MP 6.01.50
Magnetic Resonance Imaging to Monitor The Integrity of Silicone Gel–Filled Breast Implants

DISCLAIMER
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POLICY
Magnetic resonance imaging may be considered medically necessary to confirm the clinical diagnosis of rupture of silicone breast implants.

Magnetic resonance imaging 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: bilateral

BENEFIT APPLICATION

BLUECARD/NATIONAL ACCOUNT ISSUES
State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

When silicone implants are initially placed for cosmetic purposes, contract language may indicate that related subsequent services, such as magnetic resonance imaging, would also be considered a cosmetic service. Thus, contract language must be reviewed when requests for magnetic resonance imaging relate to silicone implants placed for cosmetic purposes.

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); it 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.

REGULATORY STATUS
In 2006, 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, 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, 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 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
This evidence review was created in March 2009 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through July 20, 2017.

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 follows⁶,⁷:

- 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 (eg, 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. 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) and by Collis et al (2007). The Collis study reported retrospectively on 149 patients with bilateral silicone implants who underwent MRI. 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. 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, Maijers et al reported on 2 studies from a prospective cohort of 112 women with 224 recalled implants. 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. In a subsequent blinded evaluation of available MRI results, 2 radiologists independently agreed on the condition of 208 of 214 explanted implants. 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 $\kappa$ 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. 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 (eg, 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 (eg, 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 (eg, 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. 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

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<td>NCT02919592a</td>
<td>MemoryShape® and MemoryGel® Breast Implants Post Approval New Enrollment Study (&quot;Glow Study&quot;)</td>
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<td>Sept 2028</td>
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NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

REFERENCES


### CODES

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<td>T85.81-T85.89</td>
<td>Other specified complication of internal prosthetic devices, implants and grafts (includes breast implant and prosthesis) code range</td>
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<td>Encounter for screening for malignant neoplasm of breast code range</td>
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<td>BH30ZZZ, BH31ZZZ, BH32ZZZ</td>
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