distribution of breast implants will be restricted only to health care providers and facilities that provide information to patients using the "Patient Decision Checklist." The manufacturers are required to post the following updated device labeling to their websites:

- "Boxed warning.
- Patient decision checklist, which must be reviewed with the prospective patient by the health care provider to help ensure the patient understands the risks, benefits and other information about the breast implant device. The patient must be given the opportunity to initial and sign the patient decision checklist and it must be signed by the physician implanting the device.
- Updated silicone gel-filled breast implant rupture screening recommendations.
- Device description with a list of specific materials in the device.
- Patient device card."

In June 2011 (updated 2018), the FDA released a report updating the clinical and scientific information for silicone gel-filled breast implants, including preliminary safety data from studies conducted by the manufacturers as a condition of their November 2006 approval. The conclusion in the report states that, "Based on the totality of the evidence, the FDA believes that silicone gel-filled breast implants have a reasonable assurance of safety and effectiveness when used as labeled. Despite frequent local complications and adverse outcomes, the benefits and risks of breast implants are sufficiently well understood for women to make informed decisions about their use. Manufacturers and physicians should continue to provide balanced and up-to-date information to women considering breast implants to help inform their decisions" (FDA, 2018).

Implant Rupture and Deflation

Breast implants are not considered lifetime devices. Trauma is a common cause of rupture. Some implants will spontaneously deflate or rupture immediately after implantation; some will deflate over time, while others may remain intact for 10 or more years following surgery.

Silicone Gel-Filled Implant Rupture
Silicone gel-filled implants may rupture as the result of the age of the implant, the presence of a capsular contracture, or trauma. When silicone gel-filled implants rupture, a patient may experience decreased breast size, nodules, asymmetrical appearance of the breasts, pain, tenderness, swelling, tingling or numbness. Other ruptures may be completely asymptomatic (i.e., silent ruptures). Silicone gel that extrudes beyond the reactive fibrotic capsule (i.e., extracapsular rupture) that forms surrounding the implant may migrate away from the breast. The free, migrated silicone may result in the formation of granulomas in the breast or other areas such as the chest wall or axillae. Some granulomas can migrate to lymph nodes in the axillae and may even mimic cancer. Extruded silicone gel that is contained within the fibrotic capsule is referred to as an intracapsular rupture.

MRI may be used to view the prosthesis in the breast and assist in determining if leakage of the materials has occurred. MRI may be medically necessary to confirm suspected silicone gel-filled breast implant rupture when this diagnosis cannot be confirmed by mammography or breast ultrasound.

In 2001 (reviewed 2018), the FDA completed a study on the health effects of ruptured silicone gel breast implants. The goal of this study was to determine if a correlation exists between loose silicone that migrates into the tissue and the development or progression of collagen vascular disease. A total of 343 women volunteered to participate in this study via a questionnaire concerning joint pain, swelling or stiffness, rash on the breasts and chest, and fatigue. These participants were also questioned about being diagnosed with any illnesses such as scleroderma, fibromyalgia, chronic fatigue syndrome or lupus. All participants underwent MRI to determine if their implants were intact or ruptured with extruded silicone gel. This study concluded that, for women who reported fibromyalgia, MRI did confirm that silicone gel had consistently extruded outside of the fibrous scar.

Saline-Filled Implant Rupture
Saline-filled breast implants may deflate or rupture when saline solution leaks through an unsealed or damaged valve or through a break in the implant shell. Implant deflation may occur in the immediate postoperative period or slowly develop over a period of time. An alteration in the appearance of the breast may result; however, the presence of a ruptured or leaking saline-filled implant does not lead to any medical complications that require intervention, such as removal of the implant. The leakage or rupture of a saline-filled breast implant, in the absence of other signs or symptoms (e.g., significant capsular contracture or persistent infection), is not a medically necessary indication to undergo capsulectomy and breast implant removal.

Periprosthetic Capsular Contracture
When a breast implant is inserted, a scar capsule forms around it as part of the natural healing process. Capsular contracture occurs when the scar tissue or capsule that normally forms around the implant tightens, ultimately squeezing the implant. Significant contracture may result in severe pain or may be associated with subclinical infection. The presence of a contracture may also interfere with the ability to diagnose or treat breast cancer. The degree of periprosthetic contracture is often classified by using the Baker grading system. The four Baker grades are as follows (American Society of Plastic Surgeons [ASPS], 2018):

- **Grade 1:** Grade one capsular contracture is asymptomatic (producing or showing no symptoms). The formation of scar tissue around the implant does not interfere with the size, shape or texture of the breasts. The breasts look natural and remain soft to the touch.
- **Grade 2:** Grade two capsular contracture usually presents itself with only minor cosmetic symptoms. The breasts will usually appear normal in shape but feel somewhat firm to the touch.
- **Grade 3:** Grade three capsular contracture presents itself with obvious cosmetic symptoms. The breasts will be firm to the touch and appear abnormal, e.g., they will be overly round, hard-looking and the nipples may be misshapen. However, this grade of capsular contraction often doesn't cause much (if any) pain.
- **Grade 4:** Like grade three capsular contracture, grade four capsular contracture causes the breasts to become hard and misshapen. Patients with grade four capsular contracture also experience breast soreness; their breasts will often be tender and painful to the touch."

Treatment of clinically significant contractures (i.e., Baker grade IV) can range from removing the capsular tissue (e.g., capsulectomy) to removal of the implant itself. Infections that occur due to the presence of a breast implant rupture and/or capsular contracture are typically treated with antibiotics.

The pathogenesis of fibrous capsular contracture after breast augmentation with implants is still under debate and varies from patient to patient. In a prospective study by Pajkos et al. (2003), biofilm, in particular, S. epidermis biofilm, was found in a significant proportion of patients with capsular contracture. This thin layer of bacteria can develop around the implant(s) after a type of bacteria (e.g. staph bacteria) is introduced to the breast cavity during surgery. Other theories regarding the development of capsular contracture include genetics, hematomas and seromas (ASPS, 2018).

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)
Individuals with breast implants have a risk of developing breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). BIA-ALCL is not breast cancer rather it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system). Symptoms are persistent swelling, presence of a mass or pain in the area of the breast implant. These symptoms can occur years after the implantation. In most cases, BIA-ALCL is found in the fluid surrounding the implant (seroma) or contained within the fibrous scar capsule, but in some cases, it can spread throughout the body. BIA-ALCL is diagnosed by pathology/cytology testing of the seroma fluid or mass, with Wright Giemsa-stained smears and cell block immunohistochemistry/flow cytometry testing for cluster of differentiation (CD30) and Anaplastic Lymphoma Kinase (ALK) markers. Precise risks are difficult to determine due to lack of information about how many patients have received breast implants in the U.S. and worldwide (FDA, 2019).

FDA recommendations state that BIA-ALCL has generally only been identified in patients with symptoms such as pain, lumps, persistent swelling, or breast asymmetry that occur years after implantation. Implant removal in patients without signs or symptoms for prophylactic reasons is not recommended. The FDA recommends reporting all BIA-ALCL cases to MedWatch, the FDA Safety Information and Adverse Event Reporting program and case reports to the PROFILE Registry. The PROFILE Registry was developed in 2012. On July 24, 2019, the FDA requested that Allergan, the manufacturer of a specific type of textured implant, recall specific models of its textured breast implants from the U.S. market due to the risk of BIA-ALCL. The FDA's analysis in 2019 was attributed to a worldwide reported total of 573 unique BIA-ALCL cases including 33 patient deaths. Of the 573 cases of BIA-ALCL, 481 are reported to have Allergan breast implants at the time of diagnosis. (FDA, 2019; FDA, 2019). As of June 30, 2023, there have been 1,264 unique BIA-ALCL cases combined in the United States and globally with 63 deaths (FDA, 2023).

The National Comprehensive Cancer Network® (NCCN) Clinical Guidelines in Oncology™ T Cell Lymphomas addresses BIA-ALCL. The NCCN reports that in recent years the instances of BIA-ALCL has increased. Initial workup for BIA-ALCL includes ultrasound of the breast and axilla or breast MRI in selected cases or PET/CT scan in selected cases. If ultrasound is inconclusive, breast MRI is recommended. Cytology with cell block preparation and flow cytometry immunophenotype are essential to confirm the diagnosis of BIA-ALCL. A biopsy is useful if there is a solid mass associated with the implant. Referral to a plastic surgeon for management of an implant seroma is recommended if the pathologic diagnosis is negative for lymphoma. A second pathology consultation is recommended in a tertiary cancer center if the pathologic diagnosis is indeterminate of lymphoma. Individualized management by a multidisciplinary team is recommended for histologically confirmed BIA-ALCL. The NCCN treatment recommendations for patients with BIA-ALCL include total capsulectomy with removal of the breast implant and excision of any associated mass with a biopsy of suspicious lymph nodes for all patients (NCCN, 2025).

According to the American Society of Plastic Surgeons (ASPS) statement titled "Insurance coverage criteria for third party payers - BIA-ALCL", anaplastic large cell lymphoma (ALCL) is a rare type of cancer of the immune system that is estimated to affect 1 in half a million women. BIA-ALCL is a rare lymphoma and is not a breast cancer. Most women approach their doctor with symptoms such as pain, lumps, swelling, regional lymphadenopathy, or asymmetry in their breasts years after getting implants. BIA-ALCL has been estimated to affect 1 in 1,000 to 1 in 30,000 women with textured breast implants. In patients without symptoms or other abnormalities, the FDA does not recommend screening tests or prophylactic breast implant removal. The ASPS policy follows the NCCN clinical guideline treatment recommendations for BIA-ALCL (ASPS, 2020).

Kim et al. (2011) conducted a systematic literature review to identify and analyze all reported cases of non-Hodgkin's lymphoma occurring in patients with breast implants. The total number of articles included in the analysis was 34 which included 36 cases of ALCL and other non-Hodgkin's lymphomas involving the breast: 29 (81%) were ALCL. Although detailed clinical information was lacking in many cases, ALCL often involved the capsule and/or presented as an unexplained seroma or mass, was negative for anaplastic lymphoma kinase (ALK) expression, and had a relatively indolent clinical course when it developed adjacent to a breast implant. The authors concluded that a form of ALCL, which clinically behaves more like the less aggressive primary cutaneous form of ALK–negative ALCL rather than the more aggressive systemic form, may be associated with breast implants.

Breast Implant-Associated Squamous Cell Carcinoma (BIA-SCC)
Breast implant-associated squamous cell carcinoma (BIA-SCC) is a remarkably rare malignancy which accounts for only 19 reported cases worldwide and three deaths (D'Orsi, et al., 2024). Case reports show that BIA-SCC has been identified in patients with both smooth and textured implants, as well as silicone and saline implants, used for breast augmentation and reconstruction (FDA, 2023). BIA-SCC presents similarly to BIA-ALCL, as a delayed seroma (fluid collection) around the implant and may be accompanied by a mass or capsular contracture. Diagnosis involves aspirating peri-prosthetic fluid and confirming positivity for CK5/6 and p63 markers, with flow cytometry used to detect squamous cells and keratin. The standard treatment is explantation and en-bloc capsulectomy. Reported mortality rates are high (approximately 48% at six months). Chemotherapy and radiation have been employed in treating advanced BIA-SCC; however, their effectiveness remains uncertain due to the absence of established guidelines for managing metastatic disease (D'Orsi, et al., 2024).

Autoimmune Diseases, Connective Tissue Diseases, Breast Implant Illness, Breast Cancer and the Presence of Intact Breast Implants

A constellation of symptoms that include autoimmune disorders such as rheumatoid arthritis or Sjögren's disease, as well as nonspecific disorders such as fatigue, malaise, and fibromyalgia has been referred to as breast implant illness (BII) (Nahabedian, 2023). In the early 1980s, reports suggested an association between silicone breast implants and various connective tissue diseases, but only limited analytic epidemiological data addressing this hypothesis were available at the time. As a consequence, in 1992, the FDA banned the use of silicone breast implants, restricting them to breast cancer reconstructive surgery in a strictly controlled clinical trial. In November 2006, after further scientific review, the FDA lifted their ban on silicone breast implants, approving the use of silicone implants for breast reconstruction for women of any age and for breast augmentation for women age 22 years or older.

A systematic review and meta-analysis by Trabilsy et al. (2025) evaluated 48 studies with a combined sample of 7,045 breast implant patients to determine the prevalence and characteristics of breast implant illness (BII) and related comorbidities. Of these patients, 49% (n=3,444) reported symptoms commonly associated with BII, including arthralgia/myalgia (34%), cognitive dysfunction (21%), and fatigue/malaise (24%). Statistically significant associations were identified between BII symptom reporting and history of malignancy ($R = 0.6425$, $p = 0.018$), explantation rates (0.7, CI: [0.32, 1.09], $p < 0.001$), and symptom improvement or complete resolution after explantation ($R = 0.5670$, $p < 0.001$; $R = 0.8828$, $p < 0.001$ for complete resolution). The review notes several methodological limitations, including heterogeneity in study designs and patient populations, reliance on study-level rather than individual-level data, inconsistent reporting of follow-up and attrition, and the absence of standardized diagnostic criteria for BII. Many studies were small case reports or observational cohorts, which may increase the risk of selection and reporting bias. These factors limit the ability to determine causality or robust risk factors. Additionally, 51% of patients with BII symptoms had alternative diagnoses that explained their complaints. The authors recommend further research, standardized definitions, and improved patient education and follow-up.

The American Academy of Neurology, the American College of Surgeons, the American College of Rheumatology, the American Medical Association, the American Society of Plastic Surgeons and the American Society of Clinical Oncology all agree with the findings of a 2000 study of 13,500 women researched by the National Cancer Institute. This study found no correlation between breast implants and the development of connective or autoimmune disease or an increase in breast cancer risk (Nelson, 2000).

McLaughlin et al. (2007) summarized the epidemiologic evidence regarding the safety of silicone gel-filled breast implants. The topics included in this report included connective tissue disease (CTD), suicide, offspring effects, neurologic disease, implant rupture, and local perioperative complications requiring the need for additional surgery. Based on the review of the published epidemiologic literature on the safety of breast implants, through September 2007, the authors reported that "the weight of the epidemiologic evidence does not support a causal association between breast implants and breast or any other type of cancer, definite or atypical connective tissue disease, adverse offspring effects, or neurologic disease. Women with breast implants do not present with more advanced stages of breast cancer or suffer impaired survival after breast cancer diagnosis. The only study to examine an actual incidence rate of breast implant rupture reported rupture-free survival of 98% at five years and 83%–85% at 10 years for newer "third generation" implants. Future studies are needed to determine whether the consistently observed excess of suicide among women with implants reflects underlying psychiatric illness prior to breast augmentation surgery or other factors."

A review of epidemiological evidence by Lipworth et al. (2004) concluded that the most recent epidemiological investigations have been remarkably consistent with earlier epidemiological studies in finding no evidence of an excess of any individual CTD or all CTDs combined, including

both established and atypical or undefined CTD, among women with cosmetic silicone breast implants.

Implant Shifting
Some implants may shift or move over time while remaining intact. Aside from the potential for an untoward cosmetic appearance, implant shifting does not lead to any medical complications that require intervention, such as removal of the implant. Implant shifting, in the absence of other signs or symptoms such as significant capsular contracture, persistent infection, or rupture of a silicone gel-filled implant, is not a medically necessary indication to remove.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

References

1. American Society of Plastic Surgeons (ASPS). BIA-ALCL Resources. Accessed Nov 20,2025. Available at URL address: https://www.plasticsurgery.org/patient-safety/breast-implant-safety/bia-alcl-summary/frequently-asked-questions

2. American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage for Third Party Payers. Breast Implant Associated Anaplastic Large Cell Lymphoma. Approved Oct 2017; Reapproved Jun 2020. Accessed Nov 20,2025. Available at URL address: https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/Insurance-2017-BIA-ALCL.pdf

3. American Society of Plastic Surgeons (ASPS). What is capsular contracture and how can it be treated? Jun 12, 2018. Accessed Nov 20,2025. Available at URL address: https://www.plasticsurgery.org/news/blog/what-is-capsular-contracture-and-how-can-it-be-treated/

4. D'Orsi G, Giacalone M, Calicchia A, Gagliano E, Vannucchi L, Vanni G, Buonomo OC, Cervelli V, Longo B. BIA-ALCL and BIA-SCC: Updates on Clinical Features and Genetic Mutations for Latest Recommendations. Medicina (Kaunas). 2024 May 10;60(5):793. doi: 10.3390/medicina60050793. PMID: 38792976; PMCID: PMC11122735.

5. Kim M, Ku I, Jin US. Diagnosis and management of toxic shock syndrome after breast reconstructive procedures with silicone implants. Arch Plast Surg. 2021 Mar;48(2):189-193. doi: 10.5999/aps.2020.01144. Epub 2021 Mar 15. PMID: 33765737; PMCID: PMC8007467.

6. Kim B, Roth C, Chung KC, Young VL, van Busum K, Schnyer C, Mattke S. Anaplastic large cell lymphoma and breast implants: a systematic review. Plast Reconstr Surg. 2011 Jun;127(6):2141-50.

7. Lalani T, Zenn M. Breast Implant Infections. In: UpToDate, Hall, KK, Ed. UpToDate, Oct 5, 2022. Waltham, MA. Accessed on Dec 2, 2024.

8. Lipworth L, Tarone RE, McLaughlin JK. Breast implants and fibromyalgia. a review of the epidemiologic evidence. Ann Plast Surg. 2004 March;52(3):284–7.

9. Lipworth L, Tarone RE, McLaughlin JK. Silicone breast implants and connective tissue disease: an updated review of the epidemiologic evidence. 2004 Jun;52(6):598–601.

10. McLaughlin JK, Lipworth L, Murphy DK, Walker PS. The safety of silicone gel-filled breast implants: a review of the epidemiologic evidence. Ann Plast Surg. 2007 Nov;59(5):569-80.

11. Nahabedian M. Complications of reconstructive and aesthetic breast surgery. In: UpToDate, Collins, KA, Ed. UpToDate, Apr 12, 2023. Waltham, MA. Accessed on Dec 2, 2024.

12. Nahabedian M. Implant-based breast reconstruction and augmentation. In: UpToDate, Collins, KA, Ed. UpToDate, Mar 15, 2023. Waltham, MA. Accessed on Dec 2, 2024.

13. National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Guidelines in Oncology™. T Cell Lymphomas. Version 2.2025-May 28,2025. © National Comprehensive Cancer Network, Inc., 2024. All Rights Reserved. Accessed Nov 20, 2025. Available at URL address: https://www.nccn.org/professionals/physician_gls/default.aspx

14. National Cancer Institute. Breast Reconstruction After Mastectomy. Reviewed Jan 13, 2025. Accessed Nov 21, 2025. Available at URL address: http://www.cancer.gov/types/breast/reconstruction-fact-sheet

15. Nelson NJ. Silicone breast implants not linked to breast cancer risk. J Natl Cancer Inst. 2000 Nov 1;92(21):1714-5. doi: 10.1093/jnci/92.21.1714. PMID: 11058613.

16. Pajkos A, Deva AK, Vickery K, Cope C, Chang L, Cossart YE. Detection of subclinical infection in significant breast implant capsules. Plast Reconstr Surg. 2003 Apr 15;111(5):1605–11.

17. Plastic Surgery Foundation. PROFILE (Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology) Registry. 2024. Accessed Dec 2, 2024. Available at URL address: https://www.thepsf.org/research/registries/profile

18. Trabilsy M, Haider SA, Borna S, Gomez-Cabello CA, Genovese A, Prabha S, Forte AJ, Rinker BD, Ho OA, Elegbede AI. Exploring breast implant illness and its comorbid conditions: A systematic review & meta-analysis. J Plast Reconstr Aesthet Surg. 2025 Jun;105:41-54. doi: 10.1016/j.bjps.2025.03.026. Epub 2025 Mar 12. PMID: 40203657.

19. U.S. Food and Drug Administration (FDA). Breast Implants. Page last updated: Dec 15, 2023. Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants

20. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Mentor Corporation Saline-filled and Spectrum® Breast Implants (P990075). Issued May 10, 2000. Accessed Nov 21, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

21. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Puregraft Serene Breast Implant formerly Ideal Implant® Saline-filled Breast Implant (P120011). Issued Nov 14, 2014. Accessed Nov 21, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

22. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled Breast Implant. (P040046). Issued Feb 20, 2013. Accessed Nov 21, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

23. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. MemoryShape Breast Implants (P060028). Issued Jun 14, 2013. Accessed Nov 21, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

24. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Mentor MemoryGel™ Silicone Gel-filled Breast Implants (P030053). Issued Nov 17, 2006. Accessed Nov 21, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

25. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Allergan Natrelle saline-filled breast implants (P020056). Issued Nov 17, 2006. Accessed Nov 21, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

26. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Allergan Natrelle Silicone-Filled Breast Implants (P990074). Issued May 10, 2000. Accessed Nov 21, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

27. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Sientra Silicone Gel-Filled Breast Implants (P070004). Issued Mar 9, 2012. Accessed Nov 21, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

28. U.S. Food and Drug Administration (FDA). FDA news release: FDA takes action to protect patients from risk of certain textured breast implants; requests Allergan voluntarily recall certain breast implants and tissue expanders from market. Content current as of July 24, 2019. Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan

29. U.S. Food and Drug Administration (FDA). Labeling for approved breast implants. Content current as of: Feb 6, 2025. Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/medical-devices/breast-implants/labeling-approved-breast-implants

30. U.S. Food and Drug Administration (FDA). Medical device reports of breast implant-associated anaplastic large cell lymphoma. Content current as of: Feb 6, 2025. Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma

31. U.S. Food and Drug Administration (FDA). Questions and answers about breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Page last updated Oct 23, 2019.

Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl

32. U.S. Food and Drug Administration (FDA). Reports of anaplastic large cell lymphoma (ALCL) in women with breast implants: FDA safety communication. Date issued Jan 26, 2011. Page last updated Jan 15, 2016. Accessed Nov 21, 2025. Available at URL address: http://wayback.archive-it.org/7993/20170111070030/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm240000.htm

33. U.S. Food and Drug Administration (FDA). Risks and complications of breast implants. Content current as of Dec 15, 2023. Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants

34. U.S. Food and Drug Administration (FDA). Saline, Silicone Gel, and Alternative Breast Implants. Guidance for Industry and FDA Staff. Content current as of: Sept 28, 2020. Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/saline-silicone-gel-and-alternative-breast-implants

35. U.S. Food and Drug Administration (FDA). Safety Communication. Breast implants: Reports of squamous cell carcinoma and various lymphomas in capsule around implants: FDA Safety Communication. Sep 8, 2022, updated Mar 8, 2023. Accessed on Nov 21, 2025. Available at URL address: https://www.fda.gov/medical-devices/safety-communications/update-reports-squamous-cell-carcinoma-scc-capsule-around-breast-implants-fda-safety-communication

36. U.S. Food and Drug Administration (FDA). Study of silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. May 29, 2001. Content current as of: Jan 18, 2018. Accessed Nov 21, 2025. Available at URL address: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064382.htm

37. U.S. Food and Drug Administration (FDA). Types of breast implants. Page last updated: Oct 23, 2019. Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/medical-devices/breast-implants/types-breast-implants

38. U.S. Food and Drug Administration (FDA). Update on the safety of silicone gel-filled breast implants (2011) - Executive Summary. Content current as of: Jul 16, 2018. Accessed Nov 21, 2025. Available at URL address: https://www.fda.gov/medical-devices/breast-implants/update-safety-silicone-gel-filled-breast-implants-2011-executive-summary

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Revised policy statement for: ○ Removal of either a saline-filled or silicone gel-filled breast implant when associated with breast reconstruction ○ Removal of a silicone gel-filled breast implant when there is a confirmed	4/15/2026

	rupture of the implant and/or extrusion of implant contents on imaging studies ○ The removal of either a silicone gel-filled or saline-filled implant ○ Removal of an intact silicone-gel filled breast implant ○ Not medically necessary and /or cosmetic indications	
Annual review	• Revised policy statement for removal of implant, clarified an indication	1/15/2025
Annual review	• No changes to policy statement	1/15/2024