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Subject: Breast Implant Removal  
Effective Date: May 4, 2009

Clinical Documentation and Prior Authorization Required	√	Type of Review - Case Management	
Not Covered		Type of Review – Precertification Department	√
		Administrative Process (Internal Use Only)	LPN

**Note:** Background, product, and disclaimer information is located at the end of this document.

### Overview

- Breast implant: A manufactured, silicone, prosthetic device, which is filled with sterile saline or silicone gel that is used for either breast augmentation or reconstruction.
- Baker's Classification (Spear and Baker, 1995) ranks the level of breast implant contracture on a scale (from I to IV) to determine results of implant surgery.
  - I. A soft, natural appearing breast.
  - II. An implant with mild firmness.
  - III. Moderate firmness - The breast is harder, the implant can be palpated easily, and it (or distortion from it) can be seen.
  - IV. A hard breast with obvious distortion, the breast is hard, tender, painful, and cold.

### Coverage Guidelines

- Tufts Health Plan may authorize coverage of the removal of a silicone gel-filled or a saline-filled breast implant for Members when **one** of the following criteria is met:
  - Screening or suspected diagnosis of breast cancer is not possible because of the implant.
  - The implant is interfering with the treatment of breast cancer.
  - The Member has persistent or recurrent local or systemic infection due to the presence of the breast implant that has been refractory to antibiotics.
  - The Member has a Baker Stage IV capsular contracture that is associated with pain, persistent infection refractory to antibiotics or is interfering with mammography.
  - The Member has tissue necrosis that is caused by the implant.
- Tufts Health Plan may authorize the coverage of the removal of a silicone gel-filled implant for Members when meeting **one** of the following criteria:
  - The implant is ruptured, as documented by mammography, ultrasound, or MRI.
  - The implant is considered extruded (the implant material has leaked beyond the fibrous capsule of the prosthesis).

### Limitations

- Tufts Health Plan will only cover the removal of a breast implant for indications listed above unless related to breast reconstruction for a Member following a mastectomy.

- The contralateral breast will be removed only when the clinical coverage criteria listed above are met.

## Codes

The following HCPCS/CPT code(s) require prior authorization:

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

## References

1. Spear, S.L., Baker, J.L. Classification of capsular contracture after prosthetic breast reconstruction. *Plastic Reconstructive Surgery*. 1995 Oct; 96(5):1119-23.

## Approval History

Reviewed by the Clinical Coverage Criteria Committee on September 15, 2006.

Subsequent Endorsement Date(s) and Changes Made:

- October 1, 2007: Reviewed and renewed, without changes
- March 26, 2008: Reviewed and renewed, without changes
- May 4, 2009: Reviewed and renewed, without changes

## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for Tufts Health Plan benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. Tufts Health Plan makes coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to all fully insured Tufts Health Plan products unless otherwise noted in this guideline or the Member's benefit document. This guideline does not apply to Tufts Health Plan Medicare Preferred or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. Providers in the New Hampshire service area are subject to CIGNA HealthCare's provider arrangement for the purpose of CareLink<sup>SM</sup>.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of

benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.