Effective for dates of service on or after April 1, 2013, refer to: https://www.bcbsal.org/providers/policies/careCore.cfm

Name of Policy:
Magnetic Resonance Imaging (MRI) of the Breast

Policy #: 057 Latest Review Date: February 2013
Category: Radiology Policy Grade: See below

Background:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts to have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Magnetic Resonance Imaging (MRI) of the breast can be performed using MR scanners and intravenous MR contrast agents. Specialized breast coils are used for this procedure to provide clearly defined images. Frequently these studies require that a dynamic study be performed with multiple series which are subsequently subtracted and drawn for regions of interest. The time intensity curves help to identify areas that may be malignant when a rapid enhancement pattern is identified. Three-dimensional images and maximum intensity projection images are frequently reconstructed to produce a three-dimensional view of the suspicious area. Frequently, these images are reviewed by certified breast surgeons in consultation with certified radiologists with specialized training in breast imaging. MRI of the breast has been investigated as a screening tool in specific high-risk groups of patients. High-risk groups can be identified as individuals who have a high genetic risk, family history, dense breast tissue, scar tissue from previous surgical procedures or breast implants. This technology is also being used to detect suspected occult breast primary tumors in patients with axillary nodal adenocarcinoma and negative mammogram in clinical breast exam as well as for the detection of breast cancer in contralateral breast of a patient with breast cancer.

Policy:
Effective for dates of service on or after April 1, 2013, refer to:
https://www.bcbsal.org/providers/policies/careCore.cfm

Effective for dates of service on or after February 4, 2005 through March 31, 2013, the following policy statements refer to performing MRI of the Breast with a dedicated breast coil. MRI of the breast without the use of a breast coil, regardless of the clinical indication does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational. MRI of the breast is only covered in facilities that offer MR guided biopsies when used for high-risk screening or searching for unknown breast primary in cases that present with only a positive node.

BREAST CANCER OR HIGH RISK SCREENING
Effective for dates of service on or after March 29, 2007 through March 31, 2013, MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for annual MRI screening as an adjunct to mammogram for the following:

1. BRCA mutation
2. First-degree relative of BRCA carrier, but untested
3. Lifetime risk 20-25% or greater, as defined by BRCAPRO or other models that are largely dependent on family history
4. Radiation to chest between age 10 and 30 years
5. Li-Fraumeni syndrome and first-degree relatives
6. Cowden and Bannayan-Riley-Ruvalcaba syndromes and first-degree relatives
7. Lifetime risk 15-20%, as defined by BRCAPRO or other models that are largely dependent on family history (based on shared decision making with the patient and healthcare provider)
8. Lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALG)
9. Atypical ductal hyperplasia (ADH)
10. Heterogeneously or extremely dense breast on mammography (See Key Points for definitions)
11. Women with a personal history of breast cancer, including ductal carcinoma in situ (DCIS)

Grade C

Effective for dates of service on or after March 29, 2007 through March 31, 2013:

MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for imaging a contralateral or ipsilateral breast after a recent diagnosis of unilateral breast cancer when there are no mammographic or clinical abnormalities in the contralateral breast.

The following coverage statements were not addressed in the ACS Guideline; therefore, remain unchanged.

BREAST LESION (Refer to Breast Implants section for lesions in a breast with implants)

Effective for dates of service on or after September 30, 2003 through March 31, 2013:

MRI of the breast meets Blue cross and Blue Shield of Alabama's medical criteria for coverage for patients with multiple lesions when:

- one or more lesions may require biopsy, and;
  - The lesions cannot be localized in two planes, or
  - Cannot be reached by imaged guided needle biopsy, or
  - There is a need to identify the most suspicious lesions of multiple areas of abnormality on conventional images (mammogram or ultrasound) or by physical examination. Grade D

Effective for dates of service on or after February 4, 2005 through March 31, 2013:

MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to guide localization of breast lesions to perform a needle or surgical biopsy when the suspicious lesion(s) was exclusively detected by contrast-enhanced MRI and cannot be visualized by mammography or ultrasound. Grade D

Nipple Retraction/Nipple Drainage

Effective for dates of service on or after November 24, 2004 through March 31, 2013, MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with new onset nipple retraction or drainage whose mammogram and/or ultrasound are indeterminate regarding a diagnosis.

BREAST IMPLANTS

Effective for dates of service on or after May 19, 2011 through March 31, 2013:

Magnetic Resonance Imaging (MRI) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to confirm the clinical diagnosis of rupture of silicone breast implants.
Magnetic Resonance Imaging (MRI) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational to monitor the integrity of silicone gel-filled breast implants when there are no signs or symptoms of rupture.

Magnetic Resonance Imaging (MRI) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to monitor for rupture of saline-filled implants.

Effective for dates of service September 30, 2006 through May 18, 2011:
Magnetic Resonance Imaging (MRI) of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to evaluate irregularities in breast implant contour or encapsulated implant rupture if the implant surgery was not originally performed for cosmetic purposes. Grade B

Effective for dates of service February 4, 2005 through September 29, 2006:
Magnetic Resonance Imaging (MRI) of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in patients who have suspicious lesions suggestive of silicone granulomas or cancer where the breast tissue is obscured by free silicone. (Due to the suspicious lesion, this would be covered regardless of the reason for the implant placement.) Grade D

Effective for dates of service prior to March 29, 2007:
BREAST CANCER
Effective for dates of service on or after August 15, 2002, MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in patients with personal history of breast cancer and who have scarring from previous biopsies or surgery sufficient to limit the ability of conventional mammography to be sensitive/specific in evaluation. Grade D

Effective for dates of service January 23, 2004:
MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for mammographically dense patients with a new diagnosis of invasive breast cancer to determine the extent of the disease when breast conservation is being considered. Grade D

Effective for dates of service January 23, 2004:
MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with invasive lobular carcinoma. Grade D

Effective for dates of service on or after February 4, 2005:
MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to detect the extent of residual cancer in the recently post-operative breast with positive pathological margins after incomplete lumpectomy when breast conservation is planned. Grade D

Effective for dates of service on or after August 1, 2004:
MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for detection of a suspected occult breast primary tumor in patients with axillary nodal adenocarcinoma (i.e., negative mammography and physical exam). Grade A
Effective for dates of service on or after August 1, 2004:
MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for presurgical planning in patients with locally advanced breast cancer treated with neoadjuvant chemotherapy. Grade A

Effective for dates of service on or after August 1, 2004:
MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to determine the presence of pectoralis major muscle/chest wall invasion in patients with posteriorly located tumor. Grade C

Effective for dates of service prior to March 29, 2007:
(For updated indications for genetic risk see Breast Cancer Section)
HIGH GENETIC RISK OF BREAST CANCER
MRI of the breast meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for individuals defined as high risk of developing breast cancer based on the guidelines issued from the National Comprehensive Cancer Network (NCCN) or American College of Medical Genetics (ACMG)

- www.health.state.ny.us/nysdoh/cancer/obcancer/pp6-12.htm
- www.nccn.org/professionals/physician_gls/f_guidelines.asp?button=I+Agree#site

Grade B

NON-COVERED
MRI of the breast does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for all other indications (except for indications listed above) and will be considered investigational, including but not limited to:

When MRI is used as a screening technique (except where previously identified as covered) or any MRI performed without a dedicated breast coil in lieu of mammography. Grade A

Computer-aided detection, including computer algorithm analysis of MRI data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation of the breast does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational. Grade D

MRI screening for women with <15% lifetime risk does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage. Grade C

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.
**Key Points:**

MRI of the breast is a diagnostic tool which uses available MR scanners and intravenous MR contrast agents to more clearly characterize otherwise indeterminant breast lesions identified by clinical examination, mammography or ultrasound. Specialized breast coils such as the OBC-300 breast array coil and MR compatible equipment for performing biopsies have been developed in clinical marketing by the U.S. Food and Drug Administration as substantially equivalent to predicate devices.

Breast cancer is the most commonly known cutaneous malignancy and the second most frequent cause of cancer death among women in the United States. Estimated cumulative from birth, a woman’s risk for invasive breast cancer is 1 in 8, which is equivalent to 12.5% if she lives to age 90. However, the cumulative risk for receiving the diagnosis changes as women age without breast cancer. For example, it is a 1 in 7 chance at 30 years and 1 in 10 chances at 60 years of age. The American Cancer Society estimates there will be 215,990 more cases and over 40,000 deaths of invasive breast cancer in the United States during the year of 2004. Factors that increase breast cancer risk include younger age menarche, older age at first full-term pregnancy, older age at menopause, presence or history of benign breast disease, positive family history of a first degree relative with breast cancer, certain mutations such as BRCA1 or BRCA2 genes, use of hormone replacement therapy, ionizing radiation therapy to the breast particularly early in life, substantial alcohol consumption and obesity or a higher body mass index.

In more difficult situations, the MRI of the breast can be used to more clearly define the breast lesion and to be able to accurately establish a plan of treatment. When a tumor has been identified, breast MRI may be utilized to determine which patients would be more appropriately suited to breast conservation therapy. In addition, during the course of chemotherapy, the MRI of the breast may be used to demonstrate tumor location and to evaluate chemotherapy response.

Individuals at high genetic risk of breast cancer can be identified by using guidelines from the National Comprehensive Cancer Network (NCCN) or the American College of Medical Genetics. These individuals may benefit from early identification of breast cancer. MRI of the breast can more specifically identify breast cancer in the earlier stage in these individuals. In cases where breast implants are present, a clinical diagnosis may be difficult due to irregularities in the breast implant contour or when implant rupture has occurred. MRI of the breast can be utilized to more accurately diagnose and recommend a plan of treatment for these individuals.

A recent article published by Lehman, et al, in the American Journal of Radiology concludes that “new automated software applied to interpret breast MR examinations accurately showed significant enhancement in all the malignant lesions while depicting 12 of 24 benign lesions as showing insignificant enhancement. If these results are validated by a larger study, the number of unnecessary biopsies of MR lesions could be reduced without a concomitant decrease in cancer detection”.

The Blue Cross Association, Technology Evaluation Center performed an assessment on computer-aided detection of malignancy with MRI of the breast. In their assessment they note there are no high quality current published studies of the impact of the available CAD systems on the sensitivity and specificity of breast MRI. Most of the studies focus on the development of
CAD and have study samples which are highly selective and not representative of the normal screening population. The Assessment concludes it is not possible to assess the impact of CAD on health outcomes such as treatment success or survival for breast cancer patients.

The American Cancer Society recently (2007) published new guidelines concerning the use of breast MRI to detect breast cancer. These new guidelines recommend that generally women at high-risk of developing breast cancer undergo an MRI scan and mammogram once each year beginning at age 30. High-risk is defined as at least a 20% to 25% chance of developing breast cancer during their lifetime. Several risk assessment tools such as BRCAPRO, the Claus model, and the Tyrer-Cuzick model, are available to help estimate a woman’s breast cancer risk. The high-risk group includes women who have tested positive for BRCA1 or BRCA2 gene mutation or who have had a mother, sister, or daughter who has tested positive for one of the mutations. Women who have had at least two close relatives who have had breast cancer or who themselves have had chest radiation for Hodgkin’s disease are considered high risk. The group of experts assembled by ACS, who examined research on MRIs since 2002, said that MRI screening in addition to standard mammography can double the number of cancers identified, detecting them in 6% of high-risk women screened, compared with about 3% for only mammograms. They noted that MRIs often produce false-positives at about twice the rate of mammography, but the panel said the benefits outweigh the risks for women in the high-risk group. The panel said that MRIs are cost-effective for the high-risk women. The panel also recommended that MRIs be performed at experienced medical centers that can perform follow-up biopsies.

The panel said there was insufficient evidence to recommend for or against MRI screening in women with a moderately increased risk and these women should talk to their doctors about the benefits and limitations of adding MRI screening to their yearly mammograms. These women include those with a 15-20% lifetime risk, according to risk assessment tools that are based mainly on family history; have a personal history of breast cancer, ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), atypical ductal hyperplasia (ADH), or atypical lobular hyperplasia (ALH); or have extremely dense breasts when viewed by mammogram. The panel said yearly MRI screening is not recommended for women whose lifetime risk of breast cancer is < 15%. While MRI is more sensitive than mammograms, it also has a higher false-positive rate, which would result in unneeded biopsies and other tests in a large portion of these women.

The American College of Radiology Imaging Network (ACRIN) study, supported by the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), published a study recently (2007) in the NEJM on the use of MRI scans in women with breast cancer in one breast. This ACRIN trial was designed to determine whether MRI could improve the ability to accurately diagnose the full extent of a patient’s disease, including possible cancers in the opposite (or contralateral) breast at the time of the initial diagnosis. Among 969 women with a recent diagnosis of unilateral breast cancer and no abnormalities on mammography and clinical exam of the other breast, MRI found that 30 (3.1%) women had cancer in that breast. Of these, 60% were invasive and 40% were ductal carcinoma in situ (DCIS). The investigators concluded that women with a new diagnosis of breast cancer should have an MRI of the contralateral breast prior to treatment of the initially discovered tumor.
2011 Update

Dense breast tissue has been defined in at least three different ways:

• Four progressively more dense patterns, first defined by John Wolfe, MD, and now referred to as Wolfe patterns (N1, P1, P2, DY).

• Four progressively more dense patterns defined by the American College of Radiology (ACR) Breast Imaging Reporting and Data system (BIRADS; ACR, Reston, VA):
  1. almost entirely fat (<25% glandular);
  2. scattered fibroglandular densities (25-50%) that "could obscure a lesion";
  3. heterogeneously dense tissue (51%-75%) that "may lower the sensitivity of mammography";
  4. extremely dense (> 75%) that "lowers the sensitivity of mammography."

• Percentage of parenchymal tissue density (compared with fat density) on the craniocaudal mammogram, as measured manually by planimetry, or by computer software programs.

For clinical purposes, most descriptions of breast density today use the BIRADS terminology, so that “dense breast by mammography” would indicate either BIRADS 3 or 4.

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.

The FDA also required each of the two companies to conduct post approval studies following up about 40,000 women receiving breast implants for ten 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 (e.g., focus groups to study the patient labeling) and to track each implant so that updated product information can be distributed.

In its announcement of this decision, the FDA cited the Institute of Medicine report, 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 recommends that women have their first MRI three years after initial implant surgery and then every two years after that (See discussion below). Furthermore, if the MRI indicates implant rupture, the implant should be removed and replaced, if needed.
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 patterns of rupture with each generation of implants. The age of the implant is a known risk factor for rupture.

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, 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, while a similar study of the fourth-generation Inamed implant reported 0.3% rupture with a median implantation time of six years (range: 5–9 years). Another analysis focused on single, textured, third-generation implants (mostly subglandular Mentor Siltek gel implants) using MRI; using statistical analysis, the authors estimated that implant rupture generally starts at six to seven years and that by 13 years, about 11.8% of implants will have ruptured.

The gold 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:

- 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.
- Mammography can detect primarily extracapsular ruptures, which comprise about 10–20% 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 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%. Despite the apparent superiority of MRI, alternative modalities may be used when MRI is contraindicated (e.g., due to cardiac pacemakers or aneurysm clips).

The FDA recommendation for regular MRI screening among women with silicone implants (see Description section) has met with some controversy (e.g., McCarthy et al.). 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 ten years after implantation should be considered to screen for silent rupture and at subsequent five-year intervals.” 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 and coworkers evaluated 18 studies (published 1992–1998) that included approximately 1,029 women with MRI results who subsequently had about 2,036 breast implants removed. The studies were variable in design; all but one 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 sensitivity of 100%. 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 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 was 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. 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 two false-negative findings in this selected cohort and 12 false positive results, including three 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 one of two MRIs performed about two years apart. 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 eight of nine 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.

McCarthy et al. 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. 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) 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 did not permit conclusions about the impact on health outcomes; the scientific evidence was determined to be weak.

In 2010 one 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. 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). The majority of 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 (e.g., pain, asymmetry) compared to those that did have an MRI (79% vs. 59%, 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% (51–65%) and 78% (68–86%), 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% (83–94%) and 30% (16–49%), respectively. In other words, the use of MRI increased the sensitivity and decreased the specificity. In this population, the positive predictive values (PPV) and negative predictive values (NPV) were similar for both strategies (PPV=85% [79–91%] without MRI, 83% [76–89%] with MRI; NPV=54% [47-62%] without MRI, 57% [34–77%] 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.

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.

**July 2011 Update**

A meta-analysis by Song and colleagues examined the effect of study design biases on the diagnostic accuracy of MRI imaging for detecting silicone breast implant ruptures. 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 1,211 patients, 586 of whom were operated on. More that 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 five MRI studies considered gel bleeds as not ruptured and one 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 ration 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.

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.

**Key Words:**
Magnetic resonance imaging of the breast, MRI of the breast

**Approved by Governing Bodies:**
In 2006, the Food and Drug Administration (FDA) issued a Public Health Advisory to healthcare professionals regarding Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF/NFD) which may occur in patients with moderate to end-stage kidney disease after they have a MRI or Magnetic resonance angiography (MRA) with a gadolinium-based contrast agent.

First identified in 1997, NSF/NFD is almost exclusively found in patients with renal failure and acidosis. Patients with this condition develop fibrosis of the skin and connective tissues throughout the body. The skin thickening may inhibit flexion and extension of joints, resulting in contractures. In addition, patients may develop widespread fibrosis in other organs. A skin biopsy is necessary to make a definitive diagnosis. The disease is progressive and may be fatal. Its cause is unknown.

Patients who receive gadolinium-containing contrast agents should be aware of the following possible signs and symptoms of NSF/NFD and advised to seek medical attention if these occur: swelling and tightening of the skin; difficulty extending the joints of arms, hands, legs, and feet; weakness, reddened or darkened areas on the skin; burning or itching of the skin; and deep bone pain in the hips and ribs.
Physicians should be cautious regarding the use of gadolinium-containing contrast imaging agents, especially at high doses, in patients with moderate to end-stage renal failure.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
BellSouth/AT&T contracts: No special provisions
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan.
Wal-Mart: Special benefit consideration may apply. Refer to member’s benefit plan.

**Pre-certification requirements:** Effective for dates of service on or after November 1, 2007, required when ordered by a provider in a Blue Cross and Blue Shield of Alabama’s Preferred or Participating Network for a patient covered by Blue Cross and Blue Shield of Alabama who will receive outpatient imaging services(s) from a Preferred Medical Doctor (PMD) or Preferred Radiology Participating (PRP) provider

**Exceptions to the Alabama PMD and PRP pre-certification requirement:** NASCO, Wal-Mart, Blue Advantage, Flowers Foods, Inc., FEP.

In addition to the above Blue Cross and Blue Shield of Alabama PMD/PRP Network requirement, some self-insured national account groups may require pre-certification for all MRIs effective for dates of service on or after January 1, 2009. Please confirm during your benefit verification process if a pre-certification is required.

Reviews to verify accuracy of pre-certification information will be conducted.

**Coding:**
CPT codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77058</td>
<td>Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral</td>
</tr>
<tr>
<td>77059</td>
<td>;bilateral</td>
</tr>
<tr>
<td>0159T</td>
<td>Computer aided detection including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation, breast MRI (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**References:**


Policy History:
Medical Review Committee, October 2001
Medical Policy Group, July 2002
Medical Policy Administration Committee, July 2002
Available for comment July 17-August 30, 2002
Available for comment September 18-November 1, 2002
Medical Policy Group, September 2003 (2)
Medical Policy Administration Committee, October 2003
Medical Policy Group, November 2003
Medical Policy Group, January 2004
Medical Policy Administration Committee, February 2004
Available for comment February 7-March 22, 2004
Medical Policy Group, August 2004 (2)
Medical Policy Administration Committee, April 2005
Available for comment April 8-May 23, 2005
Medical Policy Group, July 2005 (3)
Medical Policy Administration Committee, July 2005
Available for comment August 6-September 19, 2005
Medical Policy Group, August 2006 (3)
Medical Policy Administration Committee, August 2006
Available for comment August 30-September 21, 2006
Medical Policy Group, September 2006 (2)
Available for comment September 22-October 5, 2006
Medical Policy Group, January 2007 (2)
Medical Policy Group, May 2007 (3)
Medical Review Committee, May 2007
Medical Policy Administration Committee, May 2007
Available for comment May 31-June 16, 2007
Medical Policy Group, December 2008 (2)
Medical Policy Group, December 2010 (1)
Medical Policy Panel, January 2011
Medical Policy Group, February 2011 (2) Policy on Breast Implants, Key Points, References
Updated
Medical Policy Administration Committee, March 2011
Available for comment April 4 – May 18, 2011
Medical Policy Panel, July 2011
Medical Policy Group, July 2011 (2) Key Points, Reference update
Medical Policy Group, February 2013 (2) Updated policy with link to CareCore National©
medical policies effective April 1, 2013
Medical Policy Administration Committee, March 2013
Available for comment February 15 through March 31, 2013
Medical Policy Group, November 2013 (2): Updated CareCore link

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i)
research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.