



# Cigna Medical Coverage Policy

Effective Date ..... 2/15/2014  
Next Review Date ..... 2/15/2015  
Coverage Policy Number ..... 0048

## Subject Breast Implant Removal

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### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

### Coverage Policy

Coverage of breast implant removal is dependent upon benefit plan language, may be subject to the provisions of a cosmetic, reconstructive surgery or breast reconstruction benefit, and may be governed by federal and/or state mandates. Please refer to the applicable benefit plan language and federal mandates to determine the terms and conditions of coverage.

Cigna covers removal of either a saline-filled OR silicone gel-filled breast implant when associated with breast reconstruction following mastectomy or lumpectomy for ANY indication, including for the purpose of producing a symmetrical appearance of the nondiseased breast.

Cigna covers the removal of a silicone gel-filled breast implant with or without capsulectomy as 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]).

Cigna covers the removal of EITHER a silicone gel-filled OR saline-filled breast implant as medically necessary for at least ONE of the following indications:

- The implant is interfering with EITHER of the following:
  - diagnostic evaluation of a suspected breast cancer
  - adequate treatment of known breast cancer (e.g., obstructing radiation therapy)

- **The individual 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 resulting in ONE of the following:
    - pain
    - persistent infection refractory to medical management
    - interference with standard breast cancer screening
  - tissue necrosis secondary to the implant

**Cigna does not cover removal of an intact silicone gel-filled breast implant when performed solely for suspected autoimmune disease or connective tissue disease or breast cancer prevention, because these indications are considered experimental, investigational or unproven.**

**Cigna does not cover ANY of the following because each is considered not medically necessary and/or cosmetic 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 when performed for ANY of the following:
  - solely to treat psychological symptomatology or psychosocial complaints
  - solely to improve appearance
  - solely because of shifting or migration of the implant
  - removal of the implant in the opposite/contralateral breast, unless criteria are otherwise met for that breast implant
  - for any other indication not otherwise mentioned above as covered
- replacement of an implant following removal
- capsulectomy when associated with removal of a saline-filled implant

**Following removal of a breast implant, Cigna covers the subsequent surgical implantation of a new U.S. Food and Drug Administration (FDA)-approved breast implant as 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 versus 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)**

In the FDA labeling for approved breast implants Mentor™ Corp., Santa Barbara, CA, Allergan™ Corp. (formerly Inamed™), Irvine, CA and Sientra™, Inc., Santa Barbara, CA are listed as manufacturers of silicone and saline breast implants.

FDA-approved saline-filled implants:

- Allergan Medical RTV Saline-Filled Breast Implant
- Mentor Saline-Filled and Spectrum® Breast Implants

The FDA approved saline-filled breast implants for breast augmentation in women age 18 or older and for breast reconstruction in women of any age. They are also used in revision surgeries, which correct or improve the result of an original surgery.

FDA-approved silicone gel-filled breast implants:

- Allergan Natrelle®
- Allergan Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant
- Mentor MemoryGel®
- Mentor MemoryShape®
- Sientra Silicone Gel Breast Implant

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.

In June 2011 the FDA released a report updating the clinical and scientific information for silicone gel-filled breast implants, including preliminary safety data from studies conducted by the manufacturers as a condition of their November 2006 approval. The conclusion in the report states that, "Based on the totality of the evidence, the FDA believes that silicone gel-filled breast implants have a reasonable assurance of safety and effectiveness when used as labeled. Despite frequent local complications and adverse outcomes, the benefits and risks of breast implants are sufficiently well understood for women to make informed decisions about their use. Manufacturers and physicians should continue to provide balanced and up-to-date information to women considering breast implants to help inform their decisions" (FDA, 2011).

#### **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.

MRI may be used to view the prosthesis in the breast and assist in determining if leakage of the materials has occurred. MRI may be medically necessary to confirm suspected silicone gel-filled breast implant rupture when this diagnosis cannot be confirmed by mammography or breast ultrasound.

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. (2004). 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 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.

### **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 capsulectomy and breast implant removal.

### **Periprosthetic Capsular Contracture**

When a breast implant is inserted, a scar capsule forms around it as part of the natural healing process. 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., 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. epidermidis* 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.

### **Anaplastic Large Cell Lymphoma (ALCL)**

In 2011 the FDA published preliminary FDA findings and analyses of anaplastic large cell lymphoma (ALCL) in women with breast implants. As part of its analysis, the FDA conducted a thorough review of scientific literature published from January 1997 through May 2010. From this review, the FDA identified 34 unique cases of ALCL in women with breast implants throughout the world. In total, the FDA is aware of approximately 60 case reports of ALCL in women with breast implants worldwide. This number is difficult to verify because not all cases were published in the scientific literature. Some cases have been identified through the FDA's contact with other regulatory authorities, scientific experts, and breast implant manufacturers, and it is not clear how many of these are duplicates of the ones found in the literature. The number of identified cases is small compared to the estimated 5-10 million women who have received breast implants worldwide. But based on these data, the FDA believes that women with breast implants may have a very small but increased risk of ALCL. Because the risk of ALCL appears very small, FDA believes that the totality of evidence continues to support a reasonable assurance that FDA-approved breast implants are safe and effective when used as labeled (FDA, 2011c).

Kim et al. (2011) conducted a systematic literature review to identify and analyze all reported cases of non-Hodgkin's lymphoma occurring in patients with breast implants. The total number of articles included in the analysis was 34 which included 36 cases of ALCL and other non-Hodgkin's lymphomas involving the breast: 29 (81%) were ALCL. Although detailed clinical information was lacking in many cases, ALCL often involved the capsule and/or presented as an unexplained seroma or mass, was negative for anaplastic lymphoma kinase (ALK) expression, and had a relatively indolent clinical course when it developed adjacent to a breast implant. The authors concluded that a form of ALCL, which clinically behaves more like the less aggressive primary cutaneous form of ALK-negative ALCL rather than the more aggressive systemic form, may be associated with breast implants.

### **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.

McLaughlin et al. (2007) summarized the epidemiologic evidence regarding the safety of silicone gel-filled breast implants. The topics included in this report included CTD, suicide, offspring effects, neurologic disease, implant rupture, and local perioperative complications requiring the need for additional surgery. Based on the review of the published epidemiologic literature on the safety of breast implants, through September 2007, the authors reported that “the weight of the epidemiologic evidence does not support a causal association between breast implants and breast or any other type of cancer, definite or atypical connective tissue disease, adverse offspring effects, or neurologic disease. Women with breast implants do not present with more advanced stages of breast cancer or suffer impaired survival after breast cancer diagnosis. The only study to examine an actual incidence rate of breast implant rupture reported rupture-free survival of 98% at five years and 83%–85% at 10 years for newer “third-generation” implants. Future studies are needed to determine whether the consistently observed excess of suicide among women with implants reflects underlying psychiatric illness prior to breast augmentation surgery or other factors.”

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.

### **Use Outside of the US**

No relevant information was found regarding breast implant removal. Information on breast implants from the Medicines and Healthcare Products Regulatory Agency (MHRA) states that currently only breast implants filled with silicone or saline are available for use in the United Kingdom (UK). Poly Implant Prosthèse (PIP) breast implants are a brand of silicone gel filled breast implants that were available in the UK until March 2010. There are no restrictions on the sale or use of CE-marked saline-filled breast implants in the UK. Polyurethane-coated silicone gel breast implants are available for implantation in the UK. These implants consist of a silicone elastomer shell filled with silicone gel. The shell is coated with a polyurethane foam which breaks down over time. Polyurethane-coated breast implants were removed from the UK market in 1991, following concerns about the possible carcinogenic risk from the polyurethane breakdown product. The Committee on Carcinogenicity concluded that carcinogenic risk from these implants is small and unquantifiable. In April 2005, the manufacturer of one type of polyurethane-coated breast implant reintroduced them to the UK. The manufacturer claims that the incidence of capsular contracture is lower than with other types of breast implant, and that the movement or rotation is less. In April 2005, the MHRA issued a letter to the plastic surgery professional bodies to bring this issue to their attention and to inform them of the risks and claimed benefits. The following types of implants are not available in the UK: hydrogel-filled, soya bean oil-filled (Trilucent™), implants with a titanium coating (MHRA, 2013).

### **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. Women with breast implants may have a very small but increased likelihood of being diagnosed with anaplastic large cell lymphoma (ALCL). Because the risk of ALCL appears very small, the U.S. Food and Drug Administration (FDA) believes that the totality of evidence continues to support a reasonable assurance that FDA-approved breast implants are safe and effective when used as labeled.

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### **Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

### **Rupture of Gel-Filled Implant**

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
19330	Removal of mammary implant material
19371	Periprosthetic capsulectomy, breast

### **Interference with Diagnostic Evaluation or Treatment**

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19371	Periprosthetic capsulectomy, breast

### **Infection, Contracture, Tissue Necrosis**

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19371	Periprosthetic capsulectomy, breast

### **Implant Removal Associated with Breast Reconstruction or Lumpectomy**

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19371	Periprosthetic capsulectomy, breast

\*Current Procedural Terminology (CPT®) ©2013 American Medical Association: Chicago, IL.

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