

Breast Implant Removal

Date of Origin: 12/1999 Last Review Date: 06/26/2024 Effective Date: 07/01/2024

Dates Reviewed: 12/02, 11/03, 11/04, 10/05, 10/06, 10/07, 10/08, 07/10, 07/11, 05/12, 03/13, 03/14, 04/15,

05/16, 05/17, 05/18, 05/19, 05/20, 05/21, 06/22, 06/23, 06/24

Developed By: Medical Necessity Criteria Committee

I. Description

Breast implants are placed as part of a reconstruction process following a medically necessary mastectomy or for cosmetic augmentation. Removal of an implant would be necessary for complications related to the implant. These complications may include capsular leakage, infection, contractures, pain, and/or extruded implants.

Contractures are documented using the Baker Classification, which is divided into 4 categories:

Grade I Augmented breast feels as soft as a normal breast

Grade II Breast is less soft, and the implant can be palpated but is not visible

Grade III Breast is firm, the implant is palpable and visible (or its distortion is visible)

Grade IV Breast is hard, painful, cold, tender, and distorted

Note: Group Plans may have specific exclusions related to cosmetic/reconstructive surgery and complications associated with the same. Approval is subject to plan limitation and exclusions.

** Note: Removal of implants for nonspecific, somatic complaints is not a covered benefit **

II. Criteria: CWQI HCS-0010

- A. Moda Health considers **Silicone** breast implant removal when **one or more** of the following criteria are met:
 - a. Documented intra- or extra-capsular leakage of silicone implant
 - Persistent or recurrent local or systemic infection or cutaneous hypersensitivity-like reactions secondary to the breast implant that have failed to respond to conservative treatment with antibiotics, oral steroids, and topical steroids
 - c. Documentation of Baker Class III or IV contractures associated with severe pain
 - d. Extruded/exposure of implant through skin
 - e. Tissue necrosis secondary to the implant
 - f. The implant is interfering with diagnostic evaluation of suspected breast cancer
 - g. Breast cancer
 - h. Breast implant-associated anaplastic large cell lymphoma

- B. For members whose implants were placed following a medically necessary mastectomy or lumpectomy, breast implant removal is also considered medically necessary for the following additional indications.
 - a. Documentation of ongoing pain or painful contractures related to the implant/reconstruction site for the past 6 months; or
 - b. Intra- or extra-capsular leakage of saline or silicone implants.
- C. Moda Health considers removal of ruptured saline-filled breast implants **NOT** medically necessary for individuals who have undergone cosmetic breast augmentation

III. Limitations:

- A. If breast implant removal is found to be medically necessary, the following will apply:
 - a. If the above criteria for breast implant removal are met unilaterally, Moda Health will also cover removal of the implant of the other breast if both implants are removed during the same procedure.
 - b. If removal is being done due to documented rupture, coverage of the mammary implant material is also covered (CPT 19330).
 - c. Moda Health will pay only for the medically approved procedure(s). All contract exclusions apply.

IV. Not Covered:

- A. Moda Health will not cover any of the following because they are considered not medically necessary:
 - a. Removal of any type of breast implant performed solely to treat psychological symptomology or psychosocial complaints; or
 - b. Removal of any type of breast implant performed solely to improve appearance
 - c. Removal of any type of breast implant performed solely for the possible influence of breast implants on developing or existing autoimmune disease or connective tissue disorders. Note: Current literature and associated professional organizations do not support any correlation between breast implants and autoimmune disease and connective tissue disorders.

V. Reinsertion of Breast Implants:

- A. If the breast implants were placed for cosmetic reasons, Moda Health will NOT pay for the reinsertion of the new breast implants.
- B. If the breast implants were placed following a medically necessary mastectomy or lumpectomy, Moda Health will cover the reinsertion of breast implants.

VI. Information Submitted with the Prior Authorization Request:

- 1. Chart notes from the treating physician
- 2. Documentation of confirmation or reports from imaging studies if implant leakage is the reason for the removal (i.e. MRI, mammogram, or ultrasound).

VII. CPT or HCPC codes covered:

Codes	Description	
19328	Removal of intact mammary implant	
19330	Removal of mammary implant material	
19371	Periprosthetic capsulectomy, breast	
L8020, L8030, L8031,	Breast prosthesis	
L8032, L8035, L8039		
L8600	Implantable breast prosthesis, silicone or equal	

VIII. Annual Review History

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Review Date	Revisions	Effective Date	
03/2013	Annual Review: Added table with review date, revisions, and	04/03/2013	
	effective date.		
03/2014	Annual Review: No change	04/03/2014	
04/2015	Annual Review: No change	04/01/2015	
05/2016	Annual Review: Added separate section with Saline implant	05/22/2016	
	removal criteria		
05/24/2017	Annual Review: Updated to new template, removed Medical	05/24/2017	
	Director signature		
05/2018	Annual Review:	05/23/2018	
05/2019	Annual Review: Clarified the medical treatment with an indication	06/01/2019	
	that if breast cancer is associated with anaplastic large cell		
	lymphoma then it meets criteria		
05/2020	Annual Review: Grammar updates. No content changes	06/01/2020	
05/2021	Annual Review: No content change	06/01/2021	
06/2022	Annual Review: updated guidelines for breast implant removal.	07/01/2022	
	Added, removal of cosmetically placed ruptured saline implants is		
	considered not medically necessary		
06/2023	Annual Review: No changes	07/01/2023	
06/2024	Annual Review: Grammar updates	07/01/2024	

IX. References

- 1. Alfano, C, Mazzocchi, M Scuderi N. Mammary compliance: an objective measurement of capsular contracture. Aesthetic Plastic Surgery. 2004 Mar-Apr;25(2):75-9.
- 2. American Society of Plastic Surgeon (ASPS). Practice Parameter. Treatment principles of silicone breast implants. March 2005. Accessed May 19, 2017 at: Available at URL address: http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/evidence-practice/TreatmentPrinciplesofSiliconeBreastImplants.pdf

- 3. American Society of Plastic Surgeons (ASPS). Breast Implants. May 21, 2012.at: Available at URL address: accessed 05/2017 http://www.surgery.org/consumers/procedures/breast/breast-implants
- 4. American Society of Plastic Surgeons Guidelines Committee. Explanation of breast implants.
- 5. Brinton LA, Buckley LM, Dvorkina O, Lubin JH, Colton T, Murray MC, et al. Risk of connective tissue disorders among breast implant patients. Am J Epidemiol. 2004 Oct 1;160(7):619–27.
- 6. Brown, SL, Silverman, BG, Berg, WA. Rupture of silicone-gel breast implants: causes, sequelae, and diagnosis. The Lancet 1997; 350:1531-37.
- 7. Chun JK, Schulman MR. The infected breast prosthesis after mastectomy reconstruction: successful salvage of nine implants in eight consecutive patients. Plast Reconstr Surg. 2007 Sep;120(3):581-9.
- 8. Fryzek JP, Signorello LB, Hakelius L, Lipworth L, McLaughlin JK. Local complications and subsequent reporting among women with cosmetic breast implants. Plast Reconstr Surg. 2001 Jan;107(1):214–21.
- 9. Gabriel, SE, et al. Complications leading to surgery after breast implantation. N Eng J Med. 1997 Mar; 336:667-682.
- 10. Henriksen TF, Holmich LR, Fryzek JP, et al. Incidence and severity of short-term complications after breast augmentation: results from a nationwide breast implant registry. Ann Plast Surg. 2003 Dec;51(6):531-9.
- 11. Janowsky EC, Kupper LL, Hulka BS. Meta-analysis of the relation between silicone breast implants and the risk of connective tissue diseases. N Engl J Med. 2000;342(11):781-790.
- 12. Lipworth L, Holmich LR, McLaughlin JK. Silicone breast implants and connective tissue disease: no association. <u>Semin Immunopathol.</u> 2011 May;33(3):287-94. Epub 2011 Jan 10.
- 13. McIntosh SA, Horgan K. Breast cancer following augmentation mammoplasty a review of its impact on prognosis and management. J Plast Reconstr Aesthet Surg. 2007;60(10):1127-1135.
- 14. McLaughlin JK, Lipworth L, Murphy DK, Walker PS. The safety of silicone gel-filled breast implants: a review of the epidemiologic evidence. Ann Plast Surg. 2007 Nov;59(5):569-80.
- 15. Sampedro MF, Patel R. Infections associated with long-term prosthetic devices. Infect Dis Clin North Am. 2007 Sep;21(3):785-819, x.
- 16. Scaranelo AM, Marques AF, Smialowski EB, Lederman HM. Evaluation of the rupture of silicone breast implants by mammography, ultrasonography and magnetic resonance imaging in asymptomatic patients: correlation with surgical findings. Sao Paulo Med J. 2004 Mar 4;122(2):41–7. Epub 2004 Jul 5.
- 17. Spears SL, Howard MA, Boehmler JH, et al. The infected or exposed breast implant: management and treatment strategies. Plastic Reconstructive Surgery. 2004 May;113(6):1634-44.
- 18. The National Guideline Clearinghouse at www.guideline.gov
- 19. Tuli R, Flynn RA, Brill KL, et al. Diagnosis, treatment, and management of breast cancer in previously augmented women. Breast J. 2006;12(4):343-348.
- 20. U.S. Food and Drug Administration (FDA). Breast implant complications: potential local complications and reoperations. September 2, 2010. Accessed May 21, 2012.at: Available at URL address:
 - http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM259894.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=breast implants complications & utm_content=3

- 21. Centers for Medicare & Medicaid Services; Local Coverage Determination (LCD): External Breast Prostheses (L33317); Noridian Healthcare Solutions, Effective date 10/01/2015, Revision effective Date 01/01/2017; Accessed 05/19/2017
- 22. Physician Advisors

Appendix 1 – Covered Diagnosis Codes

ICD 10 code	ICD 10 Code Description	
C50.011	Malignant neoplasm of nipple and areola, right female breast	
C50.012	Malignant neoplasm of nipple and areola, left female breast	
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast	
C50.111	Malignant neoplasm of central portion of right female breast	
C50.112	Malignant neoplasm of central portion of left female breast	
C50.119	Malignant neoplasm of central portion of unspecified female breast	
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast	
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast	
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast	
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast	
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast	
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast	
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast	
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast	
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast	
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast	
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast	
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast	
C50.611	Malignant neoplasm of axillary tail of right female breast	
C50.612	Malignant neoplasm of axillary tail of left female breast	
C50.619	Malignant neoplasm of axillary tail of unspecified female breast	
C50.811	Malignant neoplasm of overlapping sites of right female breast	
C50.812	Malignant neoplasm of overlapping sites of left female breast	
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast	
C50.911	Malignant neoplasm of unspecified site of right female breast	
C50.912	Malignant neoplasm of unspecified site of left female breast	
C50.919	Malignant neoplasm of unspecified site of unspecified female breast	
C50.812	Malignant neoplasm of overlapping sites of left female breast	
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast	
C50.911	Malignant neoplasm of unspecified site of right female breast	
C50.912	Malignant neoplasm of unspecified site of left female breast	
C50.919	Malignant neoplasm of unspecified site of unspecified female breast	
D48.61	Neoplasm of uncertain behavior of right breast	
D48.62	Neoplasm of uncertain behavior of left breast	
N64.4	Mastodynia	

N63	Unspecified lump in breast	
N64.51	Induration of breast	
N64.53	Retraction of nipple	
N64.59	Other signs and symptoms in breast	
N64.81	Ptosis of breast	
N64.89	Other specified disorders of breast	
N64.89	Other specified disorders of breast	
N64.9	Disorder of breast, unspecified	
N65.0	Deformity of reconstructed breast	
N65.1	Disproportion of reconstructed breast	
Z85.3	Personal history of malignant neoplasm of breast	
Z80.3	Family history of malignant neoplasm of breast	
Z90.11	Acquired absence of right breast and nipple	
Z90.12	Acquired absence of left breast and nipple	
Z90.13	Acquired absence of bilateral breasts and nipples	
Z90.11	Acquired absence of right breast and nipple	
T85.41XA	Breakdown (mechanical) of breast prosthesis and implant, initial encounter	
T85.42XA	Displacement of breast prosthesis and implant, initial encounter	
T85.43XA	Leakage of breast prosthesis and implant, initial encounter	
T85.44XA	Capsular contracture of breast implant, initial encounter	
T85.49XA	Other mechanical complication of breast prosthesis and implant, initial encounter	
T85.79XA	Infection and inflammatory reaction due to other internal prosthetic devices,	
	implants and grafts, initial encounter	

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):		
Noridian Local Coverage Determination L33317 External Breast Prosthesis			

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC