



# CIGNA MEDICAL COVERAGE POLICY

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

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

**Effective Date ..... 10/15/2009**  
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**Coverage Policy Number ..... 0155**

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## Hyperlink to Related Coverage Policies

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 as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant'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 participant'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 participant'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 group 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 ©2009 CIGNA

## Coverage Policy

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

- evaluation of suspected breast cancer following mammography
- inconclusive mammogram due to breast characteristics limiting the sensitivity of mammography (i.e., extremely dense breasts, implants, scarring after treatment for breast cancer).
- confirmation of silicone gel-filled breast implant rupture when this diagnosis cannot be confirmed by mammography or breast ultrasound
- evaluation and monitoring of known breast cancer, including surveillance of the contralateral breast

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

- history of prior high-dose thoracic irradiation (e.g., prior therapeutic radiation therapy)
- a strong family history or genetic predisposition for breast cancer including ANY of the following:

- the individual has a known BRCA mutation
- a first-degree relative of BRCA carrier, but untested
- a five-year risk of invasive breast carcinoma risk  $\geq 1.7\%$  or a lifetime risk  $> 20\%$  as defined by BRCAPRO (i.e., Duke model) or other models that are largely dependent on family history (e.g., Gail, Claus, or Tyrer-Cusick models)
- 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 asymptomatic, average-risk individuals 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)

Although screen-film mammography and full-field digital mammography are the only imaging tools explicitly approved or grandfathered in for breast cancer screening by the FDA, other modalities are under study. Those approved by the FDA for diagnostic purposes (not screening) include MRI, ultrasound, scintimammography, thermography, and electrical impedance imaging (Elmore, 2005). 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.

### Literature Review

**Detection:** Breast MRI is indicated for the detection of cancer. Evidence in the published, peer-reviewed scientific literature supports that MRI may be indicated: for the evaluation of suspected breast cancer following mammography; to detect breast cancer in individuals with an inconclusive mammography and who have breast characteristics limiting the sensitivity of mammography (i.e., dense breasts, implants, scarring after treatment for breast cancer); to confirm silicone gel-filled breast implant rupture when this diagnosis cannot be confirmed by mammography or breast ultrasound; for the evaluation and monitoring of known breast cancer, including surveillance of the contralateral breast (Bluemke, et al., 2004; Sardanelli, et al., 2004; Lehman, et al. 2005b; Echevarria, et al., 2006; Boyd, et al., 2007).

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). 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; Leach, et al., 2005; Warren, et al., 2005; Lehman, et al., 2005b; Kriege, et al., 2006b; Saslow, et al., 2007; Lehman, et al., 2007a; Lehman, et al., 2007b; Kuhl, et al., 2007; Sardanelli, et al., 2007; Lord, et al., 2007; Port, et al., 2007; Kriege et al., 2007; Dunfield, et al., 2007; Warner, et al., 2008).

**Breast Implants:** Evidence in the published, peer-reviewed scientific literature indicates that MRI is indicated for patients with saline-filled or silicone gel-filled breast implants and/or injections in whom screening mammography is inconclusive or contraindicated. In these settings, breast MRI may be helpful in the diagnosis of breast cancer. MRI may be medically necessary to confirm suspected silicone gel-filled breast implant rupture when this diagnosis cannot be confirmed by mammography or breast ultrasound (Beekman, et al., 1999; Cher, et al., 2001; Holmich, et al., 2005).

**Treatment Planning and Monitoring:** Breast MRI is indicated for treatment planning and monitoring treatment in breast cancer patients. Evidence in the published, peer-reviewed scientific literature indicates that MRI can provide additional valuable clinical information and, therefore, is a useful tool in treatment planning (Berg, et al., 2004; Deurloo, et al., 2006; Echevarria, et al., 2006; Van Goethem, et al., 2007; Bilimoria, et al., 2007). In addition, evidence indicates that MRI provides a sensitive assessment of treatment efficacy and is predictive of treatment outcome (Drew, et al., 2001; Partridge, et al., 2005; Yeh, et al., 2005).

**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 and differences in hue 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 apparently incorporate morphological characteristics, as well, to estimate a probability of malignancy.

Williams et al. (2007) retrospectively studied the sensitivity of kinetic features measured with computer-aided evaluation at breast MRI in discriminating benign from malignant lesions. A total of 125 women (154 lesions) with suspicious breast lesions visible only at MRI, and in which biopsy had been performed with MRI guidance, were evaluated with histopathology findings used as the reference standard. After biopsy, the original MRI examinations for all lesions were retrospectively analyzed with computer-aided evaluation to determine kinetic features. Threshold enhancement was said to be present if any portion of a lesion achieved the specified minimum threshold, either 50% or 100%, as indicated by the presence of computer-aided evaluation-generated color within the lesion. The sensitivity of computer-aided evaluation based on the presence of threshold enhancement was 93% for both 50% and 100% minimum thresholds. The positive predictive value of computer-aided evaluation alone compared with that of the radiologist was 27.0% versus 26.6% at the 50% threshold, and 30.4% versus 26.6% at the 100% threshold. The false-positive rate was reduced by 8.9 % at 50% threshold and by 23.0% at the 100% threshold ( $p = .02$ ). The authors concluded that computer-aided evaluation has the potential to improve the discrimination of benign from malignant MRI breast lesions.

Lehman et al. (2006) compared the accuracy of breast MRI interpretations with and without CADstream. Thirty-three consecutive lesions seen only on MRI (nine malignant, 24 benign) were evaluated with and without the automated software system. The authors concluded that CADstream accurately showed significant enhancement in all the malignant lesions while depicting 12 of 24 benign lesions as showing insignificant enhancement. The authors stated results are promising—that if these results are validated by a larger study, the number of unnecessary biopsies of MR lesions could be reduced without a concomitant decrease in cancer detection. It should be noted that this was a single-site, retrospective study of consecutive, suspicious MR lesions recommended for biopsy, and all malignant lesions were invasive. It is not known whether these results are reproducible in a larger patient population, (e.g., using other methods of breast MRI acquisition, or using other CAD systems for breast MRI). Because the cancers in this study were all invasive carcinomas, these results may not apply to cases of ductal carcinoma in situ. In addition, the software program is limited in evaluating lesions surrounded by diffuse background enhancement. Specifically, five of 21 lesions could not be assessed independently from diffuse enhancement in the breast. This limitation will need to be addressed in future software programs. Larger, controlled (e.g., experience of reader, lesion(s) size, location or stage) studies

comparing MRI CAD detection and interpretation results to additional manual review (i.e., second opinion) detection and interpretation results, are needed.

Demartini et al. (2005) conducted a retrospective review of the MRI examinations and medical records of 15 consecutive patients with 16 locally advanced breast cancers treated with neoadjuvant chemotherapy. Results showed that prior to chemotherapy, all tumors demonstrated CAD-assessed significant enhancement. Following chemotherapy, 7/16 tumors showed no residual significant enhancement, but all had residual disease at pathology. In those patients with residual enhancement, comparison of the post-chemotherapy to pre-chemotherapy CAD enhancement profiles showed a significant decrease in percentage of washout enhancement in patients with less than 5 mm of residual microscopic disease. Radiologist-measured tumor sizes demonstrated better correlation with sizes at pathology than did CAD-generated tumor sizes. The authors stated that their preliminary results, demonstrating decreases in washout enhancement in patients with minimal residual malignancy at pathology, are promising. CAD limitations include false-negatives based on CAD assessment and lack of accuracy of CAD tumor sizes. The authors stated that their results suggest that in this patient population, CAD for breast MRI may complement but should not replace the careful assessment of tumors by the radiologist. The authors noted that future studies of CAD applied to breast MRI should include a larger patient population and utilize a broader range of MRI and CAD techniques. It should be noted that this was a single-site, retrospective pilot study of only 16 lesions, all locally advanced invasive carcinomas. Also, because there are many methods of image acquisition and post-processing methods and algorithms for breast MRI, it is not known whether these results are reproducible in a larger patient population, (e.g., using other methods of breast MRI acquisition, or using other CAD systems for breast MRI). Also needing to be validated in a larger study is if changes in CAD-assessed enhancement profiles provide a means of characterizing treatment response (Demartini, et al., 2005).

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.

**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
- postlumpectomy 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 Institute for Health and Clinical Excellence (NICE):** The NICE Guideline for early and locally advanced breast cancer (2009) states that the routine use of MRI of the breast is not recommended in the preoperative assessment of patients with biopsy-proven invasive breast cancer or ductal carcinoma in situ (DCIS). "Offer MRI of the breast to patients with invasive breast cancer:

- if there is discrepancy regarding the extent of disease from clinical examination, mammography and ultrasound assessment for planning treatment
- if breast density precludes accurate mammographic assessment
- to assess the tumour size if breast conserving surgery is being considered for invasive lobular cancer."
- Regarding follow-up imaging, "do not offer ultrasound or MRI for routine post-treatment surveillance in patients who have been treated for early invasive breast cancer or DCIS."

**National Comprehensive Cancer Network (NCCN):** The NCCN Breast Cancer Screening and Diagnosis Guidelines (v.2.2009) 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. In the NCCN cites the ACS (Saslow, et al., 2007), noting that the criteria for the use of breast MRI screening as an adjunct to mammography for high risk women include:

- Have a BRCA 1 or 2 mutation
- Have a first-degree relative with a BRCA 1 or 2 mutation and are untested
- Have a lifetime risk of breast cancer of 20-25 percent or more
- Received radiation treatment to the chest between ages 10 and 30, such as for Hodgkin's Disease

- Carry or have 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).

Also in the NCCN Breast Cancer Screening and Diagnosis Guidelines (v.2.2009), the NCCN states the following:

- Recommend annual MRI as an adjunct to screening mammogram and clinical breast exam for women aged 25 years and older with a genetic predisposition/strong family history
- Recommend annual MRI in women who have a > 20% lifetime risk of breast cancer as defined by models largely based on family history as described in Saslow et al. 2007 ACS Guidelines.
- Consider MRI for lobular carcinoma in situ (LCIS) as an adjunct to mammogram and clinical breast exam annually
- Consider MRI as an adjunct to mammogram and clinical breast exam every 6-12 months for women aged 25 years and older who have received prior thoracic irradiation

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.1.2009), MRI is recommended throughout the algorithms and narrative text, in varying clinical scenarios such as workup, loco regional treatment, preoperative chemotherapy, locally advanced, surveillance/follow-up, and Paget's disease.

**National Cancer Institute (NCI):** The Breast Cancer Risk Assessment Tool is an interactive tool 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 (2007) states that the ASBS supports the addition of breast MRI to physical examination, mammography and US 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 ipsilateral tumor extent or the presence of contralateral disease, in patients with a proven breast cancer, such as those with invasive lobular carcinoma, or when dense breast tissue precludes an accurate mammographic assessment. Emerging evidence also support MRI detection of early contralateral breast cancers that may be missed by physical exam or mammography.
3. To monitor response to neoadjuvant hormonal therapy or chemotherapy. Pre- and 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 breast cancer screening 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.

**American Society of Clinical Oncology (ASCO):** The ASCO Update of the Breast Cancer Follow-up and Management Guidelines in the Adjuvant Setting notes that breast MRI is not recommended for routine breast cancer surveillance (Khatcheressian, et al., 2006).

## Summary

Evidence in the published, peer-reviewed scientific literature demonstrates that breast MRI provides additional value in several clinical situations. Annual 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 because the benefit of MRI screening over mammography has not been proven for that population.

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:**

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

<b>HCPCS</b> <b>Codes</b>	<b>Description</b>
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</b> <b>Diagnosis</b> <b>Codes</b>	<b>Description</b>
	Multiple/varied

**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)

**\*Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.**

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## Policy History

<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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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA’s subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.