



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Magnetic Resonance Imaging (MRI) of the Breast**

**Effective Date .....05/15/2011**  
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## Hyperlink to Related Coverage Policies

- Breast Biopsy Procedures including Sentinel Node Biopsy
- Electrical Impedance Scanning (EIS) and Transillumination of the Breast
- Genetic Testing for Susceptibility to Breast and Ovarian Cancer (BRCA1 and BRCA2)
- Mammary Ductoscopy (MD)
- Mammography
- Nuclear Imaging including Single-Photon Emission Computed Tomography (SPECT)

## INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

**CIGNA covers diagnostic magnetic resonance imaging (MRI) of the breast as medically necessary for ANY of the following indications:**

- inconclusive mammography (BI-RADS of 0) AND inconclusive breast ultrasonography (e.g., dense breast, suspected recurrence)
- conflicting findings between different modalities (i.e., mammography, ultrasonography, clinical findings)
- guidance for biopsy of a breast lesion (e.g., MRI-guided biopsy)
- confirmation of a suspected silicone gel-filled breast implant rupture undetected by mammography or breast ultrasonography
- evaluation in newly diagnosed, biopsy-proven breast cancer including evaluation of the contralateral breast
- 6-month follow-up of a recent breast MRI with reported results of BI-RADS of 3 (probably benign) that was completed in follow-up to an inconclusive mammography
- axillary metastases suspicious for primary breast cancer with negative physical exam and negative mammogram

- assess tumor response to neoadjuvant chemotherapy for locally advanced breast cancer
- assess residual tumor load following lumpectomy if close or positive margins and findings may impact further treatment decisions

**CIGNA covers annual magnetic resonance imaging (MRI) of the breast for screening as medically necessary when performed as an adjunct to mammography in a woman age 25 or over at high risk for breast cancer, defined as having ANY of the following:**

- prior high-dose thoracic irradiation (e.g., prior therapeutic radiation therapy)
- family history or genetic predisposition for breast cancer including ANY of the following:
  - known BRCA mutation
  - first-degree relative of BRCA carrier
  - lifetime risk of breast cancer > 20% as determined by a risk assessment tool such as BRCAPRO (i.e., Duke model) or other model that is largely dependent on family history (e.g., BOADICEA [Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm], Gail, Claus, or Tyrer-Cusick model)
  - personal history of or first-degree relative with Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome

**CIGNA does not cover computer-aided detection (CAD) with breast MRI because it is considered experimental, investigational or unproven.**

**CIGNA does not cover MRI of the breast as a primary screening tool for the detection of breast cancer in an asymptomatic, average-risk individual because the benefit of MRI screening over mammography has not been proven and is, therefore, considered experimental, investigational or unproven.**

## General Background

Magnetic resonance imaging (MRI) of the breast is a useful tool for the detection and characterization of breast disease, assessment of local extent of disease, evaluation of treatment response, and guidance for biopsy and localization. Breast MRI may be performed bilaterally or unilaterally. To enhance the probability of accurate results, MRI findings should be correlated with clinical history, physical examination, and the results of other imaging examinations.

The American Cancer Society (ACS) (Saslow, et al., 2007) states that MRI techniques which were previously utilized in symptomatic disease, “have recently been shown to provide good sensitivity as a screening tool for breast cancer in women at increased risk based on family history.” Saslow et al. reports “contrast-enhanced MRI has been shown to have a high sensitivity for detecting breast cancer in high-risk women, and that reports regarding specificity have been variable (Kreige, et al., 2004; Warner, et al., 2004; Kuhl, et al., 2005; Leach, et al., 2005; Lehman, et al., 2005b).” Saslow et al. states “clinical trials screened participants with both MRI and mammography at the same time. There is no evidence to support one approach over the other. For the majority of women at high risk, it is critical that MRI screening be provided in addition to, not instead of, mammography, as the sensitivity and cancer yield of MRI and mammography combined is greater than for MRI alone. However, where there is a concern about raised radiation sensitivity, it may be advisable to employ MRI alone despite the overall lower sensitivity.” Saslow et al. notes “recommendations are conditional on an acceptable level of quality of MRI screening, which should be performed by experienced providers in facilities that provide MRI-guided biopsy for the follow up of any suspicious results.”

### U.S. Food and Drug Administration (FDA)

The FDA regulates MRI systems as Class II devices, and a large number of these systems have been approved via the FDA 510(k) process. Some devices are specifically designed and approved as dedicated breast MRI scanners. Post-processing software programs and image processing systems are also approved by the FDA. These computer-aided detection (CAD) systems are intended for use in analyzing MRI studies.

The FDA recommends screening with breast MRI in individuals with silicone gel-filled breast implants. MRI is recommended at three years after implantation and then every two years thereafter to screen for rupture (FDA, 2011).

### **Breast Imaging Reporting and Database System (BI-RADS®)**

The American College of Radiology publishes BI-RADS, a quality assurance guide designed to standardize breast imaging reporting and facilitate outcome monitoring. It serves as a comprehensive guide providing standardized breast imaging terminology, report organization and assessment structure, as well as a classification system for mammography, ultrasound, and MRI of the breast.

<b>Breast Imaging Reporting and Database System (BI-RADS®)</b>		
<b>Category</b>	<b>Assessment</b>	<b>Follow-up Recommendations</b>
a. Assessment is Incomplete		
0	Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison	Additional imaging and/or prior images are needed before a final assessment can be assigned
b. Assessment is Complete – Final Categories		
1	Negative	Routine Annual Screening mammography (for women over age 40)
2	Benign Findings	Routine Annual Screening mammography (for women over age 40)
3	Probably Benign Findings Initial Short Interval Follow-up Suggested	Initial Short term Follow-up (usually 6 months) examination
4	Suspicious Abnormality Biopsy Should Be Considered	Usually Requires Biopsy
5	Highly Suggestive of Malignancy Appropriate Action Should Be Taken	Requires Biopsy Or Surgical Treatment
6	Known Biopsy-Proven Malignancy Appropriate Action Should Be Taken	Category Reserved For Lesions Identified On Imaging Studies With Biopsy Proof Of Malignancy Prior To Definitive Therapy

### **Literature Review**

Evidence in the published, peer-reviewed scientific literature and professional organizations supports MRI for the evaluation of suspected breast cancer in certain individuals with an inconclusive mammography (Sardanelli, et al., 1998; Sardanelli, et al., 2004; Echevarria, et al., 2006; Boyd, et al., 2007; Moy, et al., 2009). It should be noted that careful selection of patients with inconclusive mammographic findings is important. Diagnostic evaluation with mammography and ultrasound should be exhausted before MRI is performed. If mammography and ultrasound results conflict, further investigation is warranted. MRI should not be used to determine biopsy recommendations for indeterminate lesions that can be readily biopsied, such as palpable masses and microcalcifications, but is helpful in asymmetry or architectural distortion. Additionally, evidence supports the use of MRI to aid in biopsy of a breast lesion (Bluemke, et al., 2004; Han, et al., 2008), and to confirm silicone gel-filled breast implant rupture (Beekman, et al., 1999; Cher, et al., 2001; Holmich, et al., 2005).

Evidence in the published, peer-reviewed scientific literature indicates that MRI aids in treatment planning and monitoring of known breast cancer, including evaluation of the contralateral breast. MRI is helpful evaluating newly diagnosed, biopsy-proven breast cancer; axillary metastases; tumor response following chemotherapy; and residual tumor load following lumpectomy (Drew, et al., 2001; Berg, et al., 2004; Yeh, et al., 2005; Partridge,

et al., 2005; Lehman, et al., 2005a; Gökalp, et al., 2006; Bazzocchi, et al., 2006; Deurloo, et al., 2006; Lehman, et al., 2007a; Kuhl, et al., 2007; Bilimoria, et al., 2007).

In women with increased lifetime risk due to strong family history or genetics, MRI has high sensitivity (up to 100%) for the detection of breast cancer when used as an adjunct to mammography. There is also evidence to support the use of MRI screening in women who were exposed to chest radiation as children or young adults. Because of the high rate of false positives, MRI screening should only be recommended to women at high risk of breast cancer. Evidence in the published, peer-reviewed scientific literature indicates that MRI is a useful tool for the detection of cancer in high-risk women (Warner, et al., 2004; Kriege, et al., 2004; Lehman, et al., 2005b; Leach, et al., 2005; Sardanelli, et al., 2007; Kriege, et al., 2007; Port, et al., 2007; Lord, et al., 2007; Lehman, et al., 2007b; Saslow, et al., 2007; Warner, et al., 2008; Kuhl, et al., 2010). In 2007, the American Cancer Society published guidelines recommending annual breast MRI screening as an adjunct to mammography for high-risk women (Saslow, et al., 2007) (see American Cancer Society heading below).

**Surveillance Of Silicone Breast Implants:** FDA studies addressing the safety of silicone breast implants include the following:

Inamed Silicone Breast Implant Core Study Results at 6 Years (Spears, et al., 2007): This prospective multicenter study assessed the safety of Inamed silicone breast implants (Inamed Corporation, purchased by Allergan Medical, Irvine, California). The study included 940 female individuals, approximately half were augmentation patients, one-quarter were reconstruction patients, and one-quarter were revision patients. The results presented excluded the 225 patients who underwent implantation with the Style 153 implant, a shaped device that is no longer being manufactured. Disregarding those patients who died or had all study devices removed (<10% of patients), compliance rates for the 6-year visit were 81% for augmentation, 78% for revision augmentation, 90% for reconstruction, and 92% for revision-reconstruction. Approximately one-third of patients also underwent biennial MRI evaluation to detect silent rupture. The most common local complication in all cohorts was capsular contracture, occurring in 15-20% of patients. Based on MRI, the majority of implants (96.5%) did not rupture over the 6-year follow-up period, based on Kaplan-Meier survival analyses. This means that the 6-year by-implant rupture rate was 3.5% overall.

The Mentor Core Study on Silicone MemoryGel® Breast Implants (Cunningham, 2007): This prospective multicenter trial assessed the safety of Mentor (Mentor Worldwide LLC, Santa Barbara, California) MemoryGel Breast Implants in 1007 women, distributed into four cohorts: 551 primary augmentation patients, 146 revision-augmentation patients, 251 primary reconstruction patients, and 59 revision-reconstruction patients. Of the 1007 patients, 202 primary augmentation patients, 57 revision-augmentation patients, 134 primary reconstruction patients, and 27 revision-reconstruction patients were randomized into the MRI cohort, with a sample size based on a conservative estimate of 5% rupture rate at 10 years, double the minimum sample size of 320 required for adequate statistical precision. Suspected rupture rates at 3-years reported from the MRI cohort were 0.5% for primary augmentation, 7.7% for revision-augmentation, 0.9% for primary reconstruction, and 0% for revision-reconstruction. Three-year results indicated the risk of any complication (including reoperation) at some point through 3 years after implant surgery is 36.6% for primary patients, 50.1% for revision-augmentation patients, 49.4% for primary reconstruction patients, and 47.5% for revision-reconstruction patients.

The Mentor Study on Contour Profile Gel Silicone MemoryGel Breast Implants (Cunningham, 2007): This prospective multicenter trial was very similar to the study above. The study design and protocol were essentially the same as that described in the companion article on the Mentor Core MemoryGel Study. Similar inclusion and exclusion criteria, patient assessment instruments, follow-up intervals, and outcomes reporting methods were used. The difference in the study design compared with the Core Round MemoryGel study pertained to a structured pre-surgical educational program that was incorporated into the study. Because of the novel complexities in shape, texture, and profile dimensions, compared with round saline or gel implants, it was felt that surgeons using MemoryGel devices should receive an educational module before enrolling patients. Surgeons participated in an investigator's meeting where specific and detailed technical aspects of patient preoperative planning and pocket preparation, and specified postoperative management, including guidelines for drains and garments, were demonstrated. This study included 955 patients: 572 augmentation patients, 123 revision-augmentation patients, 191 reconstruction patients, and 69 revision-reconstruction patients. Of the 955 patients, 149 primary augmentation patients, 123 revision-augmentation patients, 43 primary reconstruction patients, and 29 revision-reconstruction patients were randomized into the MRI cohort. The

follow-up rates for the MRI cohort ranged from 63-88% at the 2-year time point. Risk of any complication or reoperation at some point through 2 years after implant surgery is 24.5% for primary augmentation patients, 30.2% for revision-augmentation patients, 42.9% for primary reconstruction patients, and 41.8% for revision-reconstruction patients. The rupture rates reported from the MRI cohort were 0% for all groups. Patients re-operated on at least one time were as follows: 9.4% for primary augmentation, 12.8% for revision-augmentation, 27.3% for primary reconstruction, and 19.4 % for revision-reconstruction. This study did not note if there were statistically significant differences when surgeon training is added.

**Computer-aided detection (CAD):** Computer-aided detection (CAD) systems are purported to aid radiologists in interpreting the patterns of contrast enhancement and washout across a series of images which, in turn, may help identify lesions and their likelihood of being malignant. CAD uses color-coding to indicate the patterns of enhancement for each pixel in the breast image. It, thereby, may allow the radiologist to analyze the enhancement patterns systematically. Some CAD programs incorporate morphological characteristics, as well, to estimate a probability of malignancy. Currently, there are a few retrospectively designed studies which do not establish the accuracy or clinical utility of CAD systems (Lehman, et al., 2006; Williams, et al., 2007; Arazi-Kleinman, et al., 2009). Additional well-designed prospective trials are needed to establish what if any impact CAD systems may have on long-term breast cancer survival rates.

Blue Cross Blue Shield Technology Evaluation Center (TEC) Computer-Aided Detection of Malignancy with Magnetic Resonance Imaging of the Breast (June 2006) concluded that there are no high-quality, current published studies of the impact of commercially available CAD systems on the sensitivity and specificity of MRI of the breast. Also, 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. Given the inability to evaluate these intermediate outcomes, it is not possible to assess the impact of CAD on health outcomes such as treatment success among breast cancer patients or survival. Whether the use of CAD with MRI of the breast improves outcomes has not been established in the investigational setting.

### **Professional Societies/Organizations**

**American Cancer Society (ACS):** The ACS Recommendations for Early Breast Cancer Detection (specific to MRI) are as follows:

- Women at high risk (greater than 20% lifetime risk) should get an MRI and a mammogram every year. Women at high risk include those who:
  - have a known BRCA1 or BRCA2 gene mutation
  - have a first-degree relative (mother, father, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation, and have not had genetic testing themselves
  - have a lifetime risk of breast cancer of 20%-25% or greater, according to risk assessment tools that are based mainly on family history
  - had radiation therapy to the chest when they were between the ages of 10 and 30 years
  - have a genetic disease such as Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or have one of these syndromes in first-degree relatives
- Women at moderately increased risk (15% to 20% lifetime risk) should talk with their doctors about the benefits and limitations of adding MRI screening to their yearly mammogram. Yearly MRI screening is not recommended for women whose lifetime risk of breast cancer is less than 15%. Women at moderately increased risk include those who:
  - have a lifetime risk of breast cancer of 15%-20%, 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)
  - have extremely dense breasts or unevenly dense breasts when viewed by mammograms
- If MRI is used, it should be in addition to, not instead of, a screening mammogram. This is because while an MRI is a more sensitive test, it may still miss some cancers that a mammogram would detect.
- For most women at high risk, screening with MRI and mammograms should begin at age 30 years and continue for as long as a woman is in good health. But because the evidence is limited regarding the best age at which to start screening, this decision should be based on shared decision making between patients and their health care providers, taking into account personal circumstances and preferences.
- Several risk assessment tools, with names such as BRCAPRO, the Claus model, and the Tyrer-Cuzick model, are available to help health professionals estimate a woman's breast cancer risk. These tools

give approximate, rather than precise, estimates of breast cancer risk based on different combinations of risk factors and different data sets. As a result, they may give different risk estimates for the same woman. Their results should be discussed by a woman and her doctor when being used to decide on whether to start MRI screening.

- It is recommended that women who get screening MRI do so at a facility that can do an MRI-guided breast biopsy at the same time if needed. Otherwise, the woman will have to have a second MRI exam at another facility at the time of biopsy.
- There is no evidence at this time that MRI will be an effective screening tool for women at average risk. While MRI is more sensitive than mammograms, it also has a higher false-positive rate (where the test finds things that turn out to not be cancer), which would result in unneeded biopsies and other tests in a large portion of these women. (Smith, et al., 2003; Saslow, et al., 2007).

Saslow et al. (2007) includes the following:

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:

- Women at < 15% lifetime risk (Saslow, et al., 2007)

Saslow et al. (2007) does not address computer-aided detection.

**Society of Breast Imaging (SBI)/American College of Radiology (ACR):** The SBI with the ACR published recommendations for breast cancer screening with imaging (Lee, et al., 2010). Recommendations specific to MRI include:

- proven carriers of a deleterious BRCA mutation, annually starting by age 30.
- untested first-degree relatives of proven BRCA mutation carriers, annually starting by age 30.
- women with >20% lifetime risk for breast cancer on the basis of family history, annually starting by age 30.
- women with histories of chest irradiation (usually as treatment for Hodgkin's disease), annually starting 8 years after the radiation therapy.
- women with newly diagnosed breast cancer and normal contralateral breast by conventional imaging and physical examination, single screening MRI of the contralateral breast at the time of diagnosis.
- may be considered in women with between 15% and 20% lifetime risk for breast cancer on the basis of personal history of breast or ovarian cancer or biopsy-proven lobular neoplasia or atypical ductal hyperplasia.

**American College of Radiology (ACR):** The ACR Practice Guideline for the Performance of Contrast-enhanced Magnetic Resonance Imaging (MRI) of the Breast (revised 2008) states that current indications for breast MRI include, but are not limited to:

Screening

- screening of high-risk patients: recent clinical trials have demonstrated that breast MRI can significantly improve the detection of cancer that is otherwise clinically and mammographically occult. Patients should be referred for screening breast MRI, preferably after careful risk assessment, by personnel trained in the assessment of hereditary breast cancer or by their referring physician who has used a risk assessment model. Breast MRI may be indicated in the surveillance of women with more than a 20% lifetime risk of breast cancer (for example, individuals with genetic predisposition to breast cancer by either gene testing or family pedigree, or individuals with a history of mantle radiation for Hodgkin's disease). Although there is no direct evidence that screening with MRI will reduce mortality, it is thought that early detection by using annual MRI as surveillance, in addition to mammography, may be useful.
- screening of the contralateral breast in patients with a new breast malignancy

- breast augmentation - postoperative reconstruction and free injections Breast MRI using contrast may be indicated in the evaluation of patients with silicone or saline implants and/or free injections with silicone, paraffin, or polyacrylamide gel in whom mammography is difficult.

#### Extent of disease

- invasive carcinoma and ductal carcinoma in situ (DCIS)
- invasion deep to fascia
- post-lumpectomy with positive margins
- neoadjuvant chemotherapy

#### Additional evaluation of clinical or imaging findings

- recurrence of breast cancer: breast MRI may be useful in women with a prior history of breast cancer and suspicion of recurrence when clinical, mammographic, and/or sonographic findings are inconclusive.
- metastatic cancer when the primary is unknown and suspected to be of breast origin
- lesion characterization
- postoperative tissue reconstruction
- MRI-guided biopsy

Some additional topics discussed by the ACR include:

**False positives:** Breast MRI may detect abnormalities that are not evident clinically, mammographically, or sonographically. They may or may not be clinically significant. As with mammography or any other diagnostic test, false positive results can be expected, and the literature shows a wide range of specificity for breast MRI. The additional abnormalities detected on MRI may result in a follow-up examination or recommendation for biopsy. Published biopsy rates for MRI are similar to those for mammography.

**Simultaneous bilateral imaging:** Simultaneous bilateral high resolution imaging should be performed. Bilateral imaging is favored over unilateral imaging as the breasts are symmetric organs, and there is negligible time penalty for imaging both breasts. Unilateral imaging is reserved for mastectomy patients or individuals requiring a specifically tailored follow-up examination.

**Contrast:** Gadolinium contrast enhancement is generally needed in the evaluation of breast cancer but is not generally necessary in the evaluation of implant integrity and rupture.

**Dedicated breast MRI coil:** Examinations should be performed with a dedicated breast MRI coil unless obesity or other patient consideration requires modification of the imaging procedure.

**Inappropriate uses of breast MRI:** MRI should not supplant careful problem-solving mammographic views or ultrasound in the diagnostic setting. Because MRI will miss some cancers that mammography will detect, it should not be used as a substitute for screening mammograms. MRI should not be used in lieu of biopsy of a mammographically, clinically, and/or sonographically suspicious finding.

The ACR did not address computer-aided detection (ACR, 2008).

**National Comprehensive Cancer Network® (NCCN®):** The NCCN Breast Cancer Screening and Diagnosis Guidelines (v.1.2011) notes that although current evidence does not support the use of breast MRI to screen women at average risk of breast cancer, benefits of screening MRI in women with a genetic predisposition for breast cancer have been demonstrated in a number of studies and the ACS has published guidelines recommending the use of breast MRI as an adjunct to screening mammography in certain populations of women at high risk of breast cancer. A high false-positive rate for screening MRI was identified in some of these studies. The NCCN cites the ACS Guidelines.

**Under Diagnostic Breast MRI:** For patients with skin changes consistent with serious breast disease, consider breast MRI for those with benign biopsy of skin or nipple following Breast Imaging-Reporting and Data System (BI-RADS®) 1-3 assessment. Since a benign skin punch biopsy in a patient with a clinical suspicion of inflammatory breast cancer does not rule out malignancy, further evaluation is recommended.

The NCCN states the criteria for the performance/interpretation of high quality breast MRI include: a dedicated breast coil, radiologists experienced in breast MRI, and the ability to perform MRI-guided needle sampling and/or wire localization of MRI-detected findings.

**NCCN:** In the NCCN Breast Cancer Clinical Practice Guidelines in Oncology (v.2.2011), MRI is recommended throughout the algorithms and narrative text, in varying clinical scenarios.

Breast MRI Clinical Indications and Applications:

- May be used for staging evaluation to define extent of cancer or presence of multifocal or multicentric cancer in the ipsilateral breast or as screening of the contralateral breast cancer at time of initial diagnosis.
- May be helpful for breast cancer evaluation before and after neoadjuvant therapy to define extent of disease, response to treatment, and potential for breast conserving therapy.
- MRI may be useful to detect additional disease in women with mammographically dense breasts, but available data do not show differential detection rates by any subset by breast pattern (dense breasts) or disease type (e.g., DCIS, invasive ductal cancer, invasive lobular cancer).
- May be useful for identifying primary cancer in women with axillary nodal adenocarcinoma or with Paget's disease of the nipple with breast primary not identified on mammography, ultrasound or physical examination.

NCCN states that falsely positive findings on breast MRI are common. Surgical decisions should not be based solely on the MRI findings. Additional tissue sampling of areas of concern identified by breast MRI is recommended. NCCN notes the utility of MRI in follow-up screening of women with prior breast cancer is undefined.

**National Cancer Institute (NCI):** The Breast Cancer Risk Assessment Tool is an interactive tool based on the modified Gail model, designed for use by health professionals and is available online at the National Cancer Institute.

**American Society of Breast Surgeons (ASBS):** The ASBS Consensus Statement on the Use of Magnetic Resonance Imaging in Breast Oncology (2010) states "Breast MRI should not replace mammography for yearly screening examination in the general population. No prospective randomized trials to date have shown that the utilization of breast MRI results in a reduction in re-excision for margin control for breast conservation treatment or an improvement in overall survival. The long term data for breast MRI is continuing to evolve as clinical experience with this imaging modality continues. Based on a review of current studies, the American Society of Breast Surgeons supports the addition of breast MRI to physical examination and mammography in the following settings:

1. Axillary node metastasis from a suspected occult primary breast cancer. Breast MRI can aid the treating physician in locating the primary tumor.
2. For determining the extent of disease or presence of multi-focal or multi-centric tumor or the presence of contralateral disease, in patients with a proven breast cancer and associated conventional imaging difficulties; such as those with invasive lobular carcinoma, or when dense breast tissue precludes an accurate mammographic and physical assessment.
3. To assess response to neoadjuvant endocrine therapy or chemotherapy in select patients post-treatment. MRI can help identify those patients who are candidates for breast conservation, and assist in determining the extent of resection required.
4. As part of annual breast cancer screening, in addition to mammography, for patients at very high risk for developing breast cancer, especially those with suspected or proven deleterious mutations of BRCA 1/2, patients with a history of radiation therapy to the chest wall and others with 20% or greater lifetime risk of breast cancer.
5. For the further evaluation of suspicious clinical findings or imaging results which remain indeterminate after complete mammographic and sonographic evaluations combined with a thorough physical

examination. Since the negative predictive value of MRI is unknown, if lesions meet the criteria for biopsy by other modalities, it may be preferable to biopsy the lesion rather than obtain an MRI.”

### Summary

Evidence in the published, peer-reviewed scientific literature demonstrates that breast MRI provides additional value in several diagnostic and screening situations. Diagnostic MRI is indicated when mammography, ultrasound or physical findings are inconclusive or conflicting. MRI is used to guide breast biopsy, if silicone implant rupture is suspected, for surveillance of a silicone breast implant, and to evaluate newly diagnosed breast cancer including evaluation of the contralateral breast. MRI aids in certain clinical scenarios for treatment planning and monitoring of known breast cancer.

Annual screening MRI is recommended by the American Cancer Society as an adjunct to mammography for high-risk women. MRI of the breast is not indicated as a primary screening tool for the detection of breast cancer in asymptomatic, average-risk patients or for routine surveillance of an individual with a history of breast cancer.

There are a limited number of studies evaluating the diagnostic utility of computer-aided detection (CAD) with breast MRI. The few, small, retrospective studies that are available in the published, peer-reviewed scientific literature provide insufficient evidence to demonstrate that computer-aided detection systems used on breast MR images are as effective as having another radiologist review the MRI or would improve the accuracy of breast MRI interpretations. Large, well-designed, controlled studies are needed to answer immediate and long-term questions: whether a given CAD software program is an effective clinical tool to complement a radiologist’s interpretation of breast MRI; and how the system might ‘aid’ MRI technologists and radiologists in their current roles and detection and interpretation tasks. Also, existing and future CAD software programs need to be evaluated across a broad range of image acquisitions; programs designed for one method of examination may not apply to others.

### Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT®* Codes	Description
77021†	Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
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

†**Note:** Covered when used to report magnetic resonance guidance for biopsy of the breast

HCPCS Codes	Description
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

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
196.3	Secondary and unspecified malignant neoplasm of lymph nodes of axilla and upper limb
198.2	Secondary malignant neoplasm of skin
198.81	Secondary malignant neoplasm of breast
199.1	Other malignant neoplasm without specification of site
217	Benign neoplasm of breast
233.0	Carcinoma in situ of breast
238.3	Neoplasm of uncertain behavior of breast
239.3	Neoplasm of unspecified nature of breast
610.0	Solitary cyst of breast
610.1	Diffuse cystic mastopathy
610.2	Fibroadenosis of breast
610.3	Fibrosclerosis of breast
610.4	Mammary duct ectasia
610.8	Other specified benign mammary dysplasia
610.9	Benign mammary dysplasia, unspecified
611.0	Inflammatory disease of breast
611.1	Hypertrophy of breast
611.4	Atrophy of breast
611.71	Mastodynia
611.72	Lump or mass in breast
611.79	Other signs and symptoms in breast
611.83	Capsular contracture of breast implant
611.89	Other specified disorders of breast
611.9	Unspecified breast disorder
612.0	Deformity of reconstructed breast
612.1	Disproportion of reconstructed breast
793.80	Abnormal mammogram, unspecified
793.81	Mammographic microcalcification
793.82	Inconclusive mammogram
793.89	Other (abnormal) findings on radiological examination of breast
996.54	Mechanical complication of other specified prosthetic device, implant, and graft, due to breast prosthesis
996.69	Infection and inflammatory reaction due to other internal prosthetic device, implant and graft
V10.3	Personal history of malignant neoplasm of breast
V16.3	Family history of malignant neoplasm of breast
V76.10	Other screening breast examination

**Experimental/Investigational/Unproven/Not Covered:**

<b>CPT* Codes</b>	<b>Description</b>
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)

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
	All codes

## References

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## Policy History

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<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	10/15/2008	0155	Magnetic Resonance Imaging (MRI) of the Breast

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