

MEDICAL POLICY

SUBJECT: MAGNETIC RESONANCE IMAGING (MRI) OF THE BREAST	EFFECTIVE DATE: 08/18/05 REVISED DATE: 06/15/06, 07/19/07, 08/16/07, 06/19/08, 01/21/10, 05/19/11, 06/21/12, 08/15/13, 06/19/14, 06/18/15, 03/17/16, 3/20/17, 06/21/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer-reviewed literature, magnetic resonance imaging (MRI) has been medically proven to be effective and is **medically appropriate** for the following breast indications:
- A. Silicone breast implants:
 - 1. When necessary to confirm rupture of silicone breast implants in patients whose ultrasound is nondiagnostic of rupture; or
 - B. Indeterminate breast imaging:

Patients with indeterminate mammograms and sonograms if there is new onset of either:

 - 1. Nipple retraction; or
 - 2. Unilateral drainage from the nipple that is bloody or clear.
 - C. Patient with new diagnosis of breast cancer, including patients with high risk of breast cancer based on the diagnosis of Lobular Carcinoma In Situ (LCIS), or Ductal Carcinoma In Situ (DCIS), or Paget's disease.
 - D. To localize the site of primary occult breast cancer in patients with adenocarcinoma suggestive of breast cancer discovered as axillary node metastasis or distant metastasis without focal findings on physical examination or on mammography/ultrasonography.
 - E. Subsequent treatment strategies in patients with breast cancer; recurrence (e.g. follow-up, recurrence, surveillance):
 - 1. To detect local tumor recurrence in breast cancer patients who have undergone mastectomy and breast reconstruction with an implant or tissue transfer flaps (rectus, latissimus dorsi, or gluteal); or
 - 2. Assessment of residual tumor in patients who have undergone lumpectomy and have close or positive margins, when the findings may indicate a significant change in surgical management.
 - 3. To evaluate clinical suspicion of recurrence, following evaluations with mammography and/or ultrasound, if those evaluations are inconclusive or conflict with physical examination or other clinical indicators. This applies to intact breasts, reconstructed breasts, and possible chest wall recurrences following mastectomy.
 - 4. When there are architectural changes in the breast post-surgery / post radiation therapy precluding adequate interpretation of conventional mammography and making it difficult to view the entire breast tissue.
 - 5. High risk histologies such as atypical ductal hyperplasia (ADH), or atypical lobular hyperplasia (ALH).
 - F. Subsequent treatment strategies in patients with breast cancer; neoadjuvant chemotherapy:
 - 1. Prior to the start of chemotherapy with no prior breast MRI after the diagnosis of breast cancer; or
 - 2. After completion of chemotherapy to evaluate response prior to surgery.
 - G. Subsequent treatment strategies in patients with breast cancer; Follow up surveillance of women with prior breast cancer and one of the following:
 - 1. Lifetime risk of a breast cancer (prior to their diagnosis) greater than 20% based on models largely dependent on family history, including a family history of male breast cancer; or
 - 2. Diagnosed with cancer in both breasts; or two cancers diagnosed in the same breast; or the primary breast cancer was mammographically occult; or
 - 3. Individuals diagnosed with breast cancer at age 50 years or younger.

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H. Other:

1. When an MRI-guided biopsy is necessary for a lesion related to the above breast indications; or

I. Screening:

1. To *screen* patients with high genetic risk of breast cancer defined as having any of the following:
 - a. Patient has a confirmed BRCA1 or BRCA2 gene mutations; or
 - b. Patient has a first-degree relative who is a confirmed carrier of the BRCA1 or BRCA2 gene mutation even if patient has not been tested for BRCA mutation; or
 - c. Patient is a confirmed carrier of ATM, CDH1, CHEK2, NBN, NF1, PALB2, or STK11 gene mutations; or
 - d. Patient has a first or second degree male relative (father, brother, uncle) with breast cancer; or
 - e. At high risk (lifetime risk about 20% to 25% or greater) of developing breast cancer as identified by models that are largely defined by family history; or
 - f. Patient has one first-degree relative with either 2 breast cancers or both breast and ovarian cancer; or
 - g. Patient has two or more first degree relatives with breast cancer or ovarian cancer; or
 - h. Patient has one first degree relative with breast cancer or ovarian cancer that was diagnosed at age less than 50 years; or
 - i. Patient carries or has a first-degree relative who carries a genetic mutation in the TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes; or
 - j. Follow-up MRI in 6 months for patients with a probable benign lesion on MRI; or
2. History of radiation therapy to the chest between the ages of 10-30.

II. Based on our criteria and review of the peer-reviewed literature, MRI of the breast has not been medically proven to be effective and is considered **investigational** including but not limited to the following indications:

- A. **Screening** for the detection of breast cancer when the sensitivity of mammography is limited (e.g. dense breasts, breast implants). Breast ultrasound should be considered before MRI for this population of women;
- B. **Screening** in average-risk patients (15-20% lifetime risk based on one of the accepted risk assessment tools that utilize family history and other factors);
- C. During neoadjuvant chemotherapy to provide an early prediction of the response to neoadjuvant chemotherapy;
- D. For further evaluation of an otherwise suspicious breast lesion;
- E. For further evaluation of low-suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow-up;
- F. To evaluate breasts before biopsy in an effort to reduce the number of surgical biopsies for benign lesions; and
- G. To differentiate cysts from solid lesions.
- H. To confirm implant rupture in symptomatic patients whose ultrasonography shows rupture especially with implants greater than 10 years old (ultrasound sufficient to proceed with removal)
- I. To differentiate benign from malignant breast disease, especially clustered microcalcifications.

III. Use of computer-aided detection (CAD) is considered inclusive when performed as part of the Breast MRI.

IV. *3D Imaging* is considered inclusive when performed as part of the Breast MRI.

Refer to Corporate Medical Policy # 2.02.06 regarding Genetic Testing for BRCA1 or BRCA2 Mutation.

Refer to Corporate Medical Policy #6.01.08 regarding Magnetic Resonance Angiography.

Refer to Corporate Medical Policy #7.01.19 regarding Management of Breast Implants.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.

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POLICY GUIDELINES:

The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Magnetic resonance imaging (MRI) is a diagnostic imaging modality that uses magnetic and radio frequency fields to produce a non-invasive two-dimensional view of an internal organ or structure. Through radio frequency emissions, a tomographic image can be constructed that will represent the tissue being analyzed and the environment surrounding it. MRI is designed to identify anatomical abnormalities and to provide information on characteristics of the tissue. Breast MRI generally requires a high field strength system and a dedicated breast surface coil.

Computer-Aided Detection (CAD) for MRI (also referred to as computer-aided evaluation or CAE). Unlike CAD systems used with mammography, CAD for MRI is not aimed primarily at identifying lesions for consideration by a radiologist. CAD systems for MRI propose to provide easier ways of interpreting the patterns of contrast enhancement and washout across a series of images, which may help identify lesions and their likelihood of being malignant.

Lesions on mammography have a subtle appearance. However, most cancers enhance on MRI. The challenge is determining which lesions are benign and which are malignant. A large number of images are produced during MRI of the breast. Images are taken at varying depths throughout each breast multiplied by the number of times the breast is imaged to capture different time points in the enhancement process, which can produce hundreds of images. Radiologists view the images to detect suspicious areas, and then may choose a region of interest and look at the enhancement pattern. But there may be variations across radiologists in the regions of interest selected and in the precise definition of the region of interest. CAE systems use color-coding and differences in hue to indicate the patterns of enhancement for each pixel in the breast image, which may allow radiologists to analyze the enhancement patterns systematically.

RATIONALE:

A number of magnetic resonance scanners have been received 510(k) premarket clearance by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) for use in the U. S. Low-field MRI systems have also received 510(k) premarket clearance by the FDA CDRH, such as the ARTOSCAN (0.2 Tesla magnet) and MAGNA SL (0.3 Tesla magnet). Specialized breast coils such as the OBC-300 Breast Array Coil® (MRI Devices Corp., Waukesha, WI) and MR-compatible equipment for performing biopsy have received FDA 510(k) clearance. Computer-aided detection (CAD) systems for use with MRI of the breast have received 510(k) marketing clearance from the FDA, such as: CADstream™ (Confirma, Kirkland, WA) and 3TP Software Option (CAD Sciences, White Plains, NY).

Safety Alert: On 5/10/05 the FDA issued a Public Health Notification reminding radiology personnel and physicians that serious injury or death can occur when patients with implanted neurological stimulators undergo MRI procedures, even if the device has been turned off.

Before and after neoadjuvant chemotherapy to guide decisions to use breast conservation therapy. Available studies consistently show that breast MRI appears to be better than conventional presurgical clinical staging methods at determining extent and size of residual tumor. Compared with histopathology, the reference standard, MRI demonstrates the presence of residual tumor with estimated sensitivity ranging from 90-100% and specificity from 50-100%. MRI estimated the size and extent of tumor correctly in comparison with pathologic evaluation in 57%-97% of cases among 5 studies. Since MRI appears to provide a more accurate determination of tumor size and extent compared with clinical staging, it is likely that MRI would be more accurate in determining eligibility for breast-conservation therapy (BCT). Using staging results instead of clinical staging for presurgical planning would lead to an improvement in net health outcome by increasing the use of BCT when appropriate and avoiding the need for re-excision surgery when BCT is not appropriate.

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A prospective study of 118 women evaluated the accuracy of contrast-enhanced MRI (CE-MRI) mammography for depiction of synchronous contralateral breast cancer in patients with newly diagnosed unilateral breast cancer or high-risk lesions, with histologic analysis or follow-up as a reference. Patients had negative findings in the contralateral breast at physical examination, ultrasound and conventional mammography. CE-MRI showed contralateral lesions in 28 (24%) of 118 patients. 24 of the 28 lesions were detected in patients with dense breasts (BI-RADS breast density category 3 or 4). At histologic analysis, 22 lesions were confirmed as malignant; six were fibroadenomas.

Early prediction of response to neoadjuvant chemotherapy. There is insufficient evidence to permit conclusions on the effect on health outcomes of using breast MRI to provide an early prediction of the response to neoadjuvant chemotherapy. Available evidence is limited to a few small studies with inconsistencies in outcome measures, reporting, and use of statistical comparison. Results are not consistent.

Personal history of breast cancer. Current studies are small and retrospective but suggest some benefit for surveillance MRI after breast cancer treatment. Although MRI may demonstrate new or recurrent cancers earlier than routine mammographic and/or ultrasonographic imaging, the low yield may not be cost effective in counter-balancing its inherent low specificity and subsequent need for additional imaging and/or tissue biopsy. Many of the articles indicate that prospective studies are necessary to determine which subset of patients, if any, may benefit from MRI surveillance in the setting of previous breast cancer, and whether this early identification translates to improved disease-specific survival.

Screening high genetic-risk patients. Asymptomatic women thought to be at high risk of breast cancer due to genetic risk have a lifetime risk of cancer that is much higher than average. In addition, breast cancer often occurs at a much younger age than average. Traditional screening using mammography is thought to be less sensitive in younger vs. older women because of a higher prevalence of dense breast tissue. Clinical evidence shows at least equivalent performance for MRI in terms of sensitivity in detecting breast cancer compared to mammography. In two published studies, MRI detected 100% of cancer cases, while mammography detected 33%. In one study, the difference between MRI and mammography sensitivity was statistically significant but not in the other. Presently there are no studies that adequately define the age of initiation or the frequency for testing with MRI in high-risk women. The American Cancer Society (ACS) recommends annual screening with MRI as an adjunct to mammography for those at high risk for breast cancer (lifetime risk of 20-25% or greater); for those who received radiation to the chest between 10-30 years of age; for those with Li-Fraumeni syndrome and first-degree relatives; for those with Cowden and Bannayan-Rile-Ruvalcaba syndromes and first-degree relatives. ACS states there is insufficient evidence to recommend for or against annual MRI screening for those with: a lifetime risk for breast cancer of 15-20%, lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH), atypical ductal hyperplasia (ADH), heterogeneously or extremely dense breast n mammography, or a personal history of breast cancer including ductal carcinoma in situ (DCIS). ACS recommends against annual MRI screening for those with a less than 15% lifetime risk of breast cancer.

Lifetime risk of breast cancer may be calculated using the Gail, Claus or the Tyrer-Cuzick model. The Gail model bases its risk estimates on certain personal risk factors, like current age, age at menarche (first menstrual period) and history of prior breast biopsies, along with any history of breast cancer in first-degree relatives. The Claus model estimates risk based on family history of breast cancer in both first and second-degree relatives. The Tyrer-Cuzick model takes into account the person's history (age, extended family history of breast and ovarian cancer, child birth history, history of breast biopsy and it's pathology, age of menarche and menopause, exposure to post-menopausal hormones, Ashkenazi Jewish heritage) as well as their height/weight (higher BMI-body mass index=increased risk). These 2 models could easily give different estimates using the same data. Results from any of the risk assessment tools should be discussed by a woman and her doctor when being used to decide whether to start MRI screening.

The National Comprehensive Cancer Network (NCCN) 2016 Clinical Practice Guidelines in Oncology for Genetic/Familial High-Risk Assessment for Breast and Ovarian Cancer recommends: (1) BRCA mutation or first-degree relative BRCA carrier, but untested: annual mammogram and breast MRI screening starting at age 25 years or on an individualized timetable based on earliest age of onset in family members; (2) Li-Fraumeni syndrome and first-degree relatives: annual mammograms and/or breast MRI screening based on earliest age of onset in the family; (3) Cowden syndrome and

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Bannayan-Riley-Ruvalcaba syndrome and first-degree relatives: annual mammogram and breast MRI screening based on the earliest known breast cancer in the family (whichever comes first); 4) Radiation to chest between age 10 and 30 years. For breast and ovarian management based on genetic test results, MRI is recommended based on gene or risk level (greater than 20% risk of breast cancer) for the following individuals with mutations in the moderate-penetrant genes ATM, CDH1, CHEK2, PALB2, and STK11 as well as those high-penetrant genes BRCA, CDH1, PTEN, and TP53 as described previously.

NCCN Breast Cancer Screening and Diagnosis guidelines (2016) recommend annual MRI screening beginning at age 25 years for women with BRCA mutations and untested first-degree relatives of a BRCA carrier as well as, women with a 20% or greater lifetime risk of breast cancer as defined by models that are largely dependent on family history. Annual breast cancer screening with breast MRI should begin at age 25 years in women with mutations in TP53 and STK11. The NCCN Genetic/Familial High Risk Assessment: Breast and Ovarian panel (2017) recommends annual mammogram with mammography for women with the CDH1, NF1, PALB2, PTEN mutated gene at age 30 years. Breast MRI screening in patients with NF1 may be discontinued at age 50 years. NCCN recommends annual breast screening with mammography for women with a mutated ATM, CHEK2, NBN gene beginning at age 40 years, with consideration of annual breast MRI.

The American College of Radiology Appropriateness Criteria for Breast Cancer Screening (2017) considers MRI for screening high-risk women including women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between 10 to 30 years of age, and women with 20% or greater lifetime risk of breast cancer usually appropriate.

Screening for detection of breast cancer in patients who have breast characteristics limiting the sensitivity of mammography. The American College of Radiology Appropriateness Criteria for Breast Cancer Screening (2017) considers MRI for screening for intermediate-risk women including women with a history of breast cancer, lobular neoplasia, atypical ductal hyperplasia or 15% to 20% lifetime risk of breast may be appropriate.

Screening average-risk patients. Evidence for routine use of MRI in breast cancer screening is limited to studies, which compare the sensitivity and specificity of MRI screening to other methods such as mammography. Such evidence is limited because it does not evaluate the impact on patient outcomes. The American College of Radiology Appropriateness Criteria for Breast Cancer Screening (2017) considers MRI for screening average-risk women with less than 15% lifetime risk of breast cancer usually not appropriate.

Computer-aided detection (CAD) with MRI. Also referred to as computer-aided evaluation (CAE). There is insufficient evidence to assess whether the use of CAD with MRI of the breast improves intermediate and long-term outcomes. There are no high-quality published studies of the impact of commercially available CAD systems on the sensitivity and specificity of MRI of the breast. Literature is not clear on how CAD systems are to be used. Because CAD is not 100% sensitive, potentially malignant lesions detected on original films are followed up, as well as additional lesions identified by CAD that the radiologist determines should be worked-up. In this way, CAD can add to the sensitivity but not the specificity of MRI. With MRI of the breast, the issue is trying to increase the specificity, not the sensitivity, which is already high. Additionally, there is insufficient evidence to assess whether the use of CAD systems would maintain or increase the sensitivity, specificity and recall rates of MRI of the breast used as a screening test among women at high genetic risk of breast cancer.

Prospective, well-designed and executed studies that look specifically at the addition of CAD with MRI are needed to determine whether or not the use of CAD provides a positive clinical benefit to patients. Small studies propose the use of CAD to identify lesions that would not need to be biopsied. However, there were false negative findings. The risk of missing cancers and delaying treatment has to be weighed against the opportunity for reducing the number of unnecessary biopsies. The magnitude of this risk cannot be estimated reliably from available studies. Further research is needed that focuses on the incremental value of CAD in large samples and in a variety of settings.

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CODES: Number: Description:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; not requiring image postprocessing on an independent workstation (Inclusive to 77058 or 77059)
	76377	requiring image postprocessing on an independent workstation (Inclusive to 77058 or 77059)
	76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)
	77058	Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral
	77059	bilateral
	0159T	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) (Inclusive to 77058 or 77059 and to C8903-C8908))

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HCPCS:	C8903	Magnetic resonance imaging with contrast, breast; unilateral
	C8904	Magnetic resonance imaging without contrast, breast; unilateral
	C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
	C8906	Magnetic resonance imaging with contrast, breast; bilateral
	C8907	Magnetic resonance imaging without contrast, breast; bilateral
	C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

ICD10:	C50.011-C50.929	Malignant neoplasm of breast, female, male (code range)
	C79.81	Secondary malignant neoplasm of breast
	D05.00-D05.92	Carcinoma in situ of breast (code range)
	L59.9	Disorder of the skin and subcutaneous tissue related to radiation, unspecified
	N63	Unspecified lump in breast
	Z12.39	Encounter for other screening for malignant neoplasm of breast
	Z15.01	Genetic susceptibility to malignant neoplasm of breast
	Z80.3	Family history of malignant neoplasm of breast
	Z85.3	Personal history of malignant neoplasm of breast
	Z92.3	Personal history of irradiation

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<p>SUBJECT: MAGNETIC RESONANCE IMAGING (MRI) OF THE BREAST</p> <p>POLICY NUMBER: 6.01.35</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 08/18/05</p> <p>REVISED DATE: 06/15/06, 07/19/07, 08/16/07, 06/19/08, 01/21/10, 05/19/11, 06/21/12, 08/15/13, 06/19/14, 06/18/15, 03/17/16, 3/20/17, 06/21/18</p> <p>PAGE: 9 OF: 9</p>
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KEY WORDS:

Breast MRI, CAD MRI.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Breast Imaging: Mammography/Breast Echography (Sonography)/Breast MRI/Dictograph. Please refer to the following LCD website for Medicare Members:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33585&ver=22&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=All&bc=AggAAAIBAAA&

There is currently a Local Coverage Determination (LCD) for Category III CPT® Codes (refer to CPT code section for CAD). Please refer to the following LCD website for Medicare Members:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ver=80&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=Active&bc=AggAAAIBAAA&