Magnetic Resonance Imaging to Monitor Integrity of Silicone-Gel-Filled Breast Implants

Description

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

Background

On November 16, 2006, the U.S. Food and Drug Administration (FDA) approved the marketing of silicone implants by Allergan Corp. (formerly named Inamed Corp.), Irvine, CA, and Mentor Corp., Santa Barbara, CA. 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 in which silicone implants were not available outside of clinical trials. In 1991, the FDA had decided that premarketing approval (PMA) was required for manufacturers of silicone implants (which had previously been “grandfathered” in to the requirements of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act). In 1992, the agency determined that the PMAs submitted had insufficient evidence on safety and effectiveness to support approval. (1)

FDA also required both of the companies to conduct postapproval studies following up about 40,000 women receiving breast implants for 10 years. These studies will gather information about rates of local complications, connective tissue disease, neurological disease, and related signs and symptoms; potential effects on offspring, reproduction, and lactation; cancer and suicide rates; potential interference with mammography; and magnetic resonance imaging (MRI) compliance and rupture rates. The companies are also required to conduct several other studies (eg, focus groups to study the patient labeling) and to track each implant so that updated product information can be distributed.

In announcing this decision, FDA cited the Institute of Medicine report (2), which concluded that there was a lack of evidence on the association between silicone implants and either connective tissue disease or cancer. The labels for these implants indicate that 1) breast implants are not lifetime devices and women are likely to need additional surgeries beyond the initial placement of the implant; 2) changes to the breast following implantation are often irreversible; 3) rupture of a silicone implant is usually silent, with neither the woman nor her surgeon aware of the rupture; and 4) regular screening MRI examinations to detect silent rupture are needed over the patient’s lifetime. The FDA
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recommends that women have their first MRI 3 years after initial implant surgery and then every 2 years after that. Furthermore, if the MRI indicates implant rupture, the implant should be removed and replaced, if needed.

MRI monitoring apparently is not recommended for women with saline-filled implants. There is less concern about the leakage of saline versus silicone gel, which can migrate to other parts of the body and produce silicone granulomas. 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.

MRI to monitor for the rupture of silicone implants may be performed without contrast and is more sensitive and specific when a dedicated breast coil is used. Silicone-specific sequences are sometimes used.

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

Related Policies

6.01.29 MRI of the Breast

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

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.

Rationale

As indicated in the Description section, ruptures are more difficult to detect without some type of imaging for silicone-gel- than for saline-filled implants. 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, eg, 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 patterns of rupture with each generation of implants. The age of the implant is a known risk factor for rupture. (3, 4)

Widely divergent percentages are reported for the prevalence of silent rupture of silicone implants. This finding is due, in part, to variation in rates across different types and generations of silicone
implants, as well as in the length of follow-up. Furthermore, magnetic resonance imaging (MRI) results are used sometimes as the reference standard for determining rupture, which introduces error. One study of Inamed third-generation silicone breast implants reported rupture prevalence of 8.0% at 11 years, based on MRI and physical examination, (5) while a similar study of the fourth-generation Inamed implant reported 0.3% rupture with a median implantation time of 6 years (range: 5–9 years). (6) Another analysis focused on single, textured, third-generation implants (mostly subglandular Mentor Siltex gel implants) using MRI; using statistical analysis, the authors estimated that implant rupture generally starts at 6 to 7 years and that by 13 years, about 11.8% of implants will have ruptured. (7)

The criterion standard for the detection of ruptures is surgical explantation and examination of the implant. Most of the research on methods to detect silent ruptures of silicone implants was published in the mid-1990s. Alternatives to the use of MRI to detect silicone implant rupture include the following (3, 4):

- Clinical examination can miss many ruptured silicone implants. In a study using MRI as the reference standard (which introduces some error, as comparisons of MRI and explantation show), the sensitivity of clinical examination was 30% and the specificity was 88%. The study included 55 women with 109 implants, 43 of which were ruptured according to MRI. (8)
- Mammography can detect primarily extracapsular ruptures, which comprise about 10–20% 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 limited in the evaluation of the back wall of the implant and the tissue posterior to it.
- Computed tomography (CT) is generally avoided because of the use of ionizing radiation, especially in younger women.

In a prospective, comparative study of 32 women before the removal of 63 breast implants with 22 ruptures, the sensitivity and specificity of mammography was 23% and 98%, respectively; for ultrasonography, 59% and 79%; for CT, 82% and 88%; and for MRI, 95% and 93%. (9) Despite the apparent superiority of MRI, alternative modalities may be used when MRI is contraindicated (eg, due to cardiac pacemakers or aneurysm clips).

The U.S. Food and Drug Administration’s (FDA) recommendation for regular MRI screening among women with silicone implants (see Description section) has met with some controversy [eg, McCarthy et al (11)]. The practice parameter on silicone breast implants by the American Society of Plastic Surgeons, released in March 2005 before the FDA’s decision, states that “There is no consensus on routine silent rupture screening for silicone breast implant patients. MRI examination of asymptomatic patients 10 years after implantation should be considered to screen for silent rupture and at subsequent five-year intervals.” (11) For symptomatic rupture, the practice parameter recommends MRI or ultrasonography and mammography, although the authors note that “Studies indicate MRI is generally the accepted state-of-the-art technique for evaluation of implant integrity.” They also report that the “general consensus” is that explantation is warranted for symptomatic and/or extracapsular implant rupture. According to this practice parameter, there is less agreement on asymptomatic
ruptures, which may lead to explantation or to regular clinical examinations that include evaluation for silicone migration.

In a meta-analysis on the use of MRI to detect silicone implant ruptures, Cher et al evaluated 18 studies (published 1992–1998) that included approximately 1029 women with MRI results who subsequently had about 2036 breast implants removed. (12) The studies were variable in design; all but 1 consisted mostly of symptomatic women (spectrum bias); and in many cases, MRI results were used in deciding whether to perform surgery (verification bias). The sensitivity across studies ranged from 38.9% to 100%, while the specificity varied between 54.5% and 100%. One prospective study of 28 women (38 implants) and 47% rupture prevalence reported sensitivity of 94.4% and specificity of 100%. (13) In this study, a breast coil was used and readers were blinded to surgical findings, but the MRI results probably affected the explantation decision. Another study (14) was rated highly by the meta-analysis authors using “qualitative” criteria. It was a combined retro- and prospective study with 54 subjects (108 implants), blinded MRI reading, use of a breast coil, rupture prevalence of 28%, and explantation performed independently of the MRI results. The reported sensitivity was 86.7%, and the specificity was 78.2%. A weakness of both studies was the use of a convenience sample, which the meta-analysis authors found was associated with higher reported accuracy (p=0.0071). The summary estimate of sensitivity from the meta-analysis was 78% (95% confidence interval [CI]: 71%–83%), while the summary estimate of specificity was 91% (95% CI: 86%–94%). These results should be viewed with caution given the heterogeneity and potentially low quality of the studies included in this meta-analysis.

Two later studies were not covered in the meta-analysis. The first focused primarily on rupture rates as measured by MRI. (5) It included 21 patients with 31 implants diagnosed as ruptured using MRI who underwent bilateral explantation. Of the 42 implants, 21 were actually ruptured, 19 of which had been indicated by MRI. There were 2 false-negative findings in this selected cohort and 12 false-positive results, including 3 patients in whom both implants were intact. Two radiologists independently evaluated the MRI results. The estimated sensitivities for the two radiologists were 86% and 71%, for a combined result of 90%; the specificities were 48% and 95%, for a combined result of 43%. The generalizability of these results is limited by the fact that women with intact implants as determined by MRI (understandably) did not undergo explantation. The interrater variability in this study deserves further attention.

In another study on the use of MRI to detect silent ruptures, 64 women underwent explantation (54 bilateral; 10 unilateral) after 1 of 2 MRIs performed about 2 years apart. (15) The mean implantation time was 14.7 years (range: 6–25 years). Surgical results confirmed ruptures in 65 of the 66 cases where MRI indicated it, in 8 of 9 cases where MRI indicated possible ruptures (the ninth was a possible rupture in the surgical results as well), and in 8 of 43 implants that MRI indicated were intact. If “possible rupture” is grouped together with “rupture” for both MRI and surgical results, the sensitivity of MRI is 89% and the specificity is 97%. Again, this is a highly selected group of patients with a high prevalence of rupture. Also, the median interval between the most recent MRI and surgery was 232 days (range: 35–967 days), which opens up the possibility that some ruptures found surgically could have occurred after the MRI examination.
In 2014, Maijers et al reported on 2 studies from a prospective cohort of 112 women with 224 recalled implants. (16, 17) Patients had the breast implants for a mean time of 10 years before explantation. Review of MRI records taken before explantation correctly detected 154 intact and 35 ruptured implants. Sensitivity, specificity, positive and negative predictive value were 80%, 91%, 69%, and 95%, respectively. (16) In a subsequent blinded evaluation of available MRI results, 2 radiologists independently agreed on the condition of 208 of 214 explanted implants. (17) Agreement was also reached in 5 additional patients where the radiologists initially disagreed on the implant condition. Sensitivity, specificity, positive and negative predictive value were 93%, 93%, 77%, and 98%, respectively. The Kappa value of interobserver agreement was 0.92.

McCarthy et al (10) evaluated the FDA’s recommendation for MRI screening for silent rupture and compared it to the criteria for a successful screening program.

- **Criterion:** The target disease must be progressive and have serious consequences with a detectable preclinical state for which effective treatment is available and outcomes are improved by early intervention.
  
  **McCarthy et al [11] assessment:** There are few data on the clinical sequelae of silent rupture or of the proportion that will progress to frank or symptomatic ruptures, especially for the latest generation of implants. Expert opinion suggests that the results of silent and symptomatic ruptures differ

- **Criterion:** The prevalence must be high enough to warrant mass screening.
  
  **McCarthy et al assessment:** The prevalence is difficult to estimate because it may vary with the type of implant. The best reference standard—explantation—tends to be performed in symptomatic and self-selected patients, who are unlikely to be representative of all women with implants

- **Criterion:** The screening test must be accurate, acceptable to patients, and cost effective.
  
  **McCarthy et al assessment:** MRI appears to be the most accurate diagnostic test available for this use. But it is costly financially, and its accuracy will depend on the prevalence of rupture. In their meta-analysis, Cher et al (2001 [13]) report substantial variation in sensitivity and specificity across studies, with a positive predictive value less than 80% in a population with a prevalence of rupture less than 10%; they do not recommend its use for screening asymptomatic women.

- **Criterion:** The potential harms from screening should be taken into account.
  
  **McCarthy et al assessment:** These include financial costs, which may not be covered by health insurance; patient anxiety; and the consequences of false-positive results.

McCarthy et al concluded that “evidence from prospective studies to support its [MRI’s] use in this setting is lacking.” They, therefore, recommended shared decision making between physicians and their patients on this issue.

The evidence on the net benefit of using MRI to screen women with silicone breast implants for possible silent ruptures does not permit conclusions about the impact on health outcomes; the scientific evidence was determined to be weak.
A 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. (18) Twenty-one diagnostic cohort studies were included, 15 of which included MRI, or MRI and/or ultrasound studies; these 15 studies included a total of 1211 patients, 586 of whom were operated on. More than 50% of the MRI studies used a sample that was not representative of a screening sample. 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, as 5 MRI studies considered gel bleeds as not ruptured and 1 MRI imaging study considered gel bleeds as ruptured. 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 compared with the diagnostic odds ratio of studies with asymptomatic samples. Although the pooled summary measures across studies indicate a relatively high accuracy of MRI for detecting breast implant rupture with a pooled sensitivity of 87% and a specificity of 90%, the majority of the current literature examined only symptomatic patients. The results of the meta-analysis showed many methodologic flaws in the current literature and that the 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 a faulty MRI interpretation.

An article was published that questioned the incremental value of preoperative MRI in addition to physical examination with or without mammography to diagnose implant rupture among women with capsular contracture. (19) In this retrospective study of 171 women with 319 silicone breast implants, half had undergone MRI preoperatively; 73% had mammography within the past year. Operative findings served as the reference standard, and 192 implants (60%) had ruptured and 28 had gel bleed (9%). The median implant age was 20 years (range: 1 to 36 years). Most implants had grade III or IV capsular contracture, and patients with grade II contractures were slightly more likely to receive a preoperative MRI (31% had MRI, 23% did not; no p values reported), while those with grade IV contractures were less likely (17% had MRI, 29% did not). The use of MRI generally increased with the age of the implant, but the difference was not statistically significant. A statistically significantly larger percentage of women who did not have preoperative MRIs were symptomatic (eg, pain, asymmetry) compared to those who did have an MRI (79% vs. 59%, respectively; p=0.008).

The authors reported no difference in accuracy of detecting implant integrity between physical examination (PE) with or without mammography (76%) versus PE with or without mammography plus MRI (78%; p=0.77). The sensitivity and specificity of PE plus mammography were 58% (51% to 65%) and 78% (68% to 86%), respectively. (Note that in Table 4, which reports the diagnostic test characteristics, the table headings are “Examination + Mammography” or “Examination + Mammography + Magnetic Resonance Imaging.” The rest of the paper refers to examination with or without mammography. It is not clear whether the table reports on the subset of patients who underwent mammography or whether the headings contain an error.) Adding MRI altered the sensitivity and specificity to 89% (83% to 94%) and 30% (16% to 49%), respectively. In other words, the use of MRI increased the sensitivity and decreased the specificity. In this population, the positive predictive values (PPVs) and negative predictive values (NPVs) were similar for both strategies (PPV: 85% [79% to 91%] without MRI, 83% [76% to 89%] with MRI; NPV: 54% [47% to 62%] without MRI, 57% [34% to 77%] with MRI). Excluding the cases with gel bleeds, which are difficult to diagnose preoperatively, increased the sensitivity of both strategies (to 64% for PE plus mammography and to 94% if MRI is added also).
Although the authors report correctly that adding preoperative MRI to PE with or without mammography does not increase the accuracy of detecting implant rupture or gel bleed in patients with capsular contracture, the sensitivities and specificities are quite different. The tradeoffs between higher sensitivity and higher specificity need to be considered within the specific clinical context. More importantly, the patient characteristics differed between those who received MRI and those who did not, and no multivariable analysis was performed to attempt to account for those differences. Consequently, the comparison between PE with or without mammography versus PE with or without mammography plus MRI could be affected by variables other than simply the incremental diagnostic value of MRI. These results should, therefore, be interpreted with caution.

Ongoing and Unpublished Clinical Trials

A recent search of online database ClinicalTrials.gov identified no active trials of MRI screening for silicone breast implant integrity.

Practice Guidelines and Position Statements

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

Summary

This policy addresses the use of magnetic resonance imaging (MRI) to monitor the integrity of silicone gel-filled breast implants.

The criterion standard for the detection of silicone breast implant rupture is surgical explantation and examination of the implant. To avoid unnecessary surgery, confirmation of implant rupture may be useful before surgical explantation. Sensitivities and specificities of MRI for detection of silicone breast implant rupture are much higher than ultrasonography or mammography and have been reported in the 90th percentiles. Therefore, MRI may be considered medically necessary to confirm the clinical diagnosis of rupture of silicone breast implants.

There are few data on the clinical sequelae of silent rupture or of the proportion that will progress to frank or symptomatic ruptures, especially for the latest generation of silicone breast implants. The evidence for the net benefit of using MRI to screen women with silicone breast implants for possible silent ruptures does not permit conclusions about the impact on health outcomes; therefore the use of MRI to monitor the integrity of silicone gel-filled breast implants when there are no signs or symptoms of rupture remains investigational.

Medicare National Coverage

No national coverage determination (NCD) was identified.
References


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**Policy History**

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<tr>
<th>Date</th>
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<td>New Policy</td>
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<tr>
<td>September 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature search through June 6, 2013; no new references added; no change in policy statements.</td>
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<td>September 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 16-17 added; no change in policy statements.</td>
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**Keywords**

MRI, Silicone Breast Implants

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 12, 2014 and is effective October 15, 2014.

**Signature on File**

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