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. Effective January 1, 2019, the following CPT codes replaced codes 77058 and 77059:

- 77046: Magnetic resonance imaging, breast, without contrast material; unilateral
- 77047: Magnetic resonance imaging, breast, without contrast material; bilateral
- 77048: Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
- 77049: Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; 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

Table 1 summarizes select silicone gel-filled breast implants approved by the Food and Drug Administration through the premarket process.
Magnetic Resonance Imaging to Monitor the Integrity of Silicone Gel-Filled Breast Implants

Rationale

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

Leaks of silicone can occur at various levels: (1) contained within the fibrous capsule that commonly forms around the silicone implant (intracapsular); (2) outside of the capsule if there is a rupture, which leads to macroscopic silicone leakage into surrounding tissues (extracapsular; about 10%-20% of ruptures); or (3) 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
Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Detection of Suspected Silicone Implant Rupture
Clinical Context and Test Purpose
The purpose of magnetic resonance imaging (MRI) in patients with suspected rupture of silicone breast implants is to confirm a rupture and inform the medical management decisions.

Table 1. Select Silicone Gel–Filled Breast Implants Approved by the FDA

<table>
<thead>
<tr>
<th>Silicone Implant</th>
<th>Manufacturer</th>
<th>PMA No.</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natrelle</td>
<td>Allergan</td>
<td>P020056</td>
<td>Nov 2006</td>
</tr>
<tr>
<td>MemoryGel</td>
<td>Mentor</td>
<td>P030053</td>
<td>Nov 2006</td>
</tr>
<tr>
<td>Silicone Gel Breast Implants</td>
<td>Sientra</td>
<td>P070004</td>
<td>Mar 2012</td>
</tr>
<tr>
<td>Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants</td>
<td>Allergan</td>
<td>P040046</td>
<td>Feb 2013</td>
</tr>
<tr>
<td>MemoryShape</td>
<td>Mentor</td>
<td>P060028</td>
<td>Jun 2013</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; PMA: premarket approval.
Food and Drug Administration product code: FTR.
The question addressed in this evidence review is: Does the use of MRI improve the net health outcome in patients with suspected rupture of silicone breast implants compared to the use of mammography, ultrasonography, or surgical removal and examination?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is women with suspected rupture of silicone breast implants. Symptoms may include: pain, soreness, or swelling; change in breast size or shape; lumps in the affected breast; or softening or hardening of the affected breast.

**Interventions**
The test being considered is MRI.

**Comparators**
The following noninvasive tests are currently being used to confirm a ruptured breast implant: mammography and ultrasonography. An invasive method of confirming a ruptured breast implant involves surgical removal and examination of the implant.

**Outcomes**
Outcomes of interest related to clinical validity include sensitivity, specificity, and positive and negative predictive values. A true-positive would inform the decision of watchful waiting or surgical removal of the ruptured implant. A false-positive may lead to unnecessary surgical removal. A true-negative would allow the patient to avoid unnecessary surgery. A false-negative may delay treatment (surgical removal) of the ruptured silicone implant.

An outcome of interest related to clinical utility would be the avoidance of unnecessary surgery.

**Timing**
If the results of the test lead to the decision to surgically remove the silicone implant, the follow-up would be after the surgery. If the results of the test lead to the decision to watchfully wait, the follow-up may extend for months to years.

**Setting**
MRI is administered in a tertiary care center or another specialized center with imaging equipment.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:
- To assess the clinical validity of MRI to evaluate silicone breast implants, studies should report sensitivity, specificity, as well as positive (PPV) and negative (NPV) predictive values. Additionally, studies reporting false-positive rates and false-negative rates are informative.
- To assess the clinical utility of MRI to evaluate silicone breast implants, studies should demonstrate how results of gamma imaging impacted treatment decisions and overall management of the patient.

**Technically Reliable**
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

**Clinically Valid**
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).
Systematic Reviews
In a meta-analysis on the use of MRI to detect silicone implant ruptures, Cher et al (2001) evaluated 18 studies (published 1992-1998) that included 1029 women with MRI results who subsequently had 2036 breast implants removed. 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%. 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 imaging that used a breast surface coil. The rupture prevalence was 28%, and explantation was performed independently of MRI results. The authors reported a sensitivity of 87% and a specificity of 78%. A weakness of both the Monticciolo and the Quinn studies was their use of convenience samples, which Cher et al 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.

Case Series
In a study published subsequent to the systematic review, Collis et al (2007), focused primarily on rupture rates as measured by MRI. From a total of 149 patients with implants, 21 patients with 31 of 42 implants diagnosed as ruptured using MRI agreed to 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.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

There is no direct evidence on the clinical utility of MRI for confirming the clinical diagnosis of silicone breast rupture.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about 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:
- Clinical examination can miss many ruptured silicone implants. In a study by Hölmich et al (2005), who used 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%. That 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.

Based on indirect evidence, to avoid unnecessary surgery a 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 indirect evidence that other noninvasive approaches for 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**

**Clinical Context and Test Purpose**

The purpose of MRI in patients who are asymptomatic with silicone breast implants is to detect a rupture.

The question addressed in this evidence review is: Does the use of MRI improve the net health outcome in patients who are asymptomatic with silicone breast implants compared to the use of mammography, ultrasonography, or standard care without screening for implant rupture?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is asymptomatic women with silicone breast implants.

**Interventions**
The test being considered is MRI.

**Comparators**
The following tests and practices are currently being used to monitor breast implants for rupture: mammography, ultrasonography, and standard care without screening for breast implant integrity.

**Outcomes**
Outcomes of interest related to clinical validity include sensitivity, specificity, and positive and negative predictive values. A true-positive would inform the decision of watchful waiting or surgical removal of the ruptured implant. A false-positive may lead to unnecessary surgical removal. A true-negative would confirm that no treatment is needed. A false-negative may delay treatment (surgical removal) of the ruptured silicone implant.

An outcome of interest related to clinical utility would be the avoidance of unnecessary surgery.
Timing
If the results of the test lead to the decision to surgically remove the silicone implant, the follow-up would be after the surgery. If the results of the test are negative, the follow-up may extend to years if no symptoms develop.

Setting
MRI is administered in a tertiary care center or another specialized center with imaging equipment.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess the clinical validity of MRI to evaluate silicone breast implants, studies should report sensitivity, specificity, as well as PPV and NPV. Additionally, studies reporting false-positive rates and false-negative rates are informative.
- To assess the clinical utility of MRI to evaluate silicone breast implants, studies should demonstrate how results of gamma imaging impacted treatment decisions and overall management of the patient.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews
A meta-analysis by Song et al (2011) examined the effect of study design biases on the diagnostic accuracy of MRI 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 (the first MRI at 3 years postimplantation, then every 2 years thereafter). Sixteen MRI studies were included; reviewers noted that more than 50% of studies used a sample not representative of a screening sample. Only 2 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 defined inconsistently across studies, with 5 MRI studies not including gel bleeds as ruptures and 1 MRI study including gel bleeds as ruptures. Significant heterogeneity was present across studies for sensitivity and specificity. MRI studies using symptomatic patients had a diagnostic odds ratio that was nearly 14-fold greater than the diagnostic odds ratio of studies with asymptomatic patients. Although pooled summary measures across studies indicated a relatively high accuracy of MRI for detecting breast implant rupture (pooled sensitivity, 87%; pooled specificity, 90%), most of the current literature examined only symptomatic patients. The meta-analysis identified many methodologic flaws in the current literature. When reported MRI sensitivity and specificity estimates from symptomatic patients are applied to asymptomatic or screening patients, an overestimation of positive results may occur, leading to the unnecessary operative exploration.

Prospective and Retrospective Cohort Studies
The 2 studies of asymptomatic women identified in the Song meta-analysis were published by Scaranello 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 the diagnostic accuracy, but to determine the longevity of implants, and it did not use a criterion standard for confirming rupture.

The study by Scaranello et al (2004) 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. Maijers et al (2014) 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, PPV, and 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 was also reached in 5 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 the 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 one 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.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

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.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of MRI as a screening tool for silent breast implant ruptures cannot be established, a chain of evidence cannot be constructed.
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, the 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 validity, morbid events, and treatment-related morbidity. The available literature on MRI for the detection of suspected rupture of silicone breast implants shows reasonable clinical validity, with high sensitivity and specificity when compared with the more invasive procedure of surgical explantation. While there is no direct evidence on the clinical utility of MRI for detecting suspected rupture, there is evidence for the clinical utility of confirming rupture prior to explantation of an implant. Because other noninvasive techniques such as clinical examination, mammography, or ultrasonography have technical limitations and lower sensitivities and specificities, an MRI may be the most appropriate noninvasive diagnostic technique to confirm rupture. 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 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 surgical explantation. However, the studies have generally been conducted in select populations (e.g., women who want implants removed), and the data lack screening populations. None of the systematic reviews conducted pooled analyses that focused on asymptomatic women. Moreover, the clinical utility of MRI screening for silent rupture is unclear, i.e., 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
American Society of Breast Surgeons
The American Society of Breast Surgeons (2017) updated its guidelines on diagnostic and screening magnetic resonance imaging (MRI) of the breast.14 The guidelines stated that MRI may be used “for evaluation of suspected breast implant rupture, especially in patients with silicone implants, if the MRI findings will aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings”. However, the Society did not recommend routine MRI screening in asymptomatic patients with silicone or saline implants.

American College of Radiology
The American College of Radiology (2018) issued Appropriateness Criteria for breast implant evaluation.15 Table 2 presents the expert panel recommendations on imaging techniques for patients with suspected silicone implant complications.
Table 2. Imaging Recommendations for Women With Suspected Silicone Implant Complications

<table>
<thead>
<tr>
<th>Age</th>
<th>Imaging Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30 years</td>
<td>Magnetic resonance imaging without contrast or ultrasound</td>
</tr>
<tr>
<td>30 to 39 years</td>
<td>Magnetic resonance imaging without contrast, mammography/digital breast tomosynthesis, or ultrasound</td>
</tr>
<tr>
<td>≥40 years</td>
<td>Magnetic resonance imaging without contrast or mammography/digital breast tomosynthesis</td>
</tr>
</tbody>
</table>

European Society of Breast Imaging
The European Society of Breast Imaging (2015) published recommendations for communicating information about breast MRI to women.¹⁶ 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 3.

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00443274</td>
<td>Safety Evaluation in Subjects With Silicone- and Saline-Breast Implants (BIFS)</td>
<td>57,000</td>
<td>Oct 2026</td>
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<tr>
<td>NCT02919592</td>
<td>MemoryShape® and MemoryGel® Breast Implants Post Approval New Enrollment Study (&quot;Glow Study&quot;)</td>
<td>2818</td>
<td>Sept 2028</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
¹ Denotes industry-sponsored or cosponsored trial.

References


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**Documentation for Clinical Review**

Please provide the following documentation (if when requested):
- History and physical and/or consultation notes including:
  - Reason for MRI
  - 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 codes 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.
<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td></td>
<td>77046</td>
<td>Magnetic resonance imaging, breast, without contrast material; unilateral <em>(Code effective 1/1/2019)</em></td>
</tr>
<tr>
<td></td>
<td>77047</td>
<td>Magnetic resonance imaging, breast, without contrast material; bilateral <em>(Code effective 1/1/2019)</em></td>
</tr>
<tr>
<td></td>
<td>77048</td>
<td>Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral <em>(Code effective 1/1/2019)</em></td>
</tr>
<tr>
<td></td>
<td>77049</td>
<td>Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral <em>(Code effective 1/1/2019)</em></td>
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<td>Magnetic resonance imaging without contrast, breast; unilateral <em>(Deleted code effective 1/1/2019)</em></td>
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<tr>
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<td>C8905</td>
<td>Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral</td>
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<td>Magnetic resonance imaging with contrast, breast; bilateral</td>
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<td>Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral</td>
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<td>BH30Y0Z</td>
<td>Magnetic Resonance Imaging (MRI) of Right Breast using Other Contrast, Unenhanced and Enhanced</td>
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<td></td>
<td>BH32ZZZ</td>
<td>Magnetic Resonance Imaging (MRI) of Bilateral Breasts</td>
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**Policy History**

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

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>08/29/2014</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
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<tr>
<td>11/01/2016</td>
<td>Policy title change from Magnetic Resonance Imaging to Monitor Integrity of Silicone-Gel-Filled Breast Implants</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>
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.