



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0048

Subject **Breast Implant Removal**

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Hyperlink to Related Coverage Policies

Breast Reconstruction Following
Mastectomy or Lumpectomy
Genetic Testing for Susceptibility to Breast
and Ovarian Cancer (BRCA1 & BRCA2)
Magnetic Resonance Imaging (MRI) of the
Breast

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Proprietary information of CIGNA. Copyright ©2010 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 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 ANY 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 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
- replacement of an implant following removal
- removal of the implant in the opposite/contralateral breast, unless criteria are otherwise met for that breast implant
- capsulectomy when associated with removal of a saline-filled implant

CIGNA does not cover removal of any type of breast implant performed solely to improve appearance because it is considered as cosmetic, unless associated with breast reconstruction following mastectomy or lumpectomy.

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

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, 2009a).

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 which are made of a more firm silicone gel filler to help maintain the shape of the implant. The implant is referred to as gummy bear due to the consistency of the implant. For a patient to receive an investigational breast implant in the U.S., they must enroll in a clinical study (FDA, 2009a).

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, 2009b).

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. 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.

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.

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.

Coding/Billing Information

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

Covered when medically necessary:

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

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
238.3	Secondary malignant neoplasm of other and unspecified sites and tissues; breast
239.3	Neoplasm of uncertain nature of breast
611.0	Other disorders of breast: inflammatory disease of breast
611.3	Fat necrosis of breast
611.71	Signs and symptoms in breast; mastodynia
611.83	Capsular contracture of breast implant
996.54	Mechanical complication of other specified prosthetic device, implant, and graft; due to breast prosthesis
996.69	Infection and inflammatory reaction due to internal prosthetic device, implant, and graft; due to other internal prosthetic, device, implant, and graft
996.79	Other complications due to prosthetic device, implant and graft
V10.3	Personal history of malignant neoplasm; breast
V45.83	Other postprocedural status; breast implant removal status

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	2/15/2007	0048	Breast Implant Removal
Great-West Healthcare	8/2/2007	95.315.06	Breast Surgery, Implant Removal

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