Molina Clinical Policy
Breast Implant Removal Policy No. 315

Last Approval: 4/13/2023
Next Review Due By: April 2024

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 involves the surgical explanation of the implant device. The procedure may also include the removal of the capsule tissue that has grown around the implant. Complications of breast implantation that may require implant removal include contracture (graded according to the Baker Classification from Grade I, describing a normal implant, to Grade IV, describing an implant that is hard, cold, painful, tender, and distorted); rupture, extrusion (implant is visible through the surgical wound or skin), or infection. Some bacterial breast implant infections can be treated successfully with medical therapy alone, however implant removal is often necessary for cure, particularly for mycobacterial and fungal infections. (Lalani et al., 2022; Nahabedian, 2021; Clemens et al., 2020).

A rare complication is breast implant associated anaplastic large cell lymphoma, (BIA-ALCL). According to the American Society of Plastic Surgeons (ASPS, n.d.), BIA-ALCL is a lymphoma that currently has only been noted to occur in patients with a history of a textured breast implant device and when caught early, it is curable in most patients. BIA-ALCL is not a cancer of the breast tissue itself. BIA-ALCL is classified as a T-cell lymphoma by the National Comprehensive Cancer Network (NCCN) (2019) and other professional organizations. BIA-ALCL usually develops as a delayed swelling of the breast (average 9.75 years, range 0.8 to 27 years) after the insertion of textured breast implants, which may present as fluid collecting around the implant or marked breast asymmetry. It can also present as a lump in the breast or armpit. Surgical excision, consisting of total capsulectomy and breast implant removal, is intended to improve overall survival (OS) and event-free survival (EFS) in patients with BIA-ALCL.

United States Food and Drug Administration

Squamous Cell Carcinoma (SCC)

On September 8, 2022, the FDA issued a safety communication regarding reports of cancers, specifically SCC and various lymphomas, in the scar tissue that forms around breast implants. This includes textured and smooth breast implants as well as saline and silicone breast implants. Reported signs and symptoms included swelling, pain, lumps, or skin changes. Previous communication included various lymphomas, including BIA-ALCL. While occurrences are rare and the incidence rate is unknown, the FDA encourages Providers and impacted individuals be aware of emerging issues reported in the literature and to report cases to the FDA of SCC or any cancers related to breast implants.

BIA-ALCL

In 2011, the FDA ([1] 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. Due to the difficulty in collecting data worldwide, the FDA has taken steps to understand the issue (e.g., in-depth review of post-approval study data, medical device reports, scientific literature, breast implant-specific registries).

On August 20, 2020, the FDA provided an update on reported adverse events related to breast implants, including BIA-ALCL as well as systemic signs and symptoms referred to by patients as breast implant illness. The FDA also 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.

On July 24, 2019, Allergan announced a voluntary worldwide recall of BIOCELL® textured breast implants and tissue expanders as a precaution due to updated global safety information related to the incidence of BIA-ALCL. BIOCELL® saline-filled and silicone-filled textured breast implants and tissue expanders are no longer available. The recall does not affect Allergan's NATRELLE® smooth or MICROCELL® breast implants and tissue expanders. The FDA does not recommend removal of the implants in asymptomatic patients. ([2] FDA, 2019).

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 complications of the implant when **one or more of the** following criteria are met:
   a. Baker Classification* Class III visible contracture without pain to IV visible contracture that is causing pain and refractory to medical management
   b. Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)
   c. Breast Implant Associated Squamous Cell Carcinoma (BIA-SCC)
   d. Implant extrusion
   e. Implant interferes with breast cancer screening; or removal is needed to facilitate breast cancer treatment
   f. Infection (local or systemic) that is secondary to the implant and refractory to medical management including antibiotics
   g. Ruptured silicone implant (intracapsular or extracapsular), as indicated by **one or more** of the following:
      - Diagnosed by imaging
      - Suspected by physical examination and **one or more** of the following:
        i. Localized pain or mass
        ii. Breast contour irregularity
        iii. Change in breast size
   h. For Members with a breast implant that has been recalled by the FDA (e.g., Allergan BIOCELL textured implants and tissue expanders, McGhan Biodimensional, and others noted under FDA Home>Medical Devices>Databases), symptoms must be present and documented.

2. In addition to the indications above, for 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.

* Baker Classification:
Grade I – no visible or palpable capsular contracture
Grade II – palpable but not visible contracture
Grade III – visible contracture
Grade IV – visible contracture with pain

Limitations and Exclusions

1. For implants originally placed for cosmetic purposes, when criteria for the removal of a unilateral breast implant are met, removal of the contralateral implant is only medically necessary when the procedure meets implant removal criteria above for that contralateral implant.

2. Removal of a ruptured saline implant is considered **NOT medically necessary** in the absence of other complications as listed in criteria number one above, unless the implant was originally placed for reconstructive purposes.
3. Removal of breast implants in patients with a diagnosis of breast cancer, autoimmune and connective tissue disorders is considered **NOT medically necessary** in the absence of other complications outlined above unless breast implant removal is required to perform an adequate mastectomy.

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

McCarthy et al. (2019) reported the initial findings of the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE). The Registry was developed by the American Society of Plastic Surgeons (ASPS), the Plastic Surgery Foundation (PSF), and the FDA after the discovery of a potential association between breast implants and ALCL. Data from August 2012 to March 2018 included 186 cases of BIA-ALCL in the United States reported in PROFILE. The authors reported on the complete detailed case report forms that were received for 89 (48%) cases. Median time from implantation of any device to BIA-ALCL diagnosis was 11 years (range = 2 - 44 years). Of the cases presented, 96% had local symptoms and 9% had concurrent systemic symptoms. Periprosthetic fluid collection was the most frequently seen local symptom (86%). All patients had a history of a textured device (none had a smooth-only device). Three deaths were reported at the time of initial case report submission. The PROFILE Registry has demonstrated to be an essential tool in merging data collection regarding BIA-ALCL to further understand the disease and highlight the critical importance of comprehensive tracking. (McCarthy et al., 2019). The Registry is available here (PSF, n.d.).

As standards of care for BIA-ALCL evolve, new recommendations were presented at the 3rd World Consensus Conference on BIA-ALCL. The recommendations were developed with an emphasis on literature review with respect to epidemiology, etiology, pathogenesis, diagnosis, treatment, socio-psychological aspects, and international authority guidance. The review included a search of manuscripts from 1997 to August 2021 via PubMed. Of the 764 manuscripts, 405 were discarded. Of the 359 remaining manuscripts, a total of 218 were included in the review. The authors concluded that further research is needed as BIA-ALCL is underreported. There was also support for mandatory implant registries to better understand the disease. (di Pompeo et al., 2022).

Tevis et al. (2022) conducted a retrospective study of 52 women with BIA-ALCL from 2014 to 2019. Implants were placed for augmentation in 63% of women and reconstruction in 37%. Forty-one patients had textured implants and most patients presented with delayed seroma and without systemic symptoms (86.5%). Most patients with staging information were at Stage IA. Excellent patient outcomes were found with only two 2 disease recurrences (3.8%) – all patients achieved complete remission. Further research is needed of the growing database.

Naga et al. (2022) conducted a comprehensive analysis of variations in BIA-ALCL treatment. Data was compared from before and after 2017 with guidelines published by the NCCN. A total of 178 cases were identified in 89 publications – most presented with seroma (70%) followed by a mass (9%) or both (14%). Most patients (97%) had an en bloc capsulectomy of the affected implant. Thirty percent were given radiation therapy and 56% received chemotherapy. A total of 10 recurrences and eight fatalities attributable to BIA-ALCL with advanced presentation were reported.

A large body of medical evidence has been published including retrospective uncontrolled studies, retrospective case series, systematic reviews, meta-analysis that reviewed the history and long-term outcomes of BIA-ALCL including the impact of removal of the implant in the treatment of the disease. Many of the cases reported in the literature describe individuals who have had textured implants. The literature supports breast implant removal in symptomatic patients with BIA-ALCL and indicates that the procedure improves OS and EFS. There is evidence in support of removal of breast implants for complications that include contracture, rupture, extrusion, or infection. There is no evidence to support a connection between breast implants and connective tissue, auto immune disease, or a diagnosis of breast cancer.

A systematic review by Leberfinger et al. (2017) assessed how BIA-ALCL develops, its risk factors, diagnosis, and subsequent treatment and to disseminate information about this entity to the medical field. A total of 95 patients were included; most of the BIA-ALCL cases were associated with a textured device. The development of disease is due to chronic inflammation from indolent infections which can lead to malignant transformation of T cells that are anaplastic lymphoma kinase negative and CD30 positive. Mean time to presentation is around 10 years after implant placement – 66% of patients were initially seen with an isolated late-onset seroma and 8% with an isolated new breast mass. Ultrasonography with fluid aspiration may be used for diagnosis. Treatment includes removal of the implant and surrounding capsule; chemotherapy, radiotherapy, and lymph node dissection may be required for advanced disease. The review concluded that while rare, the incidence of BIA-ALCL is increasing.

Clemens et al. (2016) evaluated the efficacy of different therapies used in patients with BI-ALCL to determine an optimal treatment approach. The study included the clinical follow-up of 87 patients with BI-ALCL; 50 were previously reported in the literature and 37 were unreported. Median and mean follow-up times were 45 and 30 months, respectively (range 3-217 months). Median OS time following a diagnosis of BI-ALCL was 13 years; the OS rate was 93% and 89% (3 and 5 years, respectively). Better EFS and OS was reported in patients with lymphoma confined by the fibrous capsule surrounding the implant than patients with lymphoma that had spread beyond the capsule. Patients undergoing a complete surgical excision consisting of total capsulectomy with breast implant removal had improved OS and EFS than patients who received partial capsulectomy, systemic chemotherapy, or radiation therapy. To achieve optimal EFS, surgical management with complete surgical excision is crucial.

Miranda et al. (2014) reviewed literature for published cases of BIA-ALCL from 1997 to December 2012. The median OS for 60 patients was 12 years (median follow-up, 2 years; range, 0-14 years). Most patients (98%) had a capsulectomy and implant removal. Therapeutic data were available for 55 patients – 39 patients (78%) received systemic chemotherapy, and of the 16 patients (28%) who did not receive chemotherapy, 12 patients opted for watchful waiting and four patients received radiation therapy alone. Thirty-nine (93%) of 42 patients with disease confined by the fibrous capsule achieved complete remission, compared with complete remission in 13 (72%) of 18 patients with a tumor mass. Patients with a breast mass had decreased OS and progression-free survival. The OS or PFS were similar between those who received and did not receive chemotherapy. Remission was achieved in most patients with disease confined within the fibrous capsule. 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)** recommends for cases of suspicious or confirmed cases of BIA-ALCL to always submit breast implants, capsule, and effusion to pathology for examination. There is no recommended screening for asymptomatic patients. A similar recommendation was published by the College of American Pathologists. Surgeons should request that pathology laboratory perform CD30 immunohistochemistry of effusions and scar capsules in cases suspicious of an ALCL malignancy, such as spontaneous late seromas occurring after implantation. Additional BIA-ALCL Physician Resources are available from the ASPS.

The **ASPS** (2022) also 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 is monitoring research as it becomes available.

In 2017, the **NCCN** published a case series that demonstrated a need for treatment standardization for BIA-ALCL. Guidelines included a section on BIA-ALCL management as well as recommendations and therapeutic strategies (Clemens & Horwitz, 2017). A 2019 update of the guideline recommendations focused on parameters for achieving reliable diagnosis and disease management and emphasize the critical role for complete surgical ablation. Information on recurrence and management of unresectable disease and organ metastasis are included. Recommendations for adjunct treatments and chemotherapy regimens are also included for patients with advanced BIA-ALCL with lymph node involvement. (Clemens, et al., 2019).

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)

HCPCS Codes – N/A

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

4/13/2023	Policy reviewed, included indication for BIA-SCC, updated Summary of Medical Evidence section.
4/13/2022	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.
2/9/2022	Policy reviewed; indication added for removal of FDA-recalled implant; updated Overview, Summary of Medical Evidence, and Reference sections.
2/9/2021	Policy reviewed, no changes, updated references.
4/23/2020	Policy reviewed, no changes, updated references.
9/18/2019	Policy reviewed, no changes, updated references.
7/10/2018	New policy.

REFERENCES

Government Agencies

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2. United States Food and Drug Administration (FDA). Breast implants: Reports of squamous cell carcinoma and various lymphomas in capsule around implants – FDA safety communication. Published September 8, 2022. Accessed February 23, 2023. https://www.fda.gov/medical-devices/safety-communications/breast-implants-reports-squamous-cell-carcinoma-and-various-lymphomas-capsule-around-implants-fda.
3. United States Food and Drug Administration (FDA). FDA updates analysis of medical device reports of breast implant illness and breast implant-associated lymphoma. Published August 20, 2020. Accessed February 23, 2023. https://www.fda.gov/news-events/press-announcements/fda-updates-analysis-medical-device-reports-breast-implant-illness-and-breast-implant-associated.
4. [1] United States Food and Drug Administration (FDA). Questions and answers about breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Updated October 23, 2019. Accessed February 20, 2023. https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl.
5. [2] United States Food and Drug Administration (FDA). Allergan voluntarily recalls BIOCELL® textured breast implants and tissue expanders. Updated July 24, 2019. Accessed December 22, 2021. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergan-voluntarily-recalls-biocellr-textured-breast-implants-and-tissue-expanders.

National and Specialty Organizations

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2. [1] American Society of Plastic Surgeons (ASPS). ASPS statement on breast implant specimens and pathology. Accessed February 20, 2023. https://www.plasticsurgery.org/documents/Health-Policy/Positions/ASPS-Statement_Breast-Implant-Pathology.pdf.
3. [2] American Society of Plastic Surgeons (ASPS). BIA-ALCL physician resources. Accessed February 20, 2023. https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources.
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6. Plastic Surgery Foundation. Patient registry and outcomes for breast implants and anaplastic large cell lymphoma (ALCL) etiology and epidemiology (PROFILE). Accessed February 20, 2023. https://www.thepsf.org/research/registries/profile.

Peer Reviewed Publications

1. Clemens MW, Medeiros LJ, Butler CE, et al. Complete surgical excision is essential for the management of patients with breast implant-associated anaplastic large-cell lymphoma. J Clin Oncol. 2016;34(2):160-168. doi: 10.1200/JCO.2015.63.3412.
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5. Miranda RN, Aladily TN, Prince HM, et al. Breast implant-associated anaplastic large-cell lymphoma: Long-term follow-up of 60 patients. J Clin Oncol. 2014 Jan 10;32(2):114-20. doi: 10.1200/JCO.2013.52.7911. PMID: 24323027. PMCID: PMC4062709.
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Other Authoritative Publications

1. AMR Peer Review. Policy reviewed on May 19, 2018 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Plastic Surgery.
2. Clemens MW, Jacobsen E. Breast implant-associated anaplastic large cell lymphoma. Updated October 26, 2020. Accessed December 22, 2021. http://www.uptodate.com.
3. Lalani T, Zenn MR, Sexton DJ. Breast implant infections. Updated October 5, 2022. Accessed December 22, 2021. http://www.uptodate.com.
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Other Authoritative Publications (used in the development of this policy)

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*