Molina Clinical Policy
Breast Implant Removal Policy No. 315

Last Approval: 4/13/2022
Next Review Due By: April 2023

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.

A rare complication is breast implant associated anaplastic large cell lymphoma, (BIA-ALCL). According to the American Society of Plastic Surgeons (ASPS, 2021), 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) 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. In 2019, the FDA requested Allergan to voluntarily recall its Natrelle BIOCELL textured implants and tissue expanders due to an increased risk that they may be associated with BIA-ALCL (FDA, 2020).

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
   c. Implant extrusion
   d. Implant interferes with breast cancer screening; or removal is needed to facilitate breast cancer treatment
   e. Infection (local or systemic) that is secondary to the implant and refractory to medical management including antibiotics

f. 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

g. For Members with a breast implant that has been recalled by the FDA (e.g. Allergan BIOCELL textured implants and tissue expanders), symptoms must be present and documented.

2. For Members with a breast implant or implants 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, auto immune and connective tissue disorders is considered **NOT medically necessary** in the absence of other complications outlined above unless breast implant removal is required in order 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

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 breast implant-associated anaplastic large cell lymphoma (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 overall survival (OS) and event-free survival (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. 95 patients were included in this systematic review. Almost all documented BIA-ALCL cases have been associated with a textured device. The underlying mechanism is thought to be due to chronic inflammation from indolent infections, leading to malignant

transformation of T cells that are anaplastic lymphoma kinase (ALK) negative and CD30 positive. The mean time to presentation is approximately 10 years after implant placement, with 55 of 83 (66%) patients initially seen with an isolated late-onset seroma and 7 of 83 (8%) with an isolated new breast mass. Ultrasonography with fluid aspiration can be used for diagnosis. Treatment must include removal of the implant and surrounding capsule. More advanced disease may require chemotherapy, radiotherapy, and lymph node dissection. The review concluded that breast implant-associated anaplastic large cell lymphoma is a rare cancer in patients with breast implants but is increasing in incidence. It is important for all physicians involved in the care of patients with breast implants to be aware of this entity and be able to recognize initial symptoms.

Clemens et al. (2016) evaluated the efficacy of different therapies used in patients with BI-ALCL to determine an optimal treatment approach. A clinical follow-up of 87 patients with BI-ALCL, including 50 previously reported in the literature and 37 unreported was conducted. The median and mean follow-up times were 45 and 30 months, respectively (range, 3 to 217 months). The median overall survival (OS) time after diagnosis of BI-ALCL was 13 years, and the OS rate was 93% and 89% at 3 and 5 years, respectively. Patients with lymphoma confined by the fibrous capsule surrounding the implant had better event free survival (EFS) and OS than did patients with lymphoma that had spread beyond the capsule (P = .03). Patients who underwent a complete surgical excision that consisted of total capsulectomy with breast implant removal had better OS (P = .022) and EFS (P = .014) than did patients who received partial capsulectomy, systemic chemotherapy, or radiation therapy. The authors concluded that surgical management with complete surgical excision is essential to achieve optimal EFS in patients with BI-ALCL.

Miranda et al. (2014) reviewed the literature for all published cases of breast implant associated ALCL from 1997 to December 2012 and contacted corresponding authors to update clinical follow-up. The median overall survival (OS) for 60 patients was 12 years (median follow-up, 2 years; range, 0-14 years). Capsulectomy and implant removal was performed on 56 of 60 patients (93%). 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 worse OS and progression-free survival (PFS; P = .052 and P = .03, respectively). The OS or PFS were similar between patients who received and did not receive chemotherapy (P = .44 and P = .28, respectively). CONCLUSION: Most patients with breast implant associated ALCL who had disease confined within the fibrous capsule achieved complete remission. Proper management for these patients may be limited to capsulectomy and implant removal. Patients who present with a mass have a more aggressive clinical course that may be fatal, justifying cytotoxic chemotherapy in addition to removal of implants.

On July 24, 2019, the FDA requested that Allergan recall all of its BIOCELL textured saline and silicone breast implants and tissue expanders from the U.S. market due to the potential increased risk of BIA-ALCL associated with the devices. The products all have the same BIOCELL textured surface (shell), which is a unique surface used only by Allergan. 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. The FDA does not currently recommend removal of the implants in asymptomatic patients due to the low risk of developing BIA-ALCL (FDA, 2020).

The **American Society of Plastic Surgeons (ASPS)** and **American Society for Aesthetic Plastic Surgery (ASAPS)** advocate following the FDA recommendation 2 that all women, including those with breast implants follow their normal routine in medical care and follow up, including mammography when appropriate and should immediately contact their physician if they sense any abnormalities within the breast or notice any significant changes. There is no recommended screening for asymptomatic patients.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
19328	Removal of intact mammary implant
19330	Removal of mammary implant material

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

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.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Local coverage determination for cosmetic and reconstructive surgery (L33428). Available from CMS. Effective October 1, 2015. Updated July 29, 2021. Accessed December 22, 2021.
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Local coverage determination for cosmetic and reconstructive surgery (L35090). Available from CMS. Effective October 1, 2015. Updated July 11, 2021. Accessed December 22, 2021.
3. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Local coverage determination for cosmetic and reconstructive surgery (L38914). Available from CMS. Effective July 11, 2021. Accessed December 22, 2021.
4. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Local coverage determination for plastic surgery (L35163). Available from CMS. Effective October 1, 2015. Updated October 1, 2019. Accessed December 22, 2021.
5. United States Food and Drug Administration (FDA). Questions and answers. Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Updated October 23, 2019. Available from FDA. Accessed December 22, 2021.
6. United States Food and Drug Administration (FDA). The FDA requests allergan voluntarily recall natrelle biocell textured breast implants and tissue expanders from the market to protect patients: FDA safety communication. Available from FDA. Updated June 1, 2020. Accessed December 22, 2021.
7. United States Food and Drug Administration (FDA). Medical device reports for systemic symptoms in women with breast implants. Available from FDA. Updated August 20, 2020. Accessed January 31, 2022.

Evidence Based Reviews and 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. Breast implant-associated anaplastic large cell lymphoma. http://www.uptodate.com. Updated October 26, 2020. Accessed December 22, 2021. Registration and login required.
3. Lalani T, Zenn MR, Sexton DJ. Breast implant infections. http://www.uptodate.com. Updated September 9, 2020. Accessed December 23, 2021. Registration and login required.
4. Nahabedian M. Complications of reconstructive and aesthetic breast surgery. http://www.uptodate.com. Updated October 14, 2021. Accessed December 22, 2021. Registration and login required.

Peer Reviewed Publications

1. Clemens MW, Jacobsen ED, Horwitz SM. 2019 NCCN consensus guidelines on the diagnosis and treatment of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Aesthet Surg J. 2019 Jan 31;39(Suppl_1):S3-S13. doi: 10.1093/asj/sjy331. Accessed December 22, 2021.
2. 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. Accessed Dec. 23, 2021.

3. DeCoster RC, Lynch EB, et al. Breast implant-associated anaplastic large cell lymphoma: an evidence-based systematic review. Ann Surg. 2021 Mar 1;273(3):449-458. doi: 10.1097/SLA.0000000000004365. Accessed December 22, 2021.
4. Johnson L, O'Donoghue JM, et al. Breast implant associated anaplastic large cell lymphoma: The UK experience. Recommendations on its management and implications for informed consent. Eur J Surg Oncol. 2017 Aug;43(8):1393-1401. doi: 10.1016/j.ejso.2017.05.004. Accessed December 22, 2021.
5. Kanapathy M, Federani R, et al. Management of periprosthetic breast infection: a systematic review and meta-analysis. J Plast Reconstr Aesthet Surg. 2021 Nov;74(11):2831-2845. doi: 10.1016/j.bjps.2021.05.070. Accessed December 22, 2021.
6. Laurent C, Delas A, Gaulard P, et al. Breast implant associated anaplastic large cell lymphoma: Two distinct clinicopathological variants with different outcomes. Ann Oncol. 2016 Feb;27(2):306-314. Doi: 10.1093/annonc/mdv575. Accessed December 23, 2021.
7. Leberfinger AN, Behar BJ, Williams NC et al. Breast implant associated anaplastic large cell lymphoma: a systemic review. JAMA Surgery. 2017 Dec 1;152(12):1161-1168. doi: 10.1001/jamasurg.2017.4026. Accessed December 23, 2021.
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9. Mennie JC, Quaba O, Smith M, Quaba A. Diagnosing PIP breast implant failure: a prospective analysis of clinical and ultrasound accuracy. J Plast Reconstr Aesthet Surg. 2015 Apr;68(4):540-545. doi: 10.1016/j.bjps.2014.11.008. Accessed December 23, 2021.
10. 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. Accessed December 23, 2021.
11. Samuels JB, Rihrich RJ, Weatherall PT et al. Radiographic diagnosis of breast implant rupture: Current status and comparison of techniques. Plast Reconstr Surg. 1995 Sep;96(4):865-77. Doi: 10.1097/00006534-199509001-00016. Accessed December 23, 2021.
12. Washer LL, Gutowski K. Breast implant infections. Infect Dis Clin North Am. 2012 Mar;26(1):111-25. Doi: 10.1016/j.idc.2011.09.003. Accessed December 23, 2021.

National and Specialty Organizations

1. American Society of Plastic Surgeons (ASPS). BIA-ALCL Resources. www.plasticsurgery.org. Updated February 24, 2020. Accessed December 23, 2021.
2. National Comprehensive Cancer Network (NCCN). Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). NCCN Clinical Practice Guidelines in Oncology. www.nccn.org. Accessed December 22, 2021.
3. Plastic Surgery Foundation. Patient registry and outcomes for breast implants and anaplastic large cell lymphoma (ALCL) etiology and epidemiology (PROFILE). Available from Plastic Surgery Foundation. Updated 2021. Accessed Dec. 27, 2021.

APPENDIX

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