



Medical Policy

Subject: MRI of the Breast

Policy #: R AD.00036

Status: Reviewed

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Last Review Date: 05/ 15/2008

Description/Scope

Magnetic resonance imaging (MRI) is a diagnostic imaging modality that uses magnetic and radiofrequency fields to image body tissue non-invasively. MRI of the breast can be performed using MR scanners equipped with breast coils and intravenous MR contrast agents. MRI of the breast has been investigated as a clinical tool for several applications being broadly divided into screening, diagnostic and detection applications.

Policy Statement

Medically Necessary:

Annual MRI of the breast using scanners equipped with breast coils with the ability to provide needle localization for biopsy is considered **medically necessary** in the following clinical situations:

- Individuals with a BRCA1 or BRCA2 mutation;
- Individuals who are a first-degree relative of a BRCA1 or BRCA2 mutation carrier, but have not been tested for BRCA1 or BRCA2 mutation;
- Individuals with a lifetime risk for breast cancer is 20–25% or greater, as defined by BRCAPRO or other models (e.g., BOADICEA, Claus, Tyrer-Cuzick) that are largely dependent on family history;
- Individuals who have had radiation therapy to the chest between the ages of 10 and 30 years old;
- Individuals who have Li-Fraumeni syndrome (mutations of TP5 gene), Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome (mutations of PTEN gene), or have a first-degree relative with a history of one of these syndromes;
- Individuals with heterogeneously or extremely dense breast on mammography;
- Individuals considered as high familial risk, have not tested for BRCA1 or BRCA 2 or have not had a statistical risk analysis utilizing BRCAPRO or other models (e.g., BOADICEA, Claus, Tyrer-Cuzick) and whose family history includes ONE of the following:
 - Two or more first degree relatives with breast cancer; **or**
 - One first degree relative and two or more second degree or third degree relatives with breast cancer; **or**
 - One first degree relative with breast cancer before the age of 45 years and one other relative with breast cancer; **or**
 - One first degree relative with breast cancer and one or more relatives with ovarian cancer; **or**
 - Two second degree or third degree relatives with breast cancer and one or more with ovarian cancer; **or**
 - One second degree or third degree relative with breast cancer and two or more with ovarian cancer; **or**

- Three or more second degree or third degree relatives with breast cancer; **or**
- One first degree relative with bilateral breast cancer; **or**
- Breast cancer in a male relative.

MRI of the breast using scanners equipped with breast coils is considered **medically necessary** for the following diagnostic or detection indications:

- For presurgical planning in patients with locally advanced breast cancer before and after completion of neoadjuvant chemotherapy. MRI may be performed before and after completion of neoadjuvant chemotherapy to permit tumor localization and characterization;
- To determine the presence of pectoralis major muscle/chest wall invasion in patients with posteriorly located tumors;
- To detect a suspected occult breast primary in patients with positive axillary nodes, but with a mammographically normal breast;
- To evaluate the integrity of a breast implant when ultrasound imaging is inconclusive;
- To evaluate the presence of multicentric disease in patients with clinically localized breast cancer;
- For imaging of the contralateral breast in individuals within 12 months of a breast cancer diagnosis in the opposite breast is made.

Investigational and Not Medically Necessary:

Other applications of MRI of the breast are considered **investigational and not medically necessary**, including, but not limited to the following:

- To further characterize indeterminate breast lesions identified by clinical exam, mammography or ultrasound
- For the diagnosis of low suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow up;
- For the diagnosis of a suspicious breast lesion in order to avoid biopsy;
- To determine response *during* (as opposed to before and after) neoadjuvant chemotherapy in patients with locally advanced breast cancer;
- For evaluation of residual tumor in patients with positive margins after lumpectomy;
- As a screening technique in average risk patients.

Rationale

The available data for MRI imaging is inconclusive for its use for routine screening in asymptomatic individuals. The American Society of Clinical Oncologists (ASCO), in their *2006 Update of the Breast Cancer Follow-Up and Management Guidelines in the Adjuvant Setting* stated that:

"Although screening breast MRI seems to be more sensitive than conventional imaging at detecting breast cancer in high-risk women, there is no evidence that breast MRI improves outcomes when used as a breast cancer surveillance tool during routine follow-up in asymptomatic patients. The decision to use breast MRI in high-risk patients should be made on an individual basis depending on the complexity of the clinical scenario." (ASCO, 2006)

MRI for Indeterminate Breast Lesions

Validation for MR imaging of indeterminate breast lesions requires data comparing its diagnostic performance compared to breast biopsy, i.e. the gold standard. Considering the relative ease of breast biopsy, the sensitivity of breast MRI would have to be virtually 100% to confidently avoid breast

biopsy. While MRI performs well, it is clear that the sensitivity is not 100%. False negative results tend to occur particularly in certain subcategories, such as ductal carcinoma in situ. Invasive carcinoma may fail to enhance on MRI, leading to false-negative findings as well. The potential harm to health outcomes of failing to diagnose breast cancer or at least delaying the diagnosis of breast cancer is of significant concern.

In April 2006, the Agency for Healthcare Quality and Research (AHRQ) evaluated various imaging techniques for women with an average risk level for breast cancer. Based on their analysis, they concluded that for every 1000 women and who had an abnormal mammogram and who subsequently underwent MRI imaging felt to be negative, about 962 women would have avoided an unnecessary biopsy, but 38 women would have missed cancers (AHRQ, 2006).

MRI as a Technique to Evaluate Multicentric Disease

Multiple studies confirm that MRI of the breast has a better sensitivity and specificity for identifying multicentric and multifocal breast tumors compared to mammography or ultrasound. However, there is no evidence that modified radical mastectomy would add any benefit compared to breast conserving surgery with tumor bed radiation with respect to risk of local or distant recurrence or survival for these women. Multiple trials have compared the two procedures and have found outcomes to be similar in all respects. These studies have not employed MRI as part of the staging work-up, but rather relied on mammography, chest x-ray, liver enzymes and physical exam for pre-surgical staging. Although information from the MRI might change the decision from breast conserving surgery in favor of mastectomy, it is unknown whether by doing so the patient receives a better trade off of risk and benefit.

MRI in Patients with Increased Familial, Genetic or Other Risk of Breast Cancer

Several studies have suggested that MRI is more sensitive than mammography, and therefore there has been an interest in using MRI as an alternate screening methodology in patients considered to be at high risk for breast cancer; i.e. those with BRCA 1 or BRCA 2 mutations. Most recently, Krieg and colleagues (2004) reported on the results of a study that enrolled 1909 patients considered to have a lifetime risk of breast cancer of 15% or more, which included patients with known BRCA mutations or a positive family history. The patients underwent a yearly mammogram and MRI. Interpretations of the paired results were blinded. A total of 45 tumors were identified during the four year duration of the study; 32 were detected by MRI (sensitivity 71%) and 18 by mammography (sensitivity 40%). In addition, the study reported that MRI screening can detect breast cancer at an early stage in women with breast cancer. The American Cancer Society (ACS, 2007) has updated their MRI guidelines. These guidelines state:

Recommendations for Breast MRI Screening as an Adjunct to Mammography

Recommend Annual MRI Screening (Based on Evidence)*

- BRCA mutation;
- First-degree relative of BRCA carrier, but untested;
- Lifetime risk ~20–25% or greater, as defined by BRCA^{PRO} or other models that are largely dependent on family history.

Recommend Annual MRI Screening (Based on Expert Consensus Opinion†)

- Radiation to chest between age 10 and 30 years;
- Li-Fraumeni syndrome and first-degree relatives;
- Cowden and Bannayan-Riley-Ruvalcaba syndromes and first-degree relatives.

Insufficient Evidence to Recommend for or Against MRI Screening†

- Lifetime risk 15–20%, as defined by BRCAPRO or other models that are largely dependent on family history;
- Lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH);
- Atypical ductal hyperplasia (ADH);
- Heterogeneously or extremely dense breast on mammography;
- Women with a personal history of breast cancer, including ductal carcinoma in situ (DCIS).

Recommend Against MRI Screening (Based on Expert Consensus Opinion)

- Women at <15% lifetime risk.

*Evidence from nonrandomized screening trials and observational studies.

†Based on evidence of lifetime risk for breast cancer.

‡Payment should not be a barrier. Screening decisions should be made on a case-by-case basis, as there may be particular factors to support MRI. More data on these groups is expected to be published soon.

As noted above, the ACS expects more medical data for these groups to be published soon. At present the evidence regarding those with lower lifetime risk, lobular carcinoma in situ or atypical ductal hyperplasia is insufficient to support the use of MRI of the breast as a screening technique. MRI for individuals with mammographically dense breasts has been determined to be medically necessary by previous medical review based on consensus and expert review.

MRI to Determine Treatment Response in Patients with Locally Advanced Breast Cancer Receiving Neoadjuvant Chemotherapy

Compared with conventional methods of evaluating tumor size and extent (i.e. mammography, clinical exam or ultrasound), MRI of the breast provides an estimation of tumor size and extent that is at least as good or better than that based on alternatives. Drew and colleagues (2001) found MRI to be 100% sensitive and specific for defining residual tumor after chemotherapy. Conversely, mammography achieved 90% sensitivity and 57% specificity and clinical exam was only 50% sensitive and 85% specific. Similarly Partridge et al (2002) reported correlation of residual tumor size on MRI of 0.89 and clinical exam of 0.60. The role of MRI to assess response *during* a course of neoadjuvant chemotherapy is less clear. The most important use would be to reliably identify patients whose tumors are not responding to neoadjuvant chemotherapy to avoid the added morbidity of continued ineffective chemotherapy. Such chemotherapy may be discontinued or changed to an alternative and potentially effective regimen. MRI would be harmful when it falsely suggests a lack of response and leads to premature discontinuation of effective chemotherapy. The available body of evidence is limited to a few small studies with inconsistencies in outcome measures, reporting and use of statistical comparisons. Results are not consistent, and there is insufficient evidence to determine whether breast MRI can reliably predict lack of response to neoadjuvant chemotherapy.

MRI to Evaluate Suspected Chest Wall Involvement

Morris and colleagues prospectively studied 19 subjects with posteriorly located breast tumors suspected to involve the pectoralis major muscle based on either mammography or clinical exam. Thirteen of these tumors were thought to be fixed to the chest wall on clinical exam and 12 appeared to have pectoral muscle involvement on mammography. Results of MRI were compared with surgical and pathological

findings. The presence of abnormal enhancement within the pectoralis major muscle on MRI was 100% sensitive and 100% specific for identifying the 5 tumors that actually involved the pectoralis major muscle. Given the high level of diagnostic accuracy for MRI as compared with reference standard and conventional alternative techniques, the evidence is considered sufficient to permit conclusions that breast MRI improves net health outcome.

MRI to Detect Breast Cancer in the Contralateral Breast in Patients with Breast Cancer

Previously, Liberman and colleagues (2003) reported a study of 212 subjects who had negative mammograms of the asymptomatic contralateral breast and found 12 cancers (prevalence 5%) on MRI, including 6 DCIS and 6 infiltrating carcinomas. However, the positive predictive value (PPV) was only 20%, with a specificity of 76%. Most recently, Lehman and colleagues (2007) reported a study of 969 women with a recent diagnosis of unilateral breast cancer and no abnormalities on mammographic and clinical examination of the contralateral breast who underwent breast MRI. MRI detected clinically and mammographically occult breast cancer in the contralateral breast in 30 of 969 study participants (3.1%). The sensitivity of MRI in the contralateral breast was 91%, and the specificity was 88%. The negative predictive value of MRI was 99%.

MRI To Detect a Suspected Occult Breast Primary in Patients with Positive Axillary Nodes

This indication for MRI represents a small subgroup of patients, but the adjunctive use of breast MRI allows patients to avoid the morbidity of mastectomy in a substantial portion of patients (approximately 26-61%), while the risk of unnecessary biopsy is estimated to be 8%. The use of positive MRI findings to guide breast conserving surgery instead of presumptive mastectomy appears to offer the substantial benefit of breast conservation in true positive MRI cases.

MRI to Evaluate Residual Tumor after Lumpectomy with Positive Surgical Margins

Several studies have evaluated the diagnostic performance of MRI to determine the presence of residual disease after prior biopsy or lumpectomy. Most of these studies, including the single prospective study report poor sensitivity and specificity of MRI for detection of residual disease. The available evidence is not sufficient to permit conclusions whether MRI improves net health outcome when used to identify the presence and/or extent of residual disease after lumpectomy and prior to re-excision.

MRI as an Alternative to Mammography in Patients Who Have Breast Characteristics Limiting the Sensitivity of Mammography

Mammography may be technically difficult for individuals with dense breasts (i.e., younger patients). In these instances, MRI may be an alternative to mammography. Boyd and colleagues (2007) conducted a case controlled study of a previously screened population examining the association of breast density at baseline mammogram and the risk of breast cancer. They found that extensive mammography density is associated with risk of breast cancer detected by subsequent screening or other methods.

MRI as a Technique to Evaluate the Integrity of Breast Implants

Imaging techniques to detect implant rupture include mammography, ultrasonography and MRI. Various studies have suggested that MRI is the most sensitive and specific technique of the three.

The American College of Radiology (ACR), in their *Practice Guideline for the Performance of Magnetic Resonance Imaging (MRI) of the Breast*, addresses the appropriate MRI equipment required for breast MRI studies.

Background/Overview

Magnetic resonance imaging (MRI) is non invasive imaging modality that uses magnetic and

radiofrequency fields to image body tissue. These radio frequency emissions are received and a tomographic image can be constructed that will represent the tissue being analyzed and the environment surrounding it. MRI uses no ionizing radiation and is unimpeded by bone. It is designed to identify anatomical abnormalities and to provide information on the characteristics of tissue. MRI of the breast has been investigated as a clinical tool for several applications.

Definitions

BRCAPRO: a computer-based Bayesian probability model that uses first- and second-degree family history of breast or breast/ovarian cancers to determine the probability that a BRCA1 or BRCA2 gene mutation accounts for these cancers (Weitzel et al, 2007)

Contralateral: taking place or originating in a corresponding part on the opposite side of the body

Lumpectomy: the surgical removal of a small tumor in the breast which may be benign or malignant; a lumpectomy differs from a mastectomy in which the breast is removed

Multicentric disease: development of disease in different sites in the same part of the body

Neoadjuvant chemotherapy: initial use of chemotherapy in patients with localized cancer in order to decrease the tumor burden prior to treatment by other modalities

Relative, first-degree: a 50% genetic link to the patient; examples are parents, brothers, sisters, or children of an individual

Relative, second-degree: a 25% genetic link to the patient; examples are aunts, uncles, nieces, nephews, and grandparents of an individual

Relative, third-degree: a 12.5% genetic link to the patient; examples are first cousins, great grandparents, great grandchildren, of an individual

Coding

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time for service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

77058	Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral
77059	Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral

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

ICD-9 Diagnosis

All diagnoses

When services are Investigational and Not Medically Necessary:

For the codes listed above, when criteria are not met; or when the code describes a procedure indicated in the Policy section as investigational and not medically necessary.

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Peer Reviewed Publications:

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9. Lehman C, Gatsonis C, Kuhl C, et al. MRI evaluation of the contralateral breast in women with recently diagnosed breast cancer. *N Engl J Med.* 2007; 356: 1295-1306.
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13. Partridge SC, Bibbs JE, Lu Y. Accuracy of MR imaging for revealing residual breast cancer patients who have undergone neoadjuvant chemotherapy. *AJR.* 2002; 179:1193-1199.
14. Quan, ML, et al. Magnetic resonance imaging detects unsuspected disease in patients with

- invasive lobular cancer. *Ann Sug Oncol.* 2003; 10(9):1048-1053.
15. Robson ME, Morris E, Kauff N, et al. Breast cancer screening utilizing magnetic resonance imaging (MRI) in carriers of BRCA mutations. *American Society of Clinical Oncology. Cancer Prevention-Early Clinical Trials-Abstract No. 362*, 2003.
 16. Warner E, Plewes DB, Shumak RS et al. Comparison of breast magnetic resonance imaging, mammography and ultrasound for surveillance of women at high risk for hereditary breast cancer. *J Clin Oncol.* 2001; 19:3524-3531.
 17. Weitzel J, Lagos V, Cullinane C, et al. Limited family structure and BRCA gene mutation status in single cases of breast cancer. *JAMA.* 2007; 297:2587-2595.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American College of Radiology (ACR). Practice Guideline for the Performance of Magnetic Resonance Imaging (MRI) of The Breast. 2004; Revised 2006. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/breast/mri_breast.as Accessed on March 26, 2008.
2. American Society of Clinical Oncology (ASCO). 2006 Update of the Breast Cancer Follow-Up and Management Guidelines in the Adjuvant Setting. Available at: <http://www.jco.org/cgi/reprint/24/31/5091>. Accessed on March 20, 2008.
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Web Sites for Additional Information

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1. The National Breast Cancer Foundation. Available at: <http://www.nationalbreastcancer.org/>. Accessed on March 26, 2008.
2. The Susan G. Komen Breast Cancer Foundation. Available at: <http://www.komen.org/>. Accessed on March 26, 2008.

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Policy History

Status	Date	Action
Reviewed	05/15/2008	Medical Policy & Technology Assessment Committee (MPTAC) review.
Reviewed	05/14/2008	Hematology/Oncology Subcommittee review. Definitions added. References and coding updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
	11/15/2007	American Cancer Society (ACS) statement corrected in rationale.
Revised	05/17/2007	MPTAC review.
Revised	05/16/2007	Hematology/Oncology Subcommittee review. Criteria revised, rationale and references updated.
Revised	03/08/2007	MPTAC review. MRI criteria clarified, rationale updated. References updated.
Reviewed	01/01/2007	Updated coding section with 01/01/2007 CPT/HCPCS changes; removed CPT 76093, 76094 deleted 12/31/2006.
Reviewed	03/23/2006	MPTAC review.
		References updated.
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	04/28/2005	MPTAC review. Revision based on Policy Harmonization: Pre-merger Anthem and Pre-merger WellPoint.

Pre-Merger Organizations	Last Review Date	Policy Number	Title
Anthem, Inc. Scientific Statement and AMWMR UM Criteria (Historical)	UM RAD 004 01/14/2005	UM guideline RAD 004	MRI of the Breast
WellPoint Health Networks, Inc	Historical on 02/11/2005 09/23/2004	4.01.15	MRI of the Breast

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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