

Subject: Breast Implant Removal
Number: 0048

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INSTRUCTIONS FOR USE

This Medical Necessity Guideline outlines the factors CareAllies considers in determining medical necessity for this indication. Please note, the terms of a participant's particular benefit plan document or summary plan description (SPD) may differ significantly from the standard upon which this Medical Necessity Guideline is based. For example, a participant's benefit plan document or SPD may contain a specific exclusion related to the topic addressed. In the event of a conflict, a participant's benefit plan document or SPD always supercedes the information in this Medical Necessity Guideline. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document or SPD. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document or SPD in effect on the date of service; 2) any applicable laws/regulations, and; 3) the specific facts of the particular situation. Medical Necessity Guidelines are not recommendations for treatment and should never be used as treatment guidelines. ©2007 Intracorp/CareAllies

Breast reconstruction following mastectomy or lumpectomy is governed by Federal and/or State mandates.

The removal of a silicone gel-filled breast implant is considered medically necessary when rupture of the implant and/or extrusion of the implant contents have been confirmed on imaging studies (i.e., mammography, ultrasound, or magnetic resonance imaging [MRI]).

The removal of EITHER a silicone gel-filled OR saline-filled breast implant is considered medically necessary for at least ONE of the following indications:

- **The implant is interfering with ANY of the following:**
 - breast cancer screening in an individual considered at high risk[†]
 - diagnostic evaluation of a suspected breast cancer
 - adequate treatment of known breast cancer (e.g., obstructing radiation therapy)
- **The patient is experiencing ANY of the following:**
 - persistent or recurrent local or systemic infection secondary to a breast implant refractory to medical management including antibiotics
 - Baker Stage IV capsular contracture causing pain, persistent infection refractory to medical management, or interference with standard breast cancer screening
 - tissue necrosis secondary to the implant

The removal of an intact silicone gel-filled breast implant is considered experimental, investigational or unproven and thus not medically necessary when performed solely for suspected autoimmune disease or connective tissue disease or breast cancer prevention.

The following are considered not medically necessary unless associated with breast reconstruction following mastectomy or lumpectomy:

- removal of a ruptured saline-filled implant in the absence of one of the indications listed above
- removal of any type of breast implant performed solely to treat psychological symptomatology or psychosocial complaints
- removal of any type of breast implant performed solely because of shifting or migration of the implant
- removal of any type of breast implant performed solely to improve appearance

Following removal of a breast implant, the subsequent surgical implantation of a new U.S. Food and Drug Administration (FDA)-approved breast implant is considered medically necessary for EITHER of the following:

- breast reconstruction of a diseased or affected breast following mastectomy or lumpectomy
 - creation of a symmetrical appearance in the contralateral/nondiseased breast following mastectomy or lumpectomy in the opposite breast
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General Background

Breast implants vary in shell surface (e.g., smooth vs. textured), shape (e.g., round or shaped), profile (i.e., how far it protrudes), volume (i.e., size) and shell thickness. The primary components of most breast implants are a shell, otherwise known as the envelope or lumen, filler (e.g., saline, silicone gel or alternative) and a patch to cover the manufacturing hole.

While most breast implants are single lumen (i.e., shell only), some breast implants are double lumen (i.e., one shell inside the other). Some breast implants are manufactured with a fixed volume or filler; some are filled during surgery; and some allow for adjustments of the filler volume after implantation.

Breast implants are typically inserted under local or general anesthesia in an outpatient setting. If the procedure is done for cosmetic reasons, the incision is most commonly made along the lower edge of the areola, in the axilla or in the inframammary fold. For postmastectomy reconstruction, the surgical incision is used, and the implant is placed either deep in the breast on the pectoral fascia (i.e., submammary) or beneath the pectoralis major.

Surgical complications associated with breast implantation are similar to those encountered with other breast surgeries: infection, bleeding, change in nipple sensation (e.g., hypersensitivity or hyposensitivity), malposition, delayed healing, and anesthetic accidents.

Although implantable breast prostheses may be inserted for either reconstructive or cosmetic reasons, clinically significant post-implant complications may occur, necessitating removal of the implants. Local complications associated with implanted breast prostheses include: capsular contracture, persistent infection, silicone implant extrusion, tissue necrosis and silicone implant rupture. These conditions, when they become clinically significant, may require removal of the implant. Additionally, the presence of an implant may interfere with the diagnosis or treatment of breast cancer. Infections that may occur in or around an implant include wound infections, as well as infections within a capsular contracture or as a result of a ruptured implant. Removal of the implant may be necessary when the infection does not respond to antibiotics. Unstable or weakened tissue and/or interruption in wound healing may result in the implant breaking through the skin or extrusion. Necrotic tissue may form around the implant, requiring implant removal. Silicone gel-filled implant rupture may cause the contents to leak into the surrounding tissues.

U.S. Food and Drug Administration (FDA)

The FDA has approved four breast implants for marketing in the U.S. In May 2000, Mentor Corp., Santa Barbara, CA and Allergan Corp. (formerly Inamed), Irvine, CA received premarket approval for saline-filled breast implants. These implants were approved for breast augmentation in women age 18 or older and for breast reconstruction in women of any age (FDA, 2006a).

In November 2006, Allergan and Mentor received premarket approval for their silicone gel-filled breast implants (i.e., Inamed[®] Silicone-Filled Breast Implants and Mentor MemoryGel[™] Silicone Gel-Filled Breast Implants). These implants were approved for breast augmentation in women age 22 or older and for breast reconstruction in women of any age. All breast implants other than these four approved devices are considered investigational devices, including the more-cohesive ("gummy bear") implants. For a patient to receive an investigational breast implant in the U.S., they must enroll in a clinical study (FDA, 2006a).

The FDA labeling for silicone and saline breast implantation states breast implant surgery should not be performed in women with: an active infection, existing cancer or precancer of a breast that has not been adequately treated, or who are pregnant or nursing (FDA, 2006b).

As a part of the premarket approval, the FDA is requiring the manufacturers of silicone breast implants to comply with the following conditions (FDA, 2006a):

- Continue their core studies until all patients have completed their 10-year evaluation in order to assess the long-term clinical performance of their products. This involves:
 - collecting data via annual physician follow-up evaluations
 - giving all patients MRIs every other year
 - evaluating all patients whose breast implants were removed without replacement through 10 years.
- Conduct separate 10-year large post-approval studies that will:
 - involve a large number of silicone gel-filled breast implant patients (approximately 40,000)
 - involve a control group of saline-filled breast implant patients
 - provide information about certain endpoints: local complications; rates of connective tissue disease and its signs and symptoms; rates of neurological disease and its signs and symptoms; potential effects on offspring of women with breast implants; potential effects on reproduction and lactation; rates of cancer; rates of suicide; potential interference of breast implants with mammography; and patient compliance with MRI recommendation and rupture rates
 - survey patients annually using web, mail, or telephone questionnaires
 - have physician evaluations at years one, 4–6, and 9–10 for Mentor and years one, four, and 10 for Allergan to collect local complication data.
- Continue their laboratory studies to continue to further characterize the modes and causes of failure of explanted devices over a 10-year period.
- Have an independent group conduct a focus group study of the format and content of the approved patient labeling.
- Distribute approved patient labeling to women considering silicone gel-filled breast implants as part of a formal informed decision process, and monitor the process to ensure that patients are being informed of the risks and benefits.
- Stop new patient enrollment into the adjunct studies and continue to follow all currently-enrolled patients through the final five-year study time point.
- Require participation in the company's physician training program for physician access to the product.
- Comply with FDA's requirements for tracking these devices from their manufacture through the distribution chain to implantation.

The FDA intends to present an update on the status of the conditions of approval at public Advisory Panel meetings in five and 10 years, and at any other time the FDA decides is appropriate.

Implant Rupture and Deflation

Breast implants are not considered lifetime devices. Trauma is a common cause of rupture. Some implants will spontaneously deflate or rupture immediately after implantation; some will deflate over time, while others may remain intact for 10 or more years following surgery.

Silicone Gel-Filled Implant Rupture: Silicone gel-filled implants may rupture as the result of the age of the implant, the presence of a capsular contracture, or trauma. When silicone gel-filled implants rupture, a patient may experience decreased breast size, nodules, asymmetrical appearance of the breasts, pain, tenderness, swelling, tingling or numbness. Other ruptures may be completely asymptomatic (i.e., silent ruptures). Silicone gel that extrudes beyond the reactive fibrotic capsule (i.e., extracapsular rupture) that forms surrounding the implant may migrate away from the breast. The free, migrated silicone may result in the formation of granulomas in the breast or other areas such as the chest wall or axillae. Some granulomas can migrate to lymph nodes in the axillae and may even mimic cancer. Extruded silicone gel that is contained within the fibrotic capsule is referred to as an intracapsular rupture.

Conflicting data exists in the published, peer-reviewed scientific literature regarding the clinical significance of extracapsular silicone from the extracapsular rupture of a silicone gel-filled breast implant rupture. There is some limited evidence to suggest (Brown, et al., 2001) that there may be a correlation between extracapsular silicone from ruptured silicone breast implants and the subsequent development of fibromyalgia. The hypothesis of an increased risk of fibromyalgia was not confirmed in a study by Holmich et al. (2003). Although there remains uncertainty regarding the role that the presence of intra- or extracapsular silicone gel-filled breast implant ruptures play in the development of systemic disease, the FDA and general expert consensus have indicated that explantation of both extracapsular and intracapsular ruptured silicone gel-filled breast implants is generally recommended for all patients.

In 2001, the FDA completed a study on the health effects of ruptured silicone gel breast implants. The goal of this study was to determine if a correlation exists between loose silicone that migrates into the tissue and the development or progression of collagen vascular disease. A total of 343 women volunteered to participate in this study via a questionnaire concerning joint pain, swelling or stiffness, rash on the breasts and chest, and fatigue. These participants were also questioned about being diagnosed with any illnesses such as scleroderma, fibromyalgia, chronic fatigue syndrome or lupus. All participants underwent magnetic resonance imaging (MRI) to determine if their implants were intact or ruptured with extruded silicone gel. This study concluded that, for women who reported fibromyalgia, MRI did confirm that silicone gel had consistently extruded outside of the fibrous scar.

MRI may be used to view the prosthesis in the breast and assist in determining if leakage of the materials has occurred. As compared to other imaging modalities (e.g., mammography and ultrasound), MRI has been reported to be the most sensitive, especially in the detection of leakage from a silicone gel-filled implant.

Saline-Filled Implant Rupture: Saline-filled breast implants may deflate or rupture when saline solution leaks through an unsealed or damaged valve or through a break in the implant shell. Implant deflation may occur in the immediate postoperative period or slowly develop over a period of time. An alteration in the appearance of the breast may result; however, the presence of a ruptured or leaking saline-filled implant does not lead to any medical complications that require intervention, such as removal of the implant. The leakage or rupture of a saline-filled breast implant, in the absence of other signs or symptoms (e.g., significant capsular contracture or persistent infection), is not a medically necessary indication to undergo breast implant removal.

Periprosthetic Capsular Contracture

Capsular contracture occurs when the scar tissue or capsule that normally forms around the implant tightens, ultimately squeezing the implant. Significant contracture may result in severe pain or may be associated with subclinical infection. The presence of a contracture may also interfere with the ability to diagnose or treat breast cancer. The degree of periprosthetic contracture is often classified by using the Baker grading system. The four Baker classes/stages are as follows:

- **Grade I:** breast absolutely natural; augmentation not apparent on observation
- **Grade II:** minimum contracture; augmentation apparent on observation, but the patient has no complaints
- **Grade III:** moderate contracture; patient feels some firmness
- **Grade IV:** severe contracture; obvious on observation

Treatment of clinically significant contractures (i.e., Baker grade/stage IV) can range from removing the capsular tissue (e.g., capsulotomy or capsulectomy) to removal of the implant itself. Infections that occur due to the presence of a breast implant rupture and/or capsular contracture are typically treated with antibiotics.

The pathogenesis of fibrous capsular contracture after breast augmentation with implants is still under debate. In a prospective study by Pajkos et al. (2003), biofilm, in particular, *S. epidermis* biofilm, was found in a significant proportion of patients with capsular contracture.

In 1992, Mentor followed patients in a three-year prospective study to assess all complications associated with saline-filled implants. A total of 1264 augmentation patients and 428 reconstruction patients were followed annually. Nine percent of breast augmentation patients and 30% of patients with reconstructed breasts developed capsular contractures.

Autoimmune Diseases, Connective Tissue Diseases, Breast Cancer and the Presence of Intact Breast Implants

In the early 1980s, reports suggested an association between silicone breast implants and various connective tissue diseases, but only limited analytic epidemiological data addressing this hypothesis were available at the time. As a consequence, in 1992, the FDA banned the use of silicone breast implants, restricting them to breast cancer reconstructive surgery in a strictly controlled clinical trial. In November 2006, after further scientific review, the FDA lifted their ban on silicone breast implants, approving the use of silicone implants for breast reconstruction for women of any age and for breast augmentation for women age 22 years or older.

The American Academy of Neurology, the American College of Surgeons, the American College of Rheumatology, the American Medical Association, the American Society of Plastic Surgeons and the American Society of Clinical Oncology all agree with the findings of a 2000 study of 13,500 women researched by the National Cancer Institute. This study found no correlation between breast implants and the development of connective or autoimmune disease or an increase in breast cancer risk.

Hennekens et al. (1996) conducted a large retrospective study on the past experiences of women with breast implants. Almost 400,000 women, nearly 11,000 with breast implants, completed the patient questionnaire. The study showed that, over 10 years, women with breast implants were 24% more likely to report a connective tissue disease (CTD) or other disorder. When these calculations include all participants, women with and without breast implants, the risk was not statistically significant.

A review of epidemiological evidence by Lipworth et al. (2004) concluded that the most recent epidemiological investigations have been remarkably consistent with earlier epidemiological studies in finding no evidence of an excess of any individual CTD or all CTDs combined, including both established and atypical or undefined CTD, among women with cosmetic silicone breast implants.

Implant Shifting

Some implants may shift or move over time while remaining intact. Aside from the potential for an untoward cosmetic appearance, implant shifting does not lead to any medical complications that require intervention, such as removal of the implant. Implant shifting, in the absence of other signs or symptoms such as significant capsular contracture, persistent infection, or rupture of a silicone gel-filled implant, is not a medically necessary indication to undergo breast implant removal.

Summary

Implantable breast prostheses may be inserted for either reconstructive or cosmetic reasons. Clinically significant post-implant complications may occur, necessitating removal of the implants. The breast implants may require explantation due to interference with the diagnosis and treatment of breast cancer. The peer-reviewed scientific literature and consensus from professional societies have concluded there is no correlation between breast implants and the development of connective tissue disease, autoimmune disease or an increase in breast cancer risk. Re-implantation of a U.S. Food and Drug Administration (FDA)-approved breast implant is limited to patients who had the original breast implant as part of a breast reconstruction procedure following a mastectomy or lumpectomy.

† **According to the National Cancer Institute, the following are risk factors for breast cancer (National Cancer Institute, 2005):**

- **Age:** A woman over age 60 is at greater risk.
- **Personal history of breast cancer:** A woman who has had breast cancer in one breast has an increased risk of getting this disease in her other breast.
- **Family history:** A woman's risk of breast cancer is higher if her mother, sister or daughter had breast cancer, especially at a young age (before age 40).
- **Certain breast changes:** Having certain types of abnormal cells (i.e., atypical hyperplasia or lobular carcinoma in situ [LCIS]) increases risk.
- **Genetic alterations:** Changes in certain genes (BRCA1, BRCA2 and others) increases risk.
- **Reproductive and menstrual history:**
 - The older a woman is when she has her first child, the greater her chance of breast cancer.
 - Women who began menstruation at an early age (i.e., before age 12), went through menopause late (i.e., after age 55) or never had children are at increased risk.
 - Risk increases for women who take menopausal hormone therapy (either estrogen alone or estrogen plus progestin) for five or more years after menopause
- **Race:** Breast cancer occurs more often in white women than in Latina, Asian or African-American women.
- **Radiation therapy to the chest:** Women who have had radiation therapy to the chest (including breasts) before age 30 are at increased risk. This includes radiation for Hodgkin's lymphoma.
- **Breast density:** Older women who have mostly dense (not fatty) tissue on a mammogram are at increased risk.
- **Taking DES (diethylstilbestrol):** DES is a synthetic form of estrogen that was given to some pregnant women in the United States between about 1940 and 1971.
- **Being obese after menopause:** Because the body makes some of its estrogen (a hormone) in fatty tissue, obese women are more likely than thin women to have higher levels of estrogen in their bodies. High levels of estrogen may be the reason that obese women have an increased risk of breast cancer.
- **Physical inactivity:** Women who are physically inactive throughout life appear to have an increased risk of breast cancer. Being physically active may help to reduce risk by preventing weight gain and obesity.
- **Alcoholic beverages:** Some studies suggest that the more alcoholic beverages a woman drinks, the greater her risk of breast cancer.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

When medically necessary:

CPT®* Codes	Description
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
174.0-174.9	Malignant neoplasm of female breast
198.81	Secondary malignant neoplasm of other specified sites; breast
233.0	Carcinoma in situ of breast
611.0	Inflammatory disease of the breast
611.71	Mastodynia
728.82	Foreign body granuloma of the muscle
996.54	Complications due to breast prosthesis
996.69	Infections and inflammatory reaction due to breast prosthesis
996.79	Other complications due to prosthetic device, implant and graft
V10.3	Personal history of malignant neoplasm; breast
V45.71	Acquired absence of breast
V45.83	Breast implant removal status
V50.41	Prophylactic organ removal: breast
V51	Aftercare involving plastic surgery
V52.4	Fitting and adjustment of breast prosthesis and implant

***Current Procedural Terminology (CPT®) © 2006 American Medical Association: Chicago, IL.**

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