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| Policy Effective Date | 05/15/2024 |

# Breast Implant, Removal and/or Insertion

| Table of Contents |
|---|
| Coverage |
| Policy Guidelines |
| Description |
| Rationale |
| Coding |
| References |
| Policy History |

| 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 HCSC 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.

## 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 patient's presenting clinical condition(s) and the patient's breast implant history** below:

| **Clinical Conditions** | **Post Reconstructive Implant Removal (see NOTE 1)** | **Post Reconstructive Implant Reinsertion or Replacement (see NOTE 1)** | **Post Cosmetic Implant Removal (see NOTE 2)** | **Post Cosmetic Implant Reinsertion or Replacement (see NOTE 2)** |
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| 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 | **Medically Necessary** | **Medically Necessary** | **Medically Necessary** | **Check Member's Contract Prior to Requiring Medical Review** |

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| silicone gel-filled **or** saline-filled implant | | | | |
| 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 | **Not Medically Necessary** | **Not Medically Necessary** | **Check Member's Contract Prior to Requiring** | **Check Member's Contract Prior to Requiring** |

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| silicone gel-filled **or** saline-filled implant | | | **Medical Review** | **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** |
| Patient 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** |
| Patient 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 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** |
| Patient anxiety or fear of potential systemic conditions from silicone gel-filled **or** saline-filled implant, such as:<br>• Connective tissue disease, OR<br>• Autoimmune disease, OR<br>• Rheumatic conditions, OR<br>• Neurologic symptoms, OR<br>• Fibromyalgia, OR<br>• 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 and Contralateral Mammaplasty 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 Surgery 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.

**Refer to Medical Policy** – Gender Assignment Surgery and Gender Reassignment Surgery with Related Services (SUR717.001) for explanation of coverage for services related to the treatment of gender dysphoria.

## Policy Guidelines

None.

## Description

Breast implants are not lifetime devices. The longer a woman has implants, the more likely it is she will need to have surgery to remove or replace them. (1) Local complications of breast implants are frequent and may require removal of the implant.

**Background**

Breast implant, removal and/or insertion, is a surgical removal or replacement of either a silicone gel-filled or a saline-filled breast implant with a new implant. 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. Breast implants are also used to augment breast size for cosmesis. The U.S. Food and Drug Administration (FDA) updates and summaries estimate 5 to 10 million women worldwide have breast implants. (2)

The FDA has released several documents for patients and healthcare providers discussing known complications of breast implants. (1-3) According to the FDA, the following is a listing of local complications and adverse outcomes that occur in 1% or more of patients at any time after breast implant surgery done for reconstructive purposes or cosmesis:

- Asymmetry or breasts are uneven in appearance in terms of size, shape, or breast level,
- Breast feeding difficulties,
- Breast pain, sagging or ptosis, or tissue atrophy,
- Calcification or calcium build-up in breast tissue,
- Capsular contracture, hardening of the breast area around the implant (see Baker Classification below),
- Chest wall and underlying rib cage deformity,
- Deflation or leakage of breast implant,
- Delayed wound healing,
- Extrusion of implant appears through the skin, which breaks down,
- Hematoma,
- Iatrogenic injury or damage to the tissue as a result of implant surgery,
- Implant displacement, malposition, palpability, visibility, wrinkling, or rippling,
- Infection, including toxic shock syndrome,
- Inflammation or irritation,
- Necrosis,
- Nipple changes, including sensation changes,
- Redness or bruising,
- Rupture of implant,
- Scarring,
- Seroma, collection of fluid around the implant,
- Skin rash,
- Swollen or enlarged lymph nodes,
- Unsatisfactory appearance due to implant style or size, and/or
- Visibility of implant seen through the skin.

Capsular contracture, the most common local complication of breast implants, is hardening of breast tissue around the implant that can result in tightness and pain. Contractures have been graded according to the Baker Classification as follows:
Grade I: Augmented breast feels soft as a normal breast and looks natural.
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.

The FDA first identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL) in 2011. At that time, the FDA knew of so few cases of this disease that it was not possible to determine what factors increased the risk. In 2016, the World Health Organization External Link Disclaimer designated breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a T-cell lymphoma that can develop following breast implants and noted that the exact number of cases remained difficult to determine due to significant limitations in world-wide reporting and lack of global breast implant sales data. (4) ALCL is a rare type of non-Hodgkin's lymphoma or cancer involving the cells of the immune system. In women with breast implants, ALCL is found in the scar tissue and the fluid next to the implant itself, but it can spread throughout the body. Although ALCL is extremely rare, according to the FDA, the agency believes that patients with implants may have a very small but increased risk of developing this disease in the scar tissue adjacent to the implant. As of April 1, 2022, the FDA has received 1130 reports of BIA-ALCL. Fifty-nine deaths have been reported with the median age of 53. (5)

**Regulatory Status**

Several breast implants have received approval for use as part of breast reconstructive procedures or cosmesis from the FDA (6). As of August 2022, the following medical devices have been approved for augmentation or reconstruction patients (See <https://fda.gov> for the most recent updated list of implants):

- 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);
  - Allergan Natrelle® Silicone Gel-Filled Breast Implants (FDA-approved in 2009 and again in 2013 for the Natrelle 410® Highly Cohesive Anatomically Shaped Silicone-Gel Filled Breast Implant);
  - Sientra® Silicone Gel Breast Implants (FDA-approved in 2012); and
  - Allergan Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants (FDA-approved in 2013).
- Saline-filled breast implants:
  - Allergan (formerly Inamed) Natrelle® Saline Breast Implants (FDA-approved in 2004 and again in 2005);
  - Ideal Implant® Saline-Filled Breast Implant (FDA-approved in 2014); and
  - Mentor® Saline Breast Implants (FDA-approved in 2009).

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

## Rationale

This policy was created in 1992 and updated periodically with literature review. The following is a summary of the key literature from the PubMed database and the U.S. Food and Drug Administration (FDA) web site through February 28, 2023.

**Breast Implant Complications**

Complications of breast implants are common and may require removal. (7) Determining medical necessity of removal requires documentation of the type of implant and its original indication for initial insertion or placement, such as whether cosmetic or reconstructive. Since the purpose of reconstructive implants is the restoration of normal breast appearance following treatment of cancer, there are small subsets of patients requiring restoration of normal breast appearance following treatment of accident or trauma. This small subset may experience complications of breast implants and may require removal. However, removal of cosmetic implants, whether clinical conditions appear or not, are not a covered benefit as their initial placement was a cosmetic augmentation procedure which was not a covered benefit. Patients who have originally undergone implantation of a cosmetic breast implant are not candidates for additional re-insertion of another breast implant or any form of reconstructive breast surgery after the implant has been removed.

Post-implant insertion complications can be subdivided into local or systemic complications. Local complications include implant contracture, rupture, extrusion, and/or infection. Extrusion or infection is considered a medical indication for possible removal. Documented rupture of a silicone gel-filled implant is considered medical indication for removal in cases where the implant was originally done as a reconstructive treatment. However, saline-filled implant rupture is not considered an absolute medical indication for removal, except in cases where the original indication for implant insertion was done as a reconstructive treatment. Since normal saline is physiologic, rupture and extrusion does not pose a health risk; thus, removal of saline-filled implants are not medically necessary for patients with cosmetic 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. (8-10) 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 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. Documentation of rupture is considered an absolute requirement for possible removal in all cases, whether the implant was originally cosmetic or reconstructive.

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 explained earlier in the Description portion of this policy. (11) Contractures are ranked from Grade I (a normal breast with implant) to Grade IV (a breast with implant that is hard, cold, painful,

tender, and distorted). Grade IV contractures interfere with adequate mammography screening and are the cause of local symptoms, and thus their presence constitutes a health risk. Therefore, removal may be considered medically necessary when the implant was originally inserted for reconstructive purposes. Grade III contractures, which describe firm, palpable implants, do not interfere with mammography; therefore, removal of these implants is not considered an absolute indication for removal. However, since Grade III contractures have an impact on the normal appearance of the breast, removal 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, has been controversial in the past. It had been hypothesized that leakage of silicone, due to either an implant rupture or to "bleeding of silicone through an intact capsule, may incite an autoimmune response with the development of systemic symptoms. However, to date, large epidemiologic studies have not demonstrated that women with breast implants are overrepresented among all those with connective tissue disease. (12-15) In addition, there are inadequate empiric studies to demonstrate that removal of breast implants is associated with resolution of systemic symptoms. Because 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, cosmetically placed implants removed an adjunct to surgical treatment for breast cancer is not a covered benefit, as the initial placement was not a covered benefit. However, implant removal is not necessary in patients who are undergoing chemotherapy or radiation therapy for breast cancer.

An ECRI Health Technology Assessment on the cancer risk and silicone gel-filled implants was completed in 2012. (16) After the FDA mandated all silicone gel-filled devices be removed from the market in 1992, but still allowed for use for patients undergoing reconstruction post mastectomy; the FDA required a more robust study of safety and effectiveness of breast implants for the premarket approval process. Studies reviewed described a link between cancer, rheumatologic/neurologic disorders, and autoimmune diseases. In 2012, ECRI completed another literature review focusing on non-cancerous risks and adverse outcomes associated with using silicone gel-filled breast implants. (17) The most common adverse outcomes were capsular contracture, implant rupture, asymmetry of breast appearance, scarring, pain, and/or infection. According to ECRI and the FDA, there is no evidence linking silicone gel-filled breast implants can cause reproductive health conditions or connective tissue diseases, such as rheumatoid arthritis.

<u>Breast Implant Associated – Anaplastic Large-Cell Lymphoma (BIA-ALCL)</u>
In August 2020, the FDA released an update on adverse events reported to the Agency related to breast implants, including breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), and systemic signs and symptoms referred to by patients as breast implant illness (BII),

which some patients report after receiving breast implants. (19) A total of 733 unique cases and 36 patient deaths globally, which reflect an increase of 160 new cases and 3 deaths since the early-July 2019 update have been reported. In most patients, BIA-ALCL is treated successfully with surgery to remove the implant and the scar tissue surrounding the implant; however, some patients may require treatment with chemotherapy and/or radiation therapy. While there is limited use of the term “breast implant illness” in medical literature, symptoms such as fatigue, memory loss, rash, "brain fog," and joint pain may be associated with breast implants, and some patients and clinicians may use the term "breast implant illness" to describe these symptoms or use these terms when reporting them to the FDA. While the FDA does not have definitive evidence demonstrating breast implants cause these symptoms, the current evidence supports that some patients experience systemic symptoms that may resolve when their breast implants are removed.

Breast implant explantation/removal or treatment with chemotherapy and/or radiation therapy should be made on an individual basis, according to the extent of the disease involvement. The most recent National Comprehensive Cancer Network (NCCN) guidelines on T-cell lymphoma (V1.2023) stated, “Total capsulectomy with removal of the breast implant and excision of any associated mass with biopsy of suspicious lymph nodes is recommended for all patients.” (18) This position was based on a study of 87 patients with BIA-ALCL published in 2016 from Clemens et al. (20) The reviewers concluded that patients with lymphoma confined by the fibrous capsule surrounding the implant had better event-free survival (EFS) and overall survival (OS) than did patients with lymphoma that had spread beyond the capsule. Additionally, patients who underwent a complete surgical excision that consisted of total capsulectomy with breast implant removal had better EFS (p=0.014) and OS (p=0.022) than did patients who received partial capsulectomy, systemic chemotherapy, or radiation therapy.

Practice Guidelines and Position Statements: Breast Implant Complications

*National Comprehensive Cancer Network (NCCN)*

Current guidelines (V1.2023) for T-cell lymphomas recommend patients diagnosed with BIA-ALCL received individualized management by a multidisciplinary team including a medical oncologist, surgical oncologist, plastic surgeon and a hematopathologist. In accordance with the FDA recommendation, all cases of histologically confirmed BIA-ALCL should be reported to the BIA-ALCL PROFILE Registry (18).

**Breast Implant Replacement**

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.

Breast Implant Reimplantation/Replacement/Reinsertion Following Explantation/Removal Resulting from BIA-ALCL

The literature is scant regarding breast implant reimplantation following treatment of BIA-ALCL. One retrospective study was published in 2015 by Santaneilli di Pompeo et al., reporting on 4 cases of patients diagnosed with BIA-ALCL. (21) The reviewers concluded that until definitive

data emerges the exact etiopathogenesis of BIA-ALCL, only autologous reconstruction is recommended should the patient desire to restore the normal appearance of her breast. In 2015, Kim et al., released a Structured Expert Consultation Process regarding updates related to BIA-ALCL. (22) Their systematic review included 65 evaluable statements from various national organizations and professional guidelines. The panelists agreed that if reimplantation of an implant is chosen, there was uncertainty if a smooth surface implant should be selected.

In 2019, Lamaris et al. (23) reported on a case series of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) reconstruction with proposals for timing and technique selection. The standard of care treatment of BIA-ALCL involves surgical resection with implant removal and complete capsulectomy. All BIA-ALCL patients at 2 tertiary care centers and 1 private plastic surgery practice from 1998 to 2017 were retrospectively reviewed and prospectively enrolled. Demographics, treatment, reconstruction, pathology staging, patient satisfaction, and oncologic outcomes were reviewed. There were 66 consecutive BIA-ALCL patients and 18 (27%) received reconstruction. Seven patients (39%) received immediate reconstruction, and 11 (61%) received delayed reconstruction. Disease stage at presentation was IA (T1N0M0 disease confined to effusion or a layer on luminal side of capsule with no lymph node involvement and no distant spread) in 56%, IB in 17%, IC (T3N0M0 cell aggregates or sheets infiltrating the capsule, no lymph node involvement and no distant spread) in 6%, IIA (T4N0M0 lymphoma infiltrating beyond the capsule, no lymph node involvement and no distant spread) in 11%, and III in 11%. Types of reconstruction included smooth implants (72%), immediate mastopexy (11%), autologous flaps (11%), and fat grafting (6%). Outcomes included no surgical complications, but 1 patient progressed to widespread bone metastasis (6%); ultimately, all patients achieved complete remission. Ninety-four percent were satisfied/highly satisfied with reconstructions, whereas 6% were highly unsatisfied with immediate smooth implants. Researchers concluded that breast reconstruction following BIA-ALCL management can be performed with acceptable complications if complete surgical ablation is possible. Immediate reconstruction is reserved for disease confined to capsule on preoperative positive emission tomography/computed tomography scan. Genetic predisposition and bilateral cases suggest that BIA-ALCL patients should not receive textured implants. Autologous options are preferable for implant adverse BIA-ALCL patients. Patients with extensive disease at presentation should be considered for 6- to 12-month delayed reconstruction with interval positive emission tomography/computed tomography evaluation.

<u>Practice Guidelines and Position Statements: Breast Implant Replacement</u>

*American Society for Aesthetic Plastic Surgeons, Inc., et al.*

In 2017 (updated 2018), the American Society for Aesthetic Plastic Surgeons, Inc. (ASAPS), American Society of Plastic Surgeons (ASPS), and International Society of Aesthetics Plastic Surgery (ISAPS) released a “Best Practices Breast Implant Associated ALCL”. (24) They did not include breast implant replacement following treatment of BIA-ALCL. The ASAPS did release a frequently asked questions on BIA-ALCL in 2022. (25) They stated, “If you choose to have your breast implant(s) removed out of concern for BIA-ALCL, you should have a discussion with your surgeon about implant removal, implant exchange, and partial or total scar capsule

removal…Having a total capsulectomy at the time of implant removal is not known to change the risk of developing BIA-ALCL."

*Breast Surgeons of Australia*
The Breast Surgeons of Australia agreed with the ASAPS conclusion by stating, "Current treatment protocols indicated that the removal of both breast implants with the capsule around them is required because of the small number of cases that have been diagnosed on both sides at the same time. Implants are not replaced at the same operation. Smooth implants have been reinserted 12 months following the adequate treatment of BIA-ALCL without disease progression however the safety of this strategy is still being investigated." (26)

*National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology*
In 2023, the NCCN published updated guidelines to include recommendations for breast implant replacement post removal for breast implant associated anaplastic large cell lymphoma (BIA-ALCL). (18) BIA-ALCL is an uncommon and emerging peripheral T-cell lymphoma (PTCL) most frequently arising around a textured surface breast implant or in a patient with a history of a textured surface device.

Current guidelines state:
- A multidisciplinary team approach involving lymphoma oncology, surgical oncology, hematopathology, and plastic surgery is often optimal for the management of patients with BIA-ALCL, particularly those with advanced disease.
- Total capsulectomy and excision of associated mass with biopsy of suspicious node(s), explantation. Removal of contralateral implant may be considered.
- May consider immediate or delayed breast reconstruction with autologous tissue or smooth surface breast implants.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in February 2023 did not identify any ongoing or unpublished trials that would likely influence this policy.

**Summary of Evidence**
Breast implant removal and/or insertion is divided into two main classes: post reconstructive and post cosmetic. Determining medical necessity requires documentation of the type of implant and its original indication for initial insertion or placement.

<u>Breast Implant Removal</u>
The purpose of reconstructive implants is the restoration of normal breast appearance following treatment of cancer, accident, or trauma. Alternatively, cosmetic implants are generally performed to improve physical appearance. Complications of breast implants are common and often necessitate removal. The removal of reconstructive implants due to complications is considered to be a covered benefit when there is evidence of infection, rupture, extrusion, or significant contracture. However, removal of cosmetic implants, whether clinical conditions appear or not, are generally not a covered benefit as their initial placement

was not a covered benefit. The exception is the removal of implants (whether reconstructive or cosmetic) for confirmed breast cancer or breast implant associated-anaplastic large-cell lymphoma (BIA-ALCL), a rare form of T-cell lymphoma that occurs in some people who have had breast implants.

Breast Implant Reinsertion/Replacement

Patients who have undergone a reconstructive implantation and a subsequent covered implant removal are candidates for breast implant reinsertion/replacement. Patients who have undergone cosmetic implantation and subsequent removal are not generally candidates for additional reinsertion/replacement of another breast implant after the implant has been removed.

## 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.

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

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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## 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 <http://www.cms.hhs.gov>.

## Policy History/Revision

| Date | Description of Change |
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| 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. |

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| 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 |

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| | – 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. |