Molina Clinical Policy
Breast Implant Removal Policy No. 315

Last Approval: 04/09/2025
Next Review Due By: April 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Breast implant removal is a surgical procedure that involves the extraction of the implant device. In some cases, it also includes the removal of the surrounding capsule tissue that has formed around the implant. Various complications may necessitate implant removal, including capsular contracture, implant rupture, extrusion (where the implant becomes visible through the skin or surgical site), and infection. Capsular contracture is classified using the Baker scale, ranging from Grade I (a normal implant) to Grade IV (a firm, painful, tender, and distorted implant). While some bacterial infections associated with breast implants can be managed with medical therapy alone, surgical removal is often required for effective treatment, particularly in cases involving mycobacterial or fungal infections (Lalani & Zenn 2022; Nahabedian 2023; Clemens et al. 2024).

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare but serious complication linked to textured breast implants. According to the American Society of Plastic Surgeons (ASPS n.d.), this form of lymphoma has only been observed in individuals with a history of textured breast implants. When detected early, BIA-ALCL is highly treatable in most patients. It is not a type of breast cancer but is classified as a T-cell lymphoma by the National Comprehensive Cancer Network (NCCN) (Horowitz et al. 2024). BIA-ALCL typically develops years after implant placement, with an average onset of 9.75 years (ranging from 0.8 to 27 years). It often presents as delayed breast swelling, which may result from fluid accumulation around the implant, or as noticeable breast asymmetry. In some cases, it can also present as a lump in the breast or armpit. Patients frequently present with a seroma, while others may have a distinct mass near the implant because the condition in not always immediately suspected it is often only identified during implant removal surgery (Clemons (2024). The primary treatment for BIA-ALCL is surgical excision, which involves the complete removal of the implant and surrounding capsule (total capsulectomy). This approach is intended to improve overall survival (OS) and event-free survival (EFS) in affected patients.

Regulatory Status

Squamous Cell Carcinoma (SCC)

On March 8, 2023, the FDA issued a safety communication on squamous cell carcinoma in the capsule around breast implants. The FDA reports 19 cases of SCC post breast implant. They report that while SCC in the capsule around the breast implant is rare, the cause, incidence and risk factors remain unknown. Providers are and patients with breast implants are encouraged to report cases of SCC, lymphomas, or any other cancers around the implant to the FDA. The FDA continues to collect and evaluate data on cancers in the capsule around the breast implant.

BIA-ALCL

In 2011, the FDA (2019) identified a possible link between breast implants and the development of BIA-ALCL – a type of non-Hodgkin's lymphoma (it is not breast cancer). While BIA-ALCL is typically found in the scar tissue and fluid near an implant, it can spread throughout the body. Treatment includes surgery to remove the implant and scar tissue and is successful in most cases; some patients may require chemotherapy and radiation therapy. The World Health Organization designated BIA-ALCL as a T-cell lymphoma in 2016, specifying that it can develop from breast implants. The FDA (2020) announced that is qualifying the BREAST-Q Reconstruction Module as a medical device development tool to assist in the evaluation of medical devices including breast implants. Use of the tool will assess outcomes of breast reconstruction surgery, including quality of life and satisfaction.

COVERAGE POLICY

Please check individual State health plan regulations and benefit contracts before applying this MCP. Coverage of breast implant removal is applicable to individual State and Federal Health Plan Medicaid regulations and benefit contracts that define cosmetic procedures that supersedes this policy.

1. Breast implant removal (silicone or saline) may be **considered medically necessary** due to implant-related complications when AT LEAST ONE of the following criteria is met:
    a. Capsular contracture classified as Grade III or IV on the Baker Classification scale
    b. Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)
    c. Breast Implant Associated Squamous Cell Carcinoma (BIA-SCC)
    d. Implant extrusion
    e. Interference with breast cancer screening
    f. Interference with breast cancer treatment including obstruction of adequate mastectomy performance, radiation therapy, or other breast cancer treatments
    g. Infection (local or systemic) secondary to the implant and is refractory to medical management including antibiotics
    h. Ruptured silicone implant (intracapsular or extracapsular), confirmed by AT LEAST ONE of the following:
        i. Diagnosed by imaging (mammography, ultrasound, or MRI)
        ii. Suspected rupture based on physical examination, with AT LEAST ONE of the following:
            i. Localized pain or palpable mass
            ii. Breast contour irregularity
            iii. Noticeable change in breast size
    i. Ruptured saline implant accompanied by complications listed OR ruptured saline implant originally placed for reconstructive purposes
    j. **FDA-identified Implant Recall:** Presence of an implant recalled by the FDA (e.g., Allergan BIOCELL textured implants and tissue expanders, McGhan Biodimensional) and accompanying symptoms with required documentation
    k. **Cosmetic Implants:** For implants originally placed for cosmetic purposes, removal of a unilateral implant that meets the criteria above does not automatically justify removal of the contralateral implant. The contralateral implant must independently meet the medical necessity criteria above.

2. Members with breast implant(s) placed for the purposes of reconstruction (e.g., following a medically necessary mastectomy or medically necessary gender affirmation surgery), removal may be **considered medically necessary** for either of the following indications:
    a. Ruptured saline implant affecting the cosmetic outcome of the reconstructive implant (including subsequent re-insertion of new implant, if desired by the Member)
    b. Removal of an implant to provide symmetry following medically necessary removal of the contralateral implant, if desired by the Member

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The majority of the evidence that reviews the history and long-term outcomes of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), including the impact of implant removal as a treatment strategy, are retrospective uncontrolled studies and retrospective case reviews. A significant portion of reported cases involves individuals with textured implants. Current literature supports breast implant removal in symptomatic patients with BIA-ALCL, demonstrating improvements in overall survival (OS) and event-free survival (EFS). Evidence also supports the removal for complications such as contracture, rupture, extrusion, and infection. However, there is no evidence to

support a connection between breast implants and connective tissue disorders, autoimmune diseases, or breast cancer.

Systematic Reviews and Meta-Analyses
Leberfinger et al. (2017) conducted a systematic review assessing BIA-ALCL development, risk factors, diagnosis, and treatment. The review included 95 cases, with most linked to textured implants. The development of disease is due to chronic inflammation caused by indolent infections, leading to malignant transformation of anaplastic lymphoma kinase (ALK)-negative, CD30-poisitive T-cells. The average time to presentation was approximately 10 years post-implantation, with 66% of patients exhibiting late-onset seromas and 8% presenting with a new breast mass. Diagnosis may be confirmed through ultrasound-guided fluid aspiration. Standard treatment involves implant removal with total capsulectomy, while chemotherapy, radiotherapy, or lymph node dissection may be necessary for advanced disease. The review highlighted that although BIA-ALCL is rare, its incidence is increasing.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Naga et al. (2022) conducted a comprehensive analysis of variations in BIA-ALCL treatment, comparing outcomes before and after the 2017 NCCN guideline updates. A total of 178 cases were identified across 89 publications, 70% presented with seroma, 9% with a mass, and 14% with both. En bloc capsulectomy was performed in 97% of cases, with 30% undergoing radiation therapy and 56% receiving chemotherapy. A total of 10 recurrences and eight fatalities attributable to BIA-ALCL with advanced presentation were reported.

Tevis et al. (2022) conducted a retrospective study of 52 women diagnosed with BIA-ALCL from 2014 to 2019. Implants were placed for augmentation in 63% of cases and reconstruction in 37%. Among 41 patients with known implant surface types, all had textured. Most patients presented with delayed seroma (86.5%), and staging information indicated that the majority were at Stage IA. Outcomes were favorable, with only two cases of recurrences (3.8%) and all patients achieving complete remission. The study emphasized the need for continued data collection.

McCarthy et al. (2019) reported initial findings from the *Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology* (PROFILE), a registry developed by the American Society of Plastic Surgeons (ASPS), the Plastic Surgery Foundation and the FDA. From August 2012 to March 2018, 186 cases of BIA-ALCL were recorded in the United States, with complete data available for 89 cases. The median time from implantation of any device to diagnosis was 11 years (range = 2 - 44 years). Local symptoms were reported in 96% of cases, with periprosthetic fluid collection being the most common (86%). All cases involved textured implants. Three deaths were documented at the time of initial case reporting. The PROFILE Registry has been instrumental in improving data collection and further understanding of BIA-ALCL.

Clemens et al. (2016) evaluated treatment efficacy in 87 BI-ALCL patients (50 previously reported, 37 newly included). Median follow-up was 45 months, and median OS was 13 years with survival rates of 93% at three years and 89% at five years. Patients with lymphoma confined to the fibrous capsule had better OS and EFS than those with extracapsular disease. Patients undergoing a complete surgical excision (total capsulectomy with implant removal) had superior survival outcomes compared to partial capsulectomy, systemic chemotherapy, or radiation therapy alone. To achieve optimal EFS, surgical management with complete surgical excision is crucial. The findings highlight the critical role of capsulectomy in achieving the best possible event-free survival (EFS) outcomes.

Miranda et al. (2014) reviewed published BIA-ALCL cases from 1997 to 2012, analyzing 60 patients with a median OS of 12 years (median follow-up: 2 years; range: 0-14 years). Of the 55 patients with available treatment data, 98% underwent a capsulectomy and implant removal. Systematic chemotherapy was administered to 39 patients (78%), while 12 patients opted for watchful waiting and four patients received radiation therapy alone. Complete remission was achieved in 93% of patients with disease confined by the fibrous capsule, compared to 72% in those with a tumor mass. Patients presenting with a mass are at increased risk of an aggressive clinical course that may be fatal, therefore justifying cytotoxic chemotherapy in addition to removal of implants.

National and Specialty Organizations

The **American Society of Plastic Surgeons (ASPS)** and **American Society for Aesthetic Plastic Surgery (ASAPS)** recommend that in suspected or confirmed BIA-ALCL cases, all breast implants, capsules, and effusions be submitted for pathological examination. Routine screen for asymptomatic patients is not recommend. The College of American Pathologist Surgeons concurs, advising that pathology labs conduct CD30 immunohistochemistry testing in suspected malignancy cases, such as spontaneous late seromas occurring after implantation. Additional physician resources on

BIA-ALCL area available through ASPS.

The **ASPS** (2022) published a statement regarding BIA-SCC. Due to the low number of cases, it is not possible to determine factors that increase patient risk. The ASPS continues to monitor emerging research.

The **National Comprehensive Cancer Network (NCCN)** published a case series emphasizing the need for standardized treatment protocols for BIA-ALCL. The NCCN guidelines include diagnostic criteria, disease management recommendations, and treatment strategies A 2019 update of the guideline reinforced the importance of complete surgical excision and addressed recurrence management, organ metastases, and adjunct chemotherapy options for advanced-stage BIAALCL (Clemens & Horwitz 2017; Clemens et al. 2019).

SUPPLEMENTAL INFORMATION

Baker Classification of Capsular Contracture:
Grade I – Breast is soft with no visible or palpable capsular contracture
Grade II – Breast is slightly firm with palpable but not visible contracture
Grade III – Breast is firm with slight distortion and visible contracture
Grade IV – Breast is hard and distorted with visible contracture accompanied by pain

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

04/09/2025	Policy reviewed. No change to coverage criteria. Updated overview and summary of medical evidence.
04/10/2024	Policy reviewed. Updated Overview and References. IRO Peer Review on March 27, 2024, by a practicing physician board-certified in Plastic Surgery,
04/13/2023	Policy reviewed, included indication for BIA-SCC, updated Summary of Medical Evidence section.
04/13/2022	Coverage indications for removal/reinsertion of implants and contralateral implants originally placed for reconstructive purposes added, including ruptured saline implant or removal of a contralateral implant to provide symmetry.
02/09/2022	Policy reviewed; indication added for removal of FDA-recalled implant; updated Overview, Summary of Medical Evidence, and Reference sections.
02/09/2021	Policy reviewed, no changes, updated references.
04/23/2020	Policy reviewed, no changes, updated references.
09/18/2019	Policy reviewed, no changes, updated references.
07/10/2018	New policy. IRO Peer Review on May 18, 2018, by a practicing physician board-certified in Plastic Surgery.

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