

## 2011 Imaging Criteria

Magnetic Resonance Imaging (MRI), Breast<sup>(1, 2)</sup>

ICD-9-CM: 88.97  
 CPT: 77058, 77059  
 I/O Setting: Outpatient

## INDICATION(S)

- 100 Suspected silicone implant rupture
- 200 Suspected silicone granuloma after implant removal
- 300 Screening MRI in high-risk patient
- 400 Suspected breast cancer
- 500 Assessment for primary cancer
- 600 Preoperative assessment
- 700 Breast cancer

- 100 Suspected silicone implant rupture **[One]**<sup>(3\*RIN, 4)</sup>
  - 110 Localized pain/mass<sup>(5)</sup>
  - 120 Breast contour irregularity<sup>(6)</sup>
  - 130 Change in breast size
- 200 Suspected silicone granuloma after implant removal **[Both]**
  - 210 Localized pain/mass<sup>(5)</sup>
  - 220 Calcified mass on mammography<sup>(7)</sup>
- 300 Screening MRI in high-risk patient **[One]**<sup>(8\*MDR, 9)</sup>
  - 310 BRCA1/BRCA2 gene mutation by genetic testing<sup>(10, 11)</sup>
  - 320 Breast cancer in first degree relative by Hx **[One]**<sup>(12, 13)</sup>
    - 321 ≥ 2 first degree relatives with unilateral breast cancer<sup>(14)</sup>
    - 322 ≥ 1 first degree relative with bilateral breast cancer<sup>(14)</sup>
    - 323 ≥ 1 first degree relative with premenopausal breast cancer
  - 330 Chest radiation by Hx<sup>(15)</sup>
  - 340 Li Fraumeni/Cowden Syndrome<sup>(16)</sup>
  - 350 Breast cancer risk assessment **[One]**<sup>(17)</sup>
    - 351 Lifetime risk > 20%<sup>(18)</sup>
    - 352 5-year risk ≥ 1.7%
- 400 Suspected breast cancer **[All]**<sup>(19)</sup>
  - 410 Palpable mass by PE

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- 420 Mammogram/US nondiagnostic for breast cancer
- 430 Findings **[One]**
  - 431 Silicone implant<sup>(20)</sup>
  - 432 Dense fibroglandular breasts by imaging
  - 433 Breast radiation by Hx<sup>(21)</sup>
  - 434 Breast surgery by Hx/PE<sup>(21)</sup>
- 500 Assessment for primary cancer **[Both]**<sup>(22)</sup>
  - 510 Axillary metastasis/lymphadenopathy by PE<sup>(23)</sup>
  - 520 Mammogram normal/nondiagnostic for cancer
- 600 Preoperative assessment **[One]**<sup>(24)</sup>
  - 610 To confirm local extent of disease<sup>(25)</sup>
  - 620 Invasive lobular cancer by Bx
- 700 Breast cancer **[One]**<sup>(26)</sup>
  - 710 Periodic assessment during chemotherapy<sup>(27)</sup>
  - 720 Restaging for suspected recurrence/metastases

## Notes

**(1)**

The following are examples of relative and absolute contraindications to the use of magnetic resonance imaging:

- Implanted devices that are electrically or magnetically activated (e.g., cardiac pacemakers, automatic cardioverter defibrillators, drug infusion pumps, cochlear implants)
- Ferromagnetic metal objects (e.g., cerebral aneurysm clips, intraocular metallic foreign body, prostheses, screws)
- Pregnancy, first trimester
- Renal insufficiency in cases when magnetic resonance imaging is performed with gadolinium-based contrast

**(2)**

The role of MRI for evaluating suspected breast cancer in males is undetermined as there is limited research in this area. For this reason, and because most lesions in men are palpable and biopsied easily by palpation, MRI is not considered a primary diagnostic imaging test for male patients (Agrawal et al., *Breast Cancer Res Treat* 2007; 103(1): 11-21).

**(3)-RIN:**

**These criteria include silicone implants used for breast reconstruction following mastectomy, as well as those implanted for cosmetic purposes.**

**(4)**

Breast MRI, the gold standard for imaging of breast implants, can evaluate silicone breast implant integrity and differentiate extracapsular from intracapsular rupture. While mammography and breast US can diagnose extracapsular leakage (free silicone which extends beyond the fibrous capsule into surrounding tissue), they cannot adequately detect intracapsular leakage (rupture contained within the surrounding fibrous capsule) (Gorczyca et al., *Plast Reconstr Surg* 2007; 120(7 Suppl 1): 49S-61S). When compared with mammography or breast US, MRI has 93% sensitivity and 85% diagnostic accuracy for detecting intracapsular or extracapsular implant rupture (Di Benedetto et al., *Breast J* 2008; 14(6): 532-537). MRI is most accurate in diagnosing rupture in symptomatic women. MRI can also provide a view of the axilla and the surrounding musculature.

**(5)**

Microscopic amounts of silicone gel can pass through some breast implant shells (gel bleed) and this free silicone induces the formation of silicone granulomas. These granulomas present clinically as palpable, painful, nodular masses (Esen and Olgun, *Ultrasound Clin* 2008; 3(3): 295-329).

**(6)**

Contour irregularities of the breast may be caused by rupture, capsular fibrosis, calcification, or contraction of the implant.

**(7)**

MRI of the breast can characterize an abnormal mass seen on mammography and distinguish between fibrosis, hematoma, seroma, tumor, or silicone granuloma.

**(8)-MDR:**

**These criteria cover MRI used for breast cancer screening in high-risk patients. Requests for routine screening with MRI require secondary medical review.**

**(9)**

There is ongoing discussion around the role of MRI in breast cancer screening, but because of MRI's low specificity for distinguishing benign from malignant disease and its high cost, mammography remains the primary screening method for the early detection of breast cancer (Berg, *AJR Am J Roentgenol* 2009; 192(2): 390-399; Bermejo-Perez et al., *Br J Radiol* 2008; 81(963): 172-179). MRI is more sensitive than mammogram for detecting tumors in women with a genetic or familial predisposition (e.g., BRCA1, BRCA2, family history of breast disease) for the development of breast cancer but using MRI as an adjunct to mammography for this population provides greater diagnostic accuracy (Warner et al., *Ann Intern Med* 2008; 148(9): 671-679; Saslow et al., *CA Cancer J Clin* 2007; 57(2): 75-89; Kuhl et al., *J Clin Oncol* 2005; 23(33): 8469-8476; Kriege et al., *N Engl J Med* 2004; 351(5): 427-437).

**(10)**

Up to 10% of all breast and ovarian cancers are believed to be hereditary. Analysis of the BRCA1 and BRCA2 genes can identify an individual's predisposition to developing breast or ovarian cancer. BRCA1 and BRCA2 are tumor-suppressor genes responsible for regulating the growth of breast epithelial cells. Mutations of either of these genes can result in uninhibited growth of these cells. The estimated lifetime risk of developing breast cancer for those with a BRCA mutation is estimated to be 65% to 74% (American College of Obstetricians and Gynecologists, *Obstet Gynecol* 2009; 113(4): 957-966). Male mutation carriers have a 5% to 10% lifetime risk

of developing breast cancer (Berliner and Fay, *J Genet Couns* 2007; 16(3): 241-260).

**(11)**

Women with a BRCA1 or BRCA2 gene mutation are also more likely to develop breast cancer at an earlier age. The risk of developing cancer varies depending on the penetrance of the gene mutation (e.g., higher life expectancy for low-penetrance mutations) (Jatoi and Anderson, *Surg Clin North Am* 2008; 88(4): 845-861, vii-viii). These mutations are commonly seen in families of Ashkenazi ancestry; an estimated 1 in 40 Ashkenazi Jews carry the mutation (American College of Obstetricians and Gynecologists, *Obstet Gynecol* 2009; 113(4): 957-966).

**(12)-DEF:**

A first degree relative is defined as a blood-related sibling, parent, or child.

**(13)**

The listed family history patterns have been associated with an increased incidence of BRCA1 or BRCA2 gene mutations (U.S. Preventive Services Task Force, *Am Fam Physic* 2006; 73(5): 869-874).

**(14)**

A patient has a four- to six-fold increased risk of developing breast cancer if her 2 sisters had breast disease or her mother and a sister had unilateral breast cancer. There is a two-fold increase if a mother or sister had the disease. The patient is at even greater risk when the disease is bilateral (Willey and Cocilovo, *Obstet Gynecol* 2007; 110(6): 1404-1416; Nelson et al., *Ann Intern Med* 2005; 143(5): 362-379).

**(15)**

Patients with significant radiation exposure should be in a high-risk surveillance program, especially when the radiation occurred at an early age (Saslow et al., *CA Cancer J Clin* 2007; 57(2): 75-89; Willey and Cocilovo, *Obstet Gynecol* 2007; 110(6): 1404-1416).

**(16)**

Li Fraumeni Syndrome is a rare autosomal dominant disorder characterized by a predisposition to several cancers (e.g., breast, leukemia, colon, melanoma). The breast cancer associated with this syndrome presents in patients in their early 20's. Cowden Syndrome, another rare autosomal dominant disorder, predisposes the patient to multiple hematomas, as well as benign and malignant tumors of the breast, thyroid, and endometrium (Nelson et al., *Ann Intern Med* 2005; 143(5): 362-379).

**(17)**

A number of models (e.g., Gail, BRCAPro, Claus, Myriad) are available to estimate a woman's risk of having breast cancer; the Gail Model is most commonly used. These models use age, family history, ethnic background, and personal history of biopsies or atypia to calculate risk, predict which patients will benefit from chemoprevention, and to focus genetic counseling (Robson and Offit, *N Engl J Med* 2007; 357(2): 154-162; Berliner and Fay, *J Genet Couns* 2007; 16(3): 241-260).

**(18)**

American Cancer Society guidelines support MRI screening as an adjunct to mammography for women with  $\geq 20\%$  to 25% lifetime risk for the development of breast cancer (Saslow et al., *CA Cancer J Clin* 2007; 57(2): 75-89).

**(19)**

MRI can be used as a diagnostic adjunct to breast examination and mammography or US for suspected breast cancer (Saslow et al., *CA Cancer J Clin* 2007; 57(2): 75-89; Berg et al., *Radiology* 2004; 233(3): 830-849). In certain clinical situations, mammogram and US may not be sufficient for diagnosis (e.g., in patients who have silicone breast implants or who have undergone prior surgery or radiation). MRI has been shown to be useful in evaluating suspicious breast tissue and can be used preoperatively to accurately assess tumor size, vascularity, and intraductal spread (Hata et al., *J Am Coll Surg* 2004; 198(2): 190-197). The limitation of MRI is its high false positive rate, low negative predictive value, and wide range of specificity (Bruening et al., *AHRQ Comparative Effectiveness Review No. 2*, February 2006; American College of Radiology, *ACR Practice Guideline for the Performance of Magnetic Resonance Imaging (MRI) of the Breast*. 2004). The accuracy of detecting breast cancer with MRI can be improved by using breast surface coils, administering intravenous contrast, and standardizing protocols for both performing and interpreting the imaging results (Lee, *Radiol Clin North Am* 2004; 42(5): 919-934).

**(20)**

MRI is a better test for evaluating breast tissue after breast augmentation, as the high radiographic density of silicone obscures breast tissue from mammographic exam. Silicone does not impair visualization of cancers by MRI.

**(21)**

Although the diagnostic value of mammography, US, and MRI is limited in the presence of scarring from previous breast surgery or radiation therapy, MRI can more accurately define the extent of disease than can mammogram or US (Bever et al., *J Natl Compr*

Canc Netw 2009; 7(10): 1060-1096; Van Goethem et al., Curr Opin Obstet Gynecol 2009; 21(1): 74-79).

**(22)**

MRI may be used to determine the source of cancer in patients presenting with positive axillary adenopathy and a nondiagnostic mammogram (Newstead, Semin Ultrasound CT MR 2006; 27(4): 320-332; American College of Radiology, ACR Practice Guideline for the Performance of Magnetic Resonance Imaging (MRI) of the Breast. 2004).

**(23)**

Although palpable axillary lymphadenopathy may represent benign disease, evaluation is necessary to exclude malignancy (Blanchard and Farley, World J Surg 2004; 28(6): 535-539). Less than 1% of patients with breast cancer present with axillary metastases as the only clinical manifestation of their disease (Newstead, Semin Ultrasound CT MR 2006; 27(4): 320-332). Although sensitive for occult breast lesions, the specificity of MRI is low, and lesions should be confirmed histologically (de Bresser et al., Eur J Surg Oncol 2010, 36: 114-9).

**(24)**

Although several studies have shown more aggressive treatment of breast disease based on preoperative MRI findings, the use of MRI in planning the surgical approach does not guarantee improved long-term outcomes (Turnbull et al., Lancet 2010; 375(9714): 563-571; Houssami and Hayes, CA Cancer J Clin 2009; 59(5): 290-302; Li et al., Radiology 2008; 248(1): 79-87; Solin et al., J Clin Oncol 2008; 26(3): 386-391).

**(25)**

MRI can be used to assess the extent of local disease prior to performing modified radical mastectomy (MRM) or partial mastectomy by documenting tumor size, multicentricity, tumor invasion, and lymph node metastases (Newstead, Semin Ultrasound CT MR 2006; 27(4): 320-332; Smith et al., Semin Ultrasound CT MR 2006; 27(4): 308-319; American College of Radiology, ACR Practice Guideline for the Performance of Magnetic Resonance Imaging (MRI) of the Breast. 2004).

**(26)**

MRI is sometimes helpful during or after a course of chemotherapy or radiation to evaluate response to treatment, as well as to assess any residual or recurrent disease (Newstead, Semin Ultrasound CT MR 2006; 27(4): 320-332; American College of Radiology, ACR Practice Guideline for the Performance of Magnetic Resonance Imaging (MRI) of the Breast. 2004).

**(27)**

The assessment is generally not necessary more frequently than every two cycles of chemotherapy.