

#### KAISER PERMANENTE Mid-Atlantic States

# Utilization \*ALERT\*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.

# I. Procedure / Service: Breast Implant Removal

*Related Medical Coverage Policies:* For transgender members without the diagnoses listed in section II, please see Transgender Surgery Medical Coverage Policies for DC (separate) or Maryland + Virginia situs members.

# II. Diagnoses

- A. Revision of cosmetic augmentation mammoplasty;
- **B.** Breast reconstruction following a medically necessary mastectomy (e.g., mastectomy for breast cancer or a prophylactic mastectomy)
- **III. Specialty:** Plastic Surgery

# IV. Indications for Breast Implant Removal

Kaiser Permanente considers the removal of breast implants medically necessary for members who meet the following selection criteria:

- A. For members who have undergone either cosmetic augmentation mammoplasty or breast reconstruction following a medically necessary mastectomy (e.g., mastectomy for breast cancer or prophylactic mastectomy for breast cancer risks), removal of a breast implant and capsulectomy or capsulotomy is a covered medical treatment for any of the following indications:
  - 1. Extrusion of implant through skin;
  - 2. Implants complicated by recurrent infections;
  - 3. Implants with Baker Class III or Baker Class IV contracture;
  - 4. Implants with severe contracture that interferes with mammography;
  - 5. Intra- or extra-capsular rupture of implants;
  - 6. Breast cancer in the implanted breast or remnant, or in the contralateral breast, where implant removal is necessary to excise the breast cancer; *and*
  - 7. Breast implant-associated anaplastic large cell lymphoma or suspicion of diagnosis based on clinical evaluation.
- B. If criteria are met for removal of breast implant on one side, coverage is provided for the other breast (removal of the implant and capsulectomy or capsulotomy) if removal on both sides occurs at the same time.



# **Breast Implant Removal**

**Medical Coverage Policy** 

### V. Exclusions/Restrictions

- A. For diagnosis or treatment of autoimmune disease, the following procedures are not covered:
  - 1. IgG (immunoglobulin) testing in connection with silicone implants (the development of IgG antibodies is neither specific to silicone implants nor indicative of autoimmune disorders);
  - 2. Removal of silicone implants for autoimmune disease unless the member meets at least one of the selection criteria listed above (e.g., rupture of silicone-gel filled implant, etc.).
- **B.** Reinsertion of breast implant is not covered if the implants were originally inserted for cosmetic purposes, even after a medically necessary removal (as in section IV. A)

#### VI. Referral Procedure

Request for the removal of breast implants for any of the following indications requires medical review:

- Baker Class III or IV contracture associated with severe pain that does not follow a medically necessary mastectomy;
- Implant removal for a lumpectomy that can be performed with the implant in place.

#### VII. Indications for Replacement and Reinsertion of Breast Implant

Insertion of breast implants, after a medically necessary removal, are covered for:

- Replacement of breast implants inserted due to mastectomy for breast cancer or a prophylactic mastectomy;
- **B.** Initial or replacement of breast implants for women with Poland's Syndrome

# VIII. Baker Class Grading for Capsular Contractures

Class I	Augmented breast feels soft as a normal breast.	
Class II	Augmented breast is less soft, and implant can be palpated but is not visible.	
Class III	Augmented breast is firm, implant is palpable, and the implant (or distortion) is visible.	
Class IV	Augmented breast is hard, painful, cold, tender, and distorted.	



KAISER PERMANENTE Mid-Atlantic States

### References

- 1. Baek WY, Lew DH, Lee DW. A retrospective analysis of ruptured breast implants. Arch Plast Surg Nov 2014(6): 734-9. Epub Nov 2014.
- 2. Clemens MW, Miranda RN, Butler CE. Breast implant consent should include the risk of anaplastic large cell lymphoma. Plast Reconstr Surg. Apr 2016; 137(4):1117-22.
- 3. Medicare Coverage Database; No available criteria; search words: breast, implant, removal. Accessed Apr 6, 2016.
- 4. Middleton MS. MR Evaluation of breast implants. Radiol Clin North Am. May 2014; 52 3): 591-608.
- 5. Oulharj S, Pauchot J, Tropet Y. Post implant breast implant removal: a study of 828 cases. J Plast Reconstr Aesthet Surg - March 1, 2014; 67 (3); 302-7.
- 6. Quinn TT, Miller GS, Rostek M, et al. Prosthetic breast reconstruction: indications and update. Gland Surgery. Apr 2016; 5(2): 174-86.
- 7. Robbins CM, Long JN, Fix RJ, de la Torre JL, Vasconez LO. Mastectomy with breast reconstruction in previously augmented patients: indications for implant removal. Ann Plast Surg. Nov 2008; 61(5): 500-5.
- 8. Rochira D, Cavalcanti P, Ottaviani A, Tambasco D. Longitudinal Ultrasound Study of Breast Implant Rupture over a 6-year interval. Ann Plast Surg; May 2015. E pub ahead of print.
- 9. Wong T, Lo LW, Fung PY, et al. Magnetic resonance imaging of breast augmentation: a pictorial review. *Insights Imaging.* Mar 2016. Epub.
- 10. Oulharj, S.; Pauchot, J.; Tropet, Y. PIP breast implant removal: A study of 828 cases *Journal of Plastic, Reconstructive & Aesthetic Surgery*. March 2014 67(3):302.
- Ramos-Gallardo, Guillermo; Cuenca-Pardo, Jesús; Rodríguez-Olivares, Eugenio; Iribarren-Moreno, Rufino; Contreras-Bulnes, Livia; Vallarta-Rodríguez, Alfonso; Kalixto-Sanchez, Marco; Hernández, Claudia; Ceja-Martinez, Ricardo; Torres-Rivero, Cesar. Breast Implant and Anaplastic Large Cell Lymphoma Meta-Analysis. *Journal of Investigative Surgery* Feb2017, Vol. 30 Issue 1, p56-65, 10p.
- Clemens, Mark W.; Miranda, Roberto N. Coming of Age. Breast Implant–Associated Anaplastic Large Cell Lymphoma After 18 Years of Investigation. *Breast Augmentation, Clinics in Plastic Surgery*. October 2015 42(4):605-613 Language: English. DOI: 10.1016/j.cps.2015.06.006.
- Jessica G., Labadie; Dorota Z., Korta; Natalie, Barton; Natasha A., Mesinkovska. Cutaneous Hypersensitivity Like Reactions Associated With Breast Implants: A Review *Dermatologic Surgery*. Mar 01, 2018 44(3):323-329 Language: English, Database.
- Faguy, Kathryn. Adverse Effects and Imaging Appearances of Breast Implants. *Radiologic Technology*, May/Jun2018; 89(5): 467M-484M. 18p. (Article) ISSN: 0033-8397, Database: CINAHL with Full Text Subjects: Breast Implants; Silicones; Breast Implants Adverse Effects; Magnetic Resonance Imaging Methods.
- 15. A Multicenter Analysis Examining Patients Undergoing Conversion of Implant-based Breast Reconstruction to Abdominally based Free Tissue Transfer. *Journal of Reconstructive Microsurgery*, 2018, Vol. 34 Issue 9, p685-691, 7p. Publisher: Georg Thieme Verlag Stuttgart.
- 16. M Bradley Calobrace, MD, Michael R Schwartz, MD, Kamakshi R Zeidler, MD, Troy A Pittman, MD, Robert



**Medical Coverage Policy** 

Cohen, MD, W Grant Stevens, MD, Long-Term Safety of Textured and Smooth Breast Implants, Aesthetic Surgery Journal, Volume 38, Issue 1, January 2018, Pages 38–48, <u>https://doi.org/10.1093/asj/sjx157</u>

- 17. Ghione P, Cordeiro PG, Ni A, et al. Risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in a cohort of 3546 women prospectively followed after receiving textured implants. Hematol Oncol. 2019; 37:97-98.
- Collett, D. J., Rakhorst, H., Lennox, P., Magnusson, M., Cooter, R., & Deva, A. K. (2019). Current Risk Estimate of Breast Implant-Associated Anaplastic Large Cell Lymphoma in Textured Breast Implants. Plastic and reconstructive surgery, 143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma), 30S–40S. https://doi.org/10.1097/PRS.00000000005567
- Cardoso, M. J., Wyld, L., Rubio, I. T., Leidenius, M., Curigliano, G., Cutuli, B., Marotti, L., & Biganzoli, L. (2019). EUSOMA position regarding breast implant associated anaplastic large cell lymphoma (BIA-ALCL) and the use of textured implants. Breast (Edinburgh, Scotland), 44, 90–93. https://doi.org/10.1016/j.breast.2019.01.011
- Lamaris, G. A., Butler, C. E., Deva, A. K., Miranda, R. N., Hunt, K. K., Connell, T., Lipa, J. E., & Clemens, M. W. (2019). Breast Reconstruction Following Breast Implant-Associated Anaplastic Large Cell Lymphoma. Plastic and reconstructive surgery, 143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma), 51S–58S. <u>https://doi.org/10.1097/PRS.00000000005569</u>
- MCG 26<sup>th</sup> edition, Copyright © 2022 MCG Health, LLC. Mastectomy, Complete, with Insertion of Breast Prosthesis or Tissue Expander RRG: S-862-RRG (ISC), Mastectomy, Complete, with Insertion of Breast Prosthesis or Tissue Expander ORG: S-862 (ISC) Accessed February 1, 2022
- 22. American Society of Plastic Surgeons (ASPS). Practice Parameter. Treatment Principles of Silicone Breast Implants. March 2005. Available at: <u>http://www.plasticsurgery.org/Documents/medical-professionals/healthpolicy/evidence-practice/TreatmentPrinciplesofSiliconeBreastImplants.pdf</u>.
- 23. Breast Reconstruction for Deformities Unrelated to Cancer Treatment: ASPS Recommended Insurance Coverage Criteria for Third-Party Payers): <u>http://www.plasticsurgery.org/Documents/medicalprofessionals/health-policy/insurance/Breast-Reconstruction-for-Deformities-Unrelated-to-CancerTreatment.pdf</u>
- 24. Metzinger, S. E., Homsy, C., Chun, M. J., & Metzinger, R. C. (2022). Breast Implant Illness: Treatment Using Total Capsulectomy and Implant Removal. *Eplasty*, 22, e5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9097901/
- Suh, L. J., Khan, I., Kelley-Patteson, C., Mohan, G., Hassanein, A. H., & Sinha, M. (2022). Breast Implant-Associated Immunological Disorders. *Journal of immunology research*, 2022, 8536149. <u>https://doi.org/10.1155/2022/8536149</u>
- 26. McGuire, P., Clauw, D. J., Hammer, J., Haws, M., & Adams, W. P. (2022). A Practical Guide to Managing Patients With Systemic Symptoms and Breast Implants. *Aesthetic surgery journal*, 42(4), 397–407. https://doi.org/10.1093/asj/sjab375
- McKernan C. (2021). Treating breast implant-associated anaplastic large cell lymphoma. JAAPA : official journal of the American Academy of Physician Assistants, 34(4), 47–51. https://doi.org/10.1097/01.JAA.0000735780.35691.e5



**Medical Coverage Policy** 

### Approval History

Date approved by RUMC*	Date filed with the State of Maryland	Date of Implementation (Ten days after filing)
05/29/2015	06/02/2015	06/15/2015
05/27/2016	05/31/2016	06/10/2016

#### Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
06/01/2017	06/01/2017
05/29/2018	05/29/2018
05/28/2019	05/28/2019
05/14/2020	05/14/2020
04/16/2021	04/16/2021
04/25/2022	04/25/2022
04/25/2023	04/25/2023
04/25/2024	04/25/2024

\*The Regional Utilization Management Committee received **delegated authority** to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee in 2011.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based and may also include expert opinion. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.

©2024, Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. ©2024, Mid-Atlantic Permanente Medical Group, P.C.