MEDICAL POLICY

Excellus

SUBJECT: MANAGEMENT OF BREAST IMPLANTS	EFFECTIVE DATE: 12/16/99 REVISED DATE: 01/24/02, 03/06/02, 01/23/03, 02/26/04, 02/24/05, 02/23/06, 02/22/07, 02/28/08, 02/26/09, 02/25/10, 02/24/11, 02/27/12, 02/28/13, 02/27/14
POLICY NUMBER: 7.01.19 CATEGORY: Cosmetic	PAGE: 1 OF: 5

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

The following situations describe different types of breast surgery and establish criteria for the removal of the breast implant based upon whether the original implant was placed for cosmetic or reconstructive reasons.

I. Based upon our criteria and review of the peer-reviewed literature, the following medical indications for removal of breast implants are **medically appropriate** and include, but are not limited to:
   A. Rupture of either a saline or silicone implant. Rupture of a silicone breast implant should be identified through magnetic resonance imaging (MRI).
   B. Baker Class IV contracture,
   C. Recurrent infection with respect to the implant,
   D. Extruded implant, where there is skin breakdown with the implant appearing through the skin, or
   E. Post-surgical reconstruction with breast implants following surgery for breast cancer (e.g., mastectomy).

II. Based upon our criteria and review of the peer-reviewed literature, removal of a breast implant associated with a Baker Class III contracture following *reconstructive* surgery with implants is **medically appropriate**.

III. Based upon our criteria and review of the peer-reviewed literature, the following indications for removal of implants are **not medically necessary**:
   A. Systemic symptoms (e.g., connective tissue diseases, autoimmune disease, rheumatic conditions, neurologic symptoms, fibromyalgia, chronic fatigue syndrome);
   B. Patient anxiety;
   C. Baker Class III contracture following *cosmetic* surgery with implant(s) as these contractures do not interfere with mammography and are not painful; or
   D. Pain not related to contractures or rupture.

IV. Based upon our criteria and review of the peer-reviewed literature, post silicone or saline implant removal procedures (e.g., reimplantation of implants, autologous reconstruction) following:
   A. *Reconstructive* surgery is **medically appropriate**.
   B. *Cosmetic* surgery is **not medically necessary**.

Refer to Corporate Medical Policy #6.01.35 regarding Magnetic Resonance Imaging of the Breast.

Refer to Corporate Medical Policy #7.01.11 regarding Cosmetic and Reconstructive Procedures.

Refer to Corporate Medical Policy #10.01.01 regarding Breast Reconstruction Surgery.

POLICY GUIDELINES:

I. If a medical condition results from cosmetic surgery, medically necessary services required to treat the medical condition will be considered **medically necessary**.

II. Common anticipated side effects of anesthesia (e.g., nausea, vomiting), which result in a prolonged hospital stay, are considered to be part of a cosmetic procedure and are **not medically necessary**.

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DESCRIPTION:

Silicone gel-filled or saline-filled breast implants are surgically implanted under the skin and muscle for reconstructive or cosmetic purposes. The most common reason for implants is as a result of breast cancer.

Local complications (e.g., contracture, rupture, extrusion, infection) may result from breast implants resulting in the need to explant, or remove, the implant. Over time, the implant may become dislodged and/or may leak their contents. The contents may disturb structures under the skin affecting patient safety and impairing the effectiveness of such treatments as mammography.

In 1992, the U.S. Food and Drug Administration (FDA) withdrew approval for silicone breast implants for cosmetic purposes due to the complaints that silicone implants were causing a variety of ailments, among them connective tissue disease. In November 2006, the FDA approved the marketing of silicone gel-filled breast implants manufactured by Allergan Corp. and Mentor Corp. for breast reconstruction in women of all ages and breast augmentation in women ages 22 and older. In March 2012, February 2013, and June 2013, the FDA approved the marketing of additional silicone breast implants with the same indications.

Contracture is the most common local complication of breast implants. Contractures have been graded according to the Baker Classification system as follows:

Grade	Physical Assessment
I	Breast normally soft and looks natural.
II	Breast is a little firm and looks normal.
III	Breast firm and looks abnormal (visible distortion).
IV	Breast hard, painful, and looks abnormal (greater distortion).

On January 26, 2011 the FDA published an analysis of findings that there may be an association between breast implants and a rare cancer, Anaplastic Large Cell Lymphoma (ALCL). The data reviewed by the FDA suggest that patients with breast implants may have a very small but significant risk of ALCL in the scar capsule adjacent to the implant. The FDA is working with the American Society of Plastic Surgeons and other experts to establish a breast implant patient registry. Most cases reviewed by the FDA were diagnosed when patients sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. These symptoms were due to collection of fluid (peri-implant seroma), hardening of breast area around the implant (capsular contracture), or masses surrounding the breast implant. The FDA is recommending that health care professionals and women pay close attention to breast implants through monitoring and reporting findings.

RATIONALE:

The FDA regulates the marketing of breast implants. Approved saline-filled and silicone gel-filled implants are currently marketable.

On November 17, 2006, the U.S. Food and Drug Administration (FDA) approved the marketing of silicone gel-filled breast implants made by two companies (Allergan Corp and Mentor Corp) for breast reconstruction in women of all ages and breast augmentation in women ages 22 and older. On March 9, 2012, the FDA approved the marketing of silicone breast implants with the same indications manufactured by Sientra, Inc. On February 20, 2013 the FDA approved the marketing of an additional silicone implant manufactured by Allergan, Inc. and on June 14, 2013 approved an additional implant manufactured by Mentor Worldwide LLC. These implants are said to have more cross-linking in the silicone gel. The implants are approved for the same indications as the previously approved implants and require continued study by the manufacturers.

The FDA approved the silicone gel-filled breast implants with a number of conditions, including requiring each company to: conduct a large post-approval study; continue its core study through 10 years; conduct a focus group study

of the patient labeling; continue laboratory studies to further characterize types of device failure; and track each implant in the event, for example, that health professionals and patients need to be notified of updated product information.

Post-approval studies continue to gather information about the safety and effectiveness of the implants; including rates of local complications; rates of connective tissue and neurological disease and related signs and symptoms; potential effects on reproduction, lactation, and offspring of women with breast implants; rates of cancer and suicide; potential interference of breast implants with mammography; and MRI compliance and rupture rates.

Literature demonstrates that silicone breast implants have an increasing rupture rate with time. This appears to be due to the design of the implant, such as shell thickness and strength. The older implants, second generation implants used during the 1970s, have a more frequent rate of rupture, which correlates with the length of time and design.

According to the FDA and the Institutes of Medicine (IOM) it is likely women with breast implants will need additional surgical procedure(s) sometime within their lifetime due to complications from the implants. Other important factors women should consider when deciding whether to get silicone gel-filled breast implants are: many of the changes to a woman's breast following implantation are irreversible; rupture of a silicone gel-filled breast implant is most often silent; and a woman will need regular screening MRI examinations over her lifetime to determine if silent rupture has occurred. The device labeling states that a woman should have her first MRI three years after her initial implant surgery and then every two years thereafter and if implant rupture is noted on an MRI, the implant should be removed. The FDA advises that women who are not experiencing problems with their implant(s) do not need to have the implant(s) removed.

CODES:	Number	Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	19328	Removal of intact mammary implant
	19330	Removal of mammary implant material
	19370	Open periprosthetic capsulotomy, breast
	19371	Periprosthetic capsulectomy, breast

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HCPCS:	L8600	Implantable breast prosthesis, silicone or equal
ICD9:	174-174.9	Malignant neoplasm of female breast (code range)
	233.0	Carcinoma in situ of breast
	996.54	Mechanical complications due to breast prosthesis
	996.69	Infection and inflammatory reaction due to other internal prosthetic device, implant, graft (includes breast prosthesis)
	996.79	Other complications due to internal prosthetic device, implant, and graft
	V10.3	Personal history of malignant neoplasm of breast
ICD10:	C50.011-C50.019	Malignant neoplasm of nipple and areola (code range)
	C50.111-C50.119	Malignant neoplasm of central portion of female breast (code range)
	C50.211-C50.219	Malignant neoplasm of upper-inner quadrant of female breast (code range)

C50.311-C50.319	Malignant neoplasm of lower-inner quadrant of female breast (code range)
C50.411-C50.419	Malignant neoplasm of upper-outer quadrant of female breast (code range)
C50.511-C50.519	Malignant neoplasm of lower-outer quadrant of female breast (code range)
C50.611-C50.619	Malignant neoplasm of axillary tail of female breast (code range)
C50.811-C50.819	Malignant neoplasm of overlapping sites of female breast (code range)
C50.911-C50.919	Malignant neoplasm of unspecified site of female breast (code range)
D05.00-D05.92	Carcinoma in situ of breast (code range)
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
T85.82xA	Fibrosis due to internal prosthetic devices, implants and grafts, not elsewhere classified, initial encounter
T85.83xA	Hemorrhage due to internal prosthetic devices, implants and grafts, not elsewhere classified, initial encounter
T85.84xA	Pain due to internal prosthetic devices, implants and grafts, not elsewhere classified, initial encounter
T85.86xA	Thrombosis due to internal prosthetic devices, implants and grafts, not elsewhere classified, initial encounter
T85.89XA	Other specified complication of internal prosthetic devices, implants and grafts, not elsewhere classified, initial encounter
Z85.3	Personal history of malignant neoplasm of breast

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KEY WORDS:

Breast Implants, Implants, Saline Implants, Silicone Implants.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, management of breast implants is not addressed in National or Local Medicare coverage determinations or policies.