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Developed By: Medical Criteria Committee	

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Description:

Breast implants are placed as part of a reconstruction process following a 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.

Removal of implants for nonspecific, somatic complaints is not a covered benefit.

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 limitations and exclusions.

Criteria:

- I. ODS will provide coverage for breast implant removal when **one** of the following criteria is met:
 - A. Documented intra- or extra-capsular leakage of silicone implant; or
 - B. Persistent or recurrent local or systemic infection secondary to the breast implant that is refractory to medical treatment; or
 - C. Documentation of Baker Class III or IV contractures associated with severe pain; or
 - D. Extruded implant; or
 - E. Tissue necrosis secondary to the implant; or
 - F. The implant is interfering with diagnostic evaluation of a suspected breast cancer; or
 - G. Breast cancer

Note: For saline implants that were placed for cosmetic purposes, removal of the implants due to capsular leakage will not be covered unless one additional criteria listed above is met.

- II. For members whose implants were placed following a medically necessary mastectomy or lumpectomy, breast implant removal is also considered medically necessary for the 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.

Limitations:

- I. If breast implant removal is found to be medically necessary, the following will apply:
 - A. If the above criteria for breast implant removal is met unilaterally, ODS 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 removal of mammary implant material is also covered (CPT 19330).

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- C. ODS will pay only for the medically approved procedure(s). All contract exclusions apply.

Not Covered:

ODS 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

Reinsertion of Breast Implants:

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

Information to be Submitted with Pre-Authorization Request:

- A. Chart notes from the treating physician
- B. Report of MRI, mammogram, or ultrasound (if implant leakage is the reason for removal)

References:

- American Society of Plastic Surgeons Guidelines Committee. Explanation of breast implants. 1999.
- The National Guideline Clearinghouse at www.guideline.gov
- U.S. Food and Drug Administration. Breast Implant Risks. November 2000.
- Brown, SL, Silverman, BG, Berg, WA. Rupture of silicone-gel breast implants: causes, sequelae, and diagnosis. The Lancet 1997; 350:1531-37.
- Gabriel, SE, et al. Complications leading to surgery after breast implantation. N Eng J Med. 1997 Mar; 336:667-682.
- 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.
- 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.
- Alfano, C, Mazzocchi, M Scuderi N. Mammary compliance: an objective measurement of capsular contracture. Aesthetic Plastic Surgery. 2004 Mar-Apr;25(2):75-9.
- American Society of Plastic Surgeon (ASPS). Practice Parameter. Treatment principles of silicone breast implants. March 2005. Accessed September 28, 2006. Available at URL address: http://www.plasticsurgery.org/medical_professionals/Policy_Statements/Policy-Statements.cfm
- US Food and Drug Administration (FDA). Breast implant complications: potential local complications and reoperations. Updated 2005 Feb. Accessed September 28, 2006. Available at URL address: http://www.fda.gov/cdrh/breastimplants/breast_implant_risks_brochure.html.
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