



Medical Coverage Policy

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Breast Implant Removal

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Related Coverage Resources

- [Breast Imaging Guidelines](#)
- [Breast Reconstruction Following Mastectomy or Lumpectomy](#)
- [Screening Mammography](#)

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. 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 implant breast implants and subsequent surgical implantation of a new U.S. Food and Drug Administration (FDA)-approved breast implant.

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 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 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 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:**
 - persistent or recurrent local or systemic infection secondary to a breast implant refractory to medical management, including antibiotics
 - Baker Stage IV capsular contracture resulting in EITHER of the following:
 - pain
 - interference with standard breast cancer screening
 - tissue necrosis secondary to the implant
 - diagnosed breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)
 - current use of Allergan BIOCELL textured breast implants and tissue expanders

Removal of an intact silicone gel-filled breast implant when performed solely for suspected autoimmune disease or connective tissue disease or breast cancer prevention is considered experimental, investigational or unproven.

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
- capsulectomy when associated with removal of a saline-filled implant

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

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 implantable breast prostheses 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 implanted breast prostheses include: capsular contracture, 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. 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 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)

In the FDA labeling for approved breast implants Mentor™ Corp., Santa Barbara, CA; Allergan™ Corp. (formerly Inamed™), Irvine, CA; Ideal Implant®, Inc., Dallas, TX; and Sientra™, Inc., Santa Barbara, CA are listed as manufacturers of silicone and saline breast implants (FDA, 2019c).

FDA-approved saline-filled implants:

- Inamed (now Allergan) Saline Breast Implants
 - 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.
- Ideal Implant Saline-Filled Breast Implant
- Mentor Saline-Filled and Spectrum® Breast Implants

The FDA approved saline-filled breast implants for breast augmentation in women age 18 or older and for breast reconstruction in women of any age. They are also used in revision surgeries, which correct or improve the result of an original surgery.

FDA-approved silicone gel-filled breast implants:

- Allergan Natrelle® Silicone Gel-Filled Breast Implants
 - 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.
- Allergan Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant
 - 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.
- Mentor MemoryGel® Silicone Gel-Filled Breast Implants
- Mentor MemoryShape® Silicone Gel-Filled Breast Implant
- Sientra Silicone Gel Breast Implant

The FDA labeling 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.

In June 2011 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 classes/stages are as follows:

- **Grade I:** breast absolutely natural; augmentation not apparent on observation
- **Grade II:** minimum contracture; augmentation apparent on observation, but the patient has no complaints
- **Grade III:** moderate contracture; patient feels some firmness
- **Grade IV:** severe contracture; obvious on observation

Treatment of clinically significant contractures (i.e., Baker grade/stage 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. 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.

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, 2019e).

FDA recommendations state that BIA-ALCL has generally only been identified in patients with symptoms such as pain, lumps, 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 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 was attributed to a new 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, 2019b; FDA, 2019e).

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 or breast MRI in selected cases or PET/CT scan in selected cases. If ultrasound is inconclusive breast MRI is recommended. Cytologic evaluation and biopsy are essential to confirm the diagnosis of BIA-ALCL. 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, 2019).

According to the American Society of Plastic Surgeons (ASPS) statement titled insurance coverage criteria for third party payers breast implant associated anaplastic large cell lymphoma (BIA-ALCL), 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, 2019).

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.

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

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.

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.

Hennekens et al. (1996) conducted a large retrospective study on the past experiences of women with breast implants. Almost 400,000 women, nearly 11,000 with breast implants, completed the patient questionnaire. The study showed that, over 10 years, women with breast implants were 24% more likely to report a connective tissue disease (CTD) or other disorder. When these calculations include all participants, women with and without breast implants, the risk was not statistically significant.

McLaughlin et al. (2007) summarized the epidemiologic evidence regarding the safety of silicone gel-filled breast implants. The topics included in this report included 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.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): No NCDs found.
- Local Coverage Determinations (LCDs): Multiple LCDs found. Refer to the LCD table of contents link in the reference section.

Use Outside of the US

No relevant information was found regarding breast implant removal. Poly Implant Prosthèse (PIP) breast implants are a brand of silicone gel filled breast implants that were available in the UK until March 2010.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 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 or Lumpectomy

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

CPT®* Codes	Description
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19371	Periprosthetic capsulectomy, breast

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 mammary implant material
19371	Periprosthetic capsulectomy, breast

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 mammary implant
19330	Removal of mammary implant material
19371	Periprosthetic capsulectomy, breast

Infection, Contracture, Tissue Necrosis

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

CPT®* Codes	Description
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19371	Periprosthetic capsulectomy, breast

*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.

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