



Medical Policy

Subject: MRI of the Breast

Policy #: R AD.00036

Status: Reviewed

Current Effective Date: 07/ 09/2008

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.

