Subject: Breast Implant Removal		Original Effective Date: 6/14/2018
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Review Date: 9/18/2019, 4/23/2020, 2/8/2021		
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Contents

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members. [1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Breast implant removal involves the surgical explantation 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 [21] 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 [4] (ASPS), 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 lymphoma by the National Comprehensive Cancer Network (NCCN) and other professional organizations. BIA-ALCL usually develops as a delayed swelling of the breast (average 8 years, range 2 to 28 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.

POSITION STATEMENT[7-25]

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 of the following clinical conditions are present: [ONE]

   - ❑ Baker Classification* Class III visible contracture without pain to IV visible contracture that is causing pain and refractory to medical management; or
   - ❑ Breast implant-associated anaplastic large cell lymphoma; or
   - ❑ Implant extrusion; or
   - ❑ Implant interferes with breast cancer screening; or removal is needed to facilitate breast cancer treatment; or
   - ❑ Infections (local or systemic) that is secondary to the implant and refractory to medical management including antibiotics; or
   - ❑ Ruptured silicone implant (intracapsular or extracapsular):
     - Diagnosed by imaging or;
     - Suspected by physical examination and one of the following:
       - Localized pain or mass
       - Breast contour irregularity
       - Change in breast size

2. 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.

3. When replacement is required to treat asymmetry following reconstruction for mastectomy, federal mandates of Women's' Health and Cancer Rights Act apply.

4. 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 mandated by the Women's' Health and Cancer Rights Act.

5. 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.

6. ***Note:*** *Baker Classification: [22]
   - 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

SUMMARY OF MEDICAL EVIDENCE [7-24]

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. [7-25]

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. [15]

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. [10]

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. [19]

PROFESSIONAL SOCIETY GUIDELINES [3-6]

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.

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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

HCPCS	Description
L8020 -L8039	Breast prostheses
L8600	Implantable breast prosthesis, silicone or equal

ICD-10	Description: [For dates of service on or after 10/01/2015]
C50.011 - C50.929	Malignant neoplasm of breast
C84.60 - C84.69	Anaplastic large cell lymphoma, ALK-hyphenpositive
C84.70 - C84.79	Anaplastic large cell lymphoma, ALK-hyphennegative
N64.4	Mastodynia
T85.41 - T85.49	Mechanical complication of breast prosthesis and implant
T85.79	Infection and inflammatory reaction due to other internal prosthetic devices, implants, or grafts

REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: http://www.cms.gov/medicare-coverage-database/
2. U.S. Food and Drug Agency (FDA): Questions & Answers. Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Updated 2019. Accessed at: https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl

Professional Society Publications and Guidelines

3. The Plastic Surgery Foundation. McCarthy C, Eloff B, Loyo-Berrios N. Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE). 2018. Accessed at: https://www.thepsf.org/research/registries/profile
4. American Society of Plastic Surgeons (ASPS) BIA-ALCL Resources. 2018.
5. American Society for Aesthetic Plastic Surgery (ASAPS). Best Practices Breast Implant Associated ALCL. 2018. Accessed at: https://www.surgery.org/sites/default/files/BEST%20PRACTICES_1.pdf
6. National Comprehensive Cancer Network (NCCN) Guidelines. 2018-2020
   - Breast Cancer.
   - T-Cell Lymphomas. Breast Implant Associated ALCL

Peer Reviewed Literature

7. Aladily TN, Medeiros LJ, Amin MB et al. Anaplastic large cell lymphoma associated with breast implants: a report of 13 cases. Am J Surg Pathol. 2012;Jul;36(7):1000-1008.
8. Brody GS, Deapen D, Taylor CR et al. Anaplastic large cell lymphoma occurring in women with breast implants: analysis of 173 cases. Plast Reconstr Surg. 2015 Mar;135(3):695-705.
9. Chung KC, Wilkins EG, Beil RJ Jr. et al. Diagnosis of silicone gel breast implant rupture by ultrasonography. Plas Reconstruct Surg 1996; 97(1):104-109. PMID 8532766

10. 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.
11. Clemens, Mark W, Brody, Garry S, Mahabir, Raman C, et al. How to Diagnose and Treat Breast Implant Associated Anaplastic Large Cell Lymphoma Plastic and Reconstructive Surgery. 2018:141(4):586e-599e.
12. Gabriel SE, Woods JE, O'Fallon WM, Beard CM, Kurland LT, Melton LJ 3rd. Complications leading to surgery after breast implantation. N Engl J Med. 1997;336(10):677.
13. Johnson L, O'Donoghue JM, McLean N 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.
14. 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;27(2):306-314.
15. Leberfinger AN, Behar BJ, Williams NC et al. Breast implant associated anaplastic large cell lymphoma: a systemic review. JAMA Surgery. 2017;152(12):1161-1168.
16. Loch-Wilkinson A, Beath KJ et al. Breast Implant-Associated Anaplastic Large Cell Lymphoma in Australia and New Zealand High-Surface-Area Textured Implants Are Associated with Increased Risk. Plastic and Reconstructive Surgery 2018; 141(1): 177e–178e.
17. Locke MB, Lofts J. Variable presentation of anaplastic large-cell lymphoma in patients with breast implants. ANZ J Surg. 2017;87(10):789-794.
18. 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. PMID 25496719
19. 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. Epub 2013 Dec 9.
20. Netscher DT, Wiezer G, Malone RS et al. Diagnostic value of clinical examination and various imaging techniques for breast implant rupture as determined in 81 patients having implant removal. South Med J 1996; 89(4):397-404. PMID 8614880
21. Samuels JB, Rihrich RJ, Weatherall PT et al. Radiographic diagnosis of breast implant rupture: Current status and comparison of techniques. Plast Reconstr Surg 1995; 96(4):865-877. PMID 7652061
22. Spear SL, Baker JL Jr. Classification of capsular contracture after prosthetic breast reconstruction. Plast Reconstr Surg. 1995 Oct;96(5):1119-23; discussion 1124.
23. Spear SL, Howard MA, Boehmler JH, et al. The infected or exposed breast implant: management and treatment strategies. Plast Reconstr Surg 2004; 113:1634.
24. Thompson PA1, Prince HM. Breast implant-associated anaplastic large cell lymphoma: a systematic review of the literature and mini-meta analysis. Curr Hematol Malig Rep. 2013 Sep;8(3):196-210. doi: 10.1007/s11899-013-0164-3.
25. Washer LL, Gutowski K. Breast implant infections. Infect Dis Clin North Am 2012; 26:111.

Other Resources:

26. IRO Peer Review: Policy reviewed by AMR practicing physician Board certified in Plastic Surgery, 5/19/18.
27. McKesson InterQual CP Procedures. Breast Implant Removal. 2019.

28. UpToDate [website]: Waltham, MA: Walters Kluwer Health; 2021.
- Clemens M, Jacobson E. Breast implant-associated anaplastic large cell lymphoma.
- Lalani T, Zen M, Sezton D. Breast implant infections.
- Nahabedian M. Implant-based breast reconstruction and augmentation.

29. Hayes a Division of TractManager. Winifred Hayes Inc. Lansdale, PA.
- Evidence Analysis Research Brief. Breast Implant Removal Following Diagnosis of Breast Implant-Associated Anaplastic Large Cell Lymphoma. April 2018. Archive 2019.
- Clinical Research Response. Anaplastic Large Cell Lymphoma (ALCL) Associated with Textured Silicone Breast Implants. Dec, 2018.

REVIEW/REVISION HISTORY

7/10/18: New Policy
9/18/19, 4/23/20, 2/9/21: Policy reviewed, no changes. References updated.