

6.01.50 Magnetic Resonance Imaging to Monitor the Integrity of Silicone Gel-Filled Breast Implants			
Original Policy Date:	August 29, 2014	Effective Date:	November 1, 2017
Section:	6.0 Radiology	Page:	Page 1 of 8

Policy Statement

Magnetic resonance imaging (MRI) may be considered **medically necessary** to confirm the clinical diagnosis of rupture of silicone breast implants.

Magnetic resonance imaging (MRI) is considered **investigational** to monitor the integrity of silicone gel-filled breast implants when there are no signs or symptoms of rupture.

Policy Guidelines

There is no CPT code specific to this particular use of magnetic resonance imaging (MRI) in the breast. The standard breast MRI codes would be used:

- **77058:** Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral
- **77059:** Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral

Description

This evidence review addresses the use of magnetic resonance imaging (MRI) to monitor the integrity of silicone gel-filled breast implants (hereafter, referred to as silicone implants).

Related Policies

- Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2006, the FDA approved the marketing of silicone implants by Allergan Corp. (formerly Inamed Corp.) and Mentor Corp. These products were approved for use in breast reconstruction for women of all ages and for breast augmentation among women at least 22 years old. This decision followed 14 years during which silicone implants were not available outside of clinical trials. In 1991, the FDA decided that premarketing approval was required for manufacturers of silicone implants (which had previously been "grandfathered" into the requirements of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act). In 1992, the FDA determined that the premarketing approvals submitted had insufficient evidence on safety and effectiveness to support approval.¹

Several silicone breast implants have been cleared for marketing by the FDA through the 510(k) process. They include the Mentor® MemoryShape® and MemoryGel® implants (Mentor Corp.); Natrelle® and Inamed® implants (Allergan, Irvine, CA); and Sientra® implants (Sientra Corp., Santa Barbara, CA). FDA product code: FTR.

Rationale

Background Breast Implants

Silicone or saline breast implants may be used with breast reconstruction or for breast augmentation.

Leaks of silicone can be contained within the fibrous capsule that commonly forms around the silicone implant (intracapsular); the capsule may also rupture and lead to macroscopic silicone leakage into surrounding tissues (extracapsular; about 10%-20% of ruptures); or the silicone may “bleed” through the silicone envelope that contains it without any gross holes or tears.

Extracapsular ruptures are of particular concern because silicone may occasionally migrate to different parts of the body (e.g., to the axillary lymph nodes, arms, and abdomen) and may form silicone granulomas. Surgery is sometimes needed to remove silicone deposits in other parts of the body. The design of implants has changed over time, with the potential for different rupture rates and rupture patterns with each generation of implants. The age of the implant is a known risk factor for rupture.

Magnetic resonance imaging monitoring is not recommended for women with saline-filled implants. There is less concern about the leakage of saline than silicone gel. Rupture of a saline-filled implant is more obvious to patients and physicians, while silicone implants are more likely to maintain their shape after rupture.

This review does not address the injection of silicone into the breast.

Literature Review

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical reliability (test-retest reliability or interrater reliability); (2) clinical validity (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) clinical utility demonstrating that the diagnostic information can be used to improve patient outcomes.

Detection of Suspected Silicone Implant Rupture

Technical Reliability

In a 2001 meta-analysis on the use of magnetic resonance imaging (MRI) to detect silicone implant ruptures, Cher et al evaluated 18 studies (published 1992-1998) that included 1029 women with MRI results who subsequently had 2036 breast implants removed.² The studies varied by design; all but one comprised mostly symptomatic women, and in many cases, MRI results were used to decide whether to perform surgery. MRI sensitivity across studies ranged from 39% to 100%, while specificity ranged from 55% to 100%. One prospective study (Monticciolo et al, 1994) of 28 women (38 implants) and 47% rupture prevalence reported a sensitivity of 94% and a sensitivity of 100%.³ Another study (Quinn et al, 1996) rated highly in the meta-analysis was a combined retrospective and prospective study with 54 subjects (108 implants), a blinded MRI reading, and use of a breast coil; the rupture prevalence was 28%, and explantation was performed independently of MRI results.⁴ The authors reported a sensitivity of 87% and specificity of 78%. A weakness of both the Monticciolo and the Quinn studies was their use of convenience samples, which the meta-analysis found was associated with higher reported accuracy ($p=0.007$). The summary estimate of sensitivity from the meta-analysis was 78% (95% confidence interval [CI], 71% to 83%), while the summary estimate of specificity was 91% (95% CI, 86% to

94%). These results should be viewed cautiously given the heterogeneity and potentially low quality of the studies assessed.

A more recent study, published in 2007, focused primarily on rupture rates as measured by MRI.⁵ It included 21 patients with 31 of 42 implants diagnosed as ruptured using MRI who underwent bilateral explantation. Of the 42 implants, 21 were actually ruptured, 19 of which had been detected by MRI. There were 2 false-negative findings in this select cohort and 12 false-positive results, including 3 patients in whom both implants were intact. Two radiologists independently evaluated the MRI results. Estimated sensitivities for the 2 radiologists, respectively, were 86% and 71%, for a combined result of 90%; specificities were 48% and 95%, for a combined result of 43%. The generalizability of these results is limited because women with intact implants as determined by MRI did not undergo explantation.

Clinical Utility

The alternative for suspected breast implant ruptures is surgical explantation and examination of the implant. Studies have shown that other nonsurgical approaches are inadequate for verifying rupture, as follows^{6,7}:

- Clinical examination can miss many ruptured silicone implants. In a study using MRI as the reference standard (which introduces some error, as comparisons between MRI and explantation have shown), the sensitivity of clinical examination was 30%, and the specificity was 88%.⁸ The 2015 study included 55 women with 109 implants, 43 of which were ruptured according to MRI.
- Mammography can detect primarily extracapsular ruptures, which comprise 10% to 20% of ruptures. Also, the compression used could potentially worsen the rupture (e.g., convert it from intra- to extracapsular); and mammography uses ionizing radiation.
- The accuracy of ultrasound is highly operator dependent and is not optimal in the evaluation of the back wall of the implant and the tissue posterior to it.
- Computed tomography is generally avoided, especially in younger women, because of the use of ionizing radiation.

There is no direct evidence on the clinical utility of MRI for confirming the clinical diagnosis of silicone breast rupture; however, to avoid unnecessary surgery, confirmation of implant rupture may be useful before surgical explantation.

Section Summary: Detection of Suspected Silicone Implant Rupture

A number of studies on the diagnostic accuracy of MRI for detecting suspected rupture of silicone breast implants have been published. A meta-analysis of 18 studies (all but one of which was conducted in symptomatic patients) found that MRI had a pooled sensitivity of 78% and a pooled specificity of 91% compared with surgical explantation. There is no direct evidence on the clinical utility of MRI for detecting suspected rupture. However, there is some evidence that other approaches to diagnosing suspected rupture are inadequate and it is clinically useful to confirm rupture before undergoing surgery.

Screening for Silent Silicone Implant Rupture in Asymptomatic Women **Technical Reliability**

Systematic Reviews

A 2011 meta-analysis by Song et al examined the effect of study design biases on the diagnostic accuracy of MRI imaging for detecting silicone breast implant ruptures.⁹ The meta-analysis was initiated because the Food and Drug Administration recommended that women with silicone breast implants undergo MRI screening to detect silent rupture. Sixteen MRI studies were included; reviewers noted that more than 50% of studies used a sample not representative of a screening sample. Only two indicated that study populations were asymptomatic patients. The reference test diagnostic criteria were not specified in 44% of studies, and 44% of studies had partial verification bias. Gel bleeds were addressed inconsistently across studies, because 5 MRI studies did not consider gel bleeds as ruptures and 1 MRI study considered gel bleeds as

ruptures. Significant heterogeneity was present across studies for sensitivity and specificity. MRI studies using symptomatic samples had a diagnostic odds ratio that was nearly 14-fold greater than the diagnostic odds ratio of studies with asymptomatic samples. Although pooled summary measures across studies indicated a relatively high accuracy of MRI for detecting breast implant rupture with a pooled sensitivity of 87% and a pooled specificity of 90%, most of the current literature examined only symptomatic patients. The meta-analysis identified many methodologic flaws in the current literature; reported MRI sensitivity and specificity estimates may be high if applied to asymptomatic or screening samples and could result in unnecessary operative exploration based on inaccurate MRI interpretation.

Prospective and Retrospective Cohort Studies

The 2 studies of asymptomatic women, identified in the Song meta-analysis, were published by Scaranelo et al (2004)¹⁰ and by Collis et al (2007).⁵ The Collis study reported retrospectively on 149 patients with bilateral silicone implants who underwent MRI.⁵ Twenty-three patients were found to have 33 radiologically detected implant ruptures. The study was not designed to evaluate diagnostic accuracy, but to determine longevity of implants, and it did not use a criterion standard for confirming rupture. The Scaranelo study included 44 asymptomatic women with silicone breast implants; all women wanted their implants surgically removed.¹⁰ Thirty-nine women had bilateral implants, and 5 had unilateral implants (total implants, 83). Before surgery, patients underwent mammography and ultrasonography, and 41 also underwent MRI. On surgical removal, 30 (36%) of 83 implants were found to be ruptured. The sensitivities of mammography, ultrasound, and MRI for detecting rupture were 20%, 30%, and 64%, respectively. Specificities were 89%, 81%, and 77%, respectively.

Several studies were published after the 2011 meta-analysis. In 2014, Majers et al reported on 2 studies from a prospective cohort of 112 women with 224 recalled implants.^{11,12} Patients had the breast implants for 10 years on average before explantation. Review of magnetic resonance images before explantation correctly detected 154 intact and 35 ruptured implants; sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were 80%, 91%, 69%, and 95%, respectively.¹¹ In a subsequent blinded evaluation of available MRI results, 2 radiologists independently agreed on the condition of 208 of 214 explanted implants.¹² Agreement also was also reached in five additional patients where the radiologists initially disagreed on the implant condition; sensitivity, specificity, PPV, and NPV were 93%, 93%, 77%, and 98%, respectively. The κ value of interobserver agreement was 0.92.

Rietjens et al (2014) prospectively studied 102 consecutive women with 130 implants who were undergoing breast implant replacement for aesthetic improvement.¹³ The median duration of implantation was 57 months (range, 6-166 months). Intraoperative evaluation identified 36 ruptured implants (prevalence, 28%). Preoperative magnetic resonance images were evaluated by 1 experienced MRI reader. MRI sensitivity, specificity, PPV, and NPV were 83% (95% CI, 66% to 93%), 98% (95% CI, 92% to 100%), 94% (95% CI, 79% to 99%), and 94% (95% CI, 88% to 97%), respectively. Although patients did not present with symptoms of implant rupture or history of trauma, patients presenting for “aesthetic” improvement may not represent a typical screening population.

Clinical Utility

There is no direct evidence of the clinical utility of MRI for screening asymptomatic women with silicone breast implants for silent rupture. Moreover, the complications that may result from asymptomatic leakage of silicone are not well-characterized, limiting the potential clinical benefit of early detection.

Section Summary: Screening for Silent Silicone Implant Rupture in Asymptomatic Women

There are fewer studies of MRI screening for silent rupture in asymptomatic women with silicone breast implants compared with MRI studies in symptomatic patients. No systematic review reported pooled diagnostic accuracy estimates of studies in asymptomatic women. In the available studies reporting diagnostic accuracy, sensitivity of MRI compared with surgical

explantation ranged from 64% to 93% and specificity ranged from 77% to 98%. The evidence base is limited because studies of asymptomatic women have generally been conducted in select populations (e.g., women who want their implants removed), and data are lacking in screening populations. Moreover, the clinical utility of MRI screening for silent rupture is unclear (e.g., complications that may result from asymptomatic leakage of silicone are not well-characterized).

Summary of Evidence

For individuals who have suspected rupture of silicone breast implants who receive screening with MRI, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are test accuracy and validity, morbid events, and treatment-related morbidity. The available literature on MRI for detection of suspected rupture of silicone breast implants has suggested a reasonably high sensitivity and specificity compared with surgical explantation. There is no direct evidence on the clinical utility of MRI for detecting suspected rupture. However, some evidence has suggested that other approaches to diagnosing suspected rupture are inadequate. There is clinical utility to confirming rupture prior to explantation of an implant. However, clinical examination may be inadequate and other imaging modalities have technical limitations or increase exposure to radiation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are asymptomatic with silicone breast implants who receive screening with MRI, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are test accuracy and validity, morbid events, and treatment-related morbidity. Studies of MRI screening for silent rupture in asymptomatic women with silicone implants have demonstrated reasonably high sensitivity and specificity compared with explantation and these studies reported reasonably high sensitivity and specificity compared with surgical explantation. However, the studies have generally been conducted in select populations (e.g., women who want implants removed), and the data lacks screening populations. Moreover, the clinical utility of MRI screening for silent rupture is unclear, ie, complications that may result from asymptomatic leakage of silicone are not well-characterized. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

In 2015, the European Society of Breast Imaging published recommendations for communicating information about breast magnetic resonance imaging (MRI) to women.¹⁴ The recommendations stated: "MRI is the most sensitive technique to detect breast implant ruptures when an appropriate protocol is performed.... In the absence of symptoms, breast implants do not need to be screened for integrity with breast MRI."

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for the use of MRI to monitor for silicone breast implant rupture have been identified.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT00443274 ^a	Safety Evaluation in Subjects With Silicone- and Saline-Breast Implants (BIFS)	57,000	Oct 2026

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02919592 ^a	MemoryShape® and MemoryGel® Breast Implants Post Approval New Enrollment Study ("Glow Study")	2818	Sept 2028

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

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3. Monticciolo DL, Nelson RC, Dixon WT, et al. MR detection of leakage from silicone breast implants: value of a silicone-selective pulse sequence. *AJR Am J Roentgenol.* Jul 1994;163(1):51-56. PMID 8010247
4. Quinn SF, Neubauer NM, Sheley RC, et al. MR imaging of silicone breast implants: evaluation of prospective and retrospective interpretations and interobserver agreement. *J Magn Reson Imaging.* Jan-Feb 1996;6(1):213-218. PMID 8851430
5. Collis N, Litherland J, Enion D, et al. Magnetic resonance imaging and explantation investigation of long-term silicone gel implant integrity. *Plast Reconstr Surg.* Oct 2007;120(5):1401-1406. PMID 17898620
6. Brown SL, Silverman BG, Berg WA. Rupture of silicone-gel breast implants: causes, sequelae, and diagnosis. *Lancet.* Nov 22 1997;350(9090):1531-1537. PMID 9388410
7. Gorczyca DP, Gorczyca SM, Gorczyca KL. The diagnosis of silicone breast implant rupture. *Plast Reconstr Surg.* Dec 2007;120(7 Suppl 1):49S-61S. PMID 18090814
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12. Majers MC, Niessen FB, Veldhuizen JF, et al. MRI screening for silicone breast implant rupture: accuracy, inter- and intraobserver variability using explantation results as reference standard. *Eur Radiol.* Jun 2014;24(6):1167-1175. PMID 24599622
13. Rietjens M, Villa G, Toesca A, et al. Appropriate use of magnetic resonance imaging and ultrasound to detect early silicone gel breast implant rupture in postmastectomy reconstruction. *Plast Reconstr Surg.* Jul 2014;134(1):13e-20e. PMID 25028829
14. Mann RM, Balleyguier C, Baltzer PA, et al. Breast MRI: EUSOBI recommendations for women's information. *Eur Radiol.* Dec 2015;25(12):3669-3678. PMID 26002130
15. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 6.01.50 (September 2017).

Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:

- o Reason for MRI
- o Signs and/or symptoms of rupture

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Type	Code	Description
CPT®	77058	Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral
	77059	Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral
HCPCS	C8903	Magnetic resonance imaging with contrast, breast; unilateral
	C8904	Magnetic resonance imaging without contrast, breast; unilateral
	C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
	C8906	Magnetic resonance imaging with contrast, breast; bilateral
	C8907	Magnetic resonance imaging without contrast, breast; bilateral
	C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral
ICD-10 Procedure	BH30Y0Z	Magnetic Resonance Imaging (MRI) of Right Breast using Other Contrast, Unenhanced and Enhanced
	BH31Y0Z	Magnetic Resonance Imaging (MRI) of Left Breast using Other Contrast, Unenhanced and Enhanced
	BH32Y0Z	Magnetic Resonance Imaging (MRI) of Bilateral Breasts using Other Contrast, Unenhanced and Enhanced
	BH30YZZ	Magnetic Resonance Imaging (MRI) of Right Breast using Other Contrast
	BH31YZZ	Magnetic Resonance Imaging (MRI) of Left Breast using Other Contrast
	BH32YZZ	Magnetic Resonance Imaging (MRI) of Bilateral Breasts using Other Contrast
	BH30ZZZ	Magnetic Resonance Imaging (MRI) of Right Breast
	BH31ZZZ	Magnetic Resonance Imaging (MRI) of Left Breast
	BH32ZZZ	Magnetic Resonance Imaging (MRI) of Bilateral Breasts
ICD-10 Diagnosis	All Diagnoses	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
08/29/2014	BCBSA Medical Policy adoption	Medical Policy Committee
11/01/2016	Policy title change from Magnetic Resonance Imaging to Monitor Integrity of Silicone-Gel-Filled Breast Implants Policy revision without position change	Medical Policy Committee
11/01/2017	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.