Magnetic Resonance Imaging (MRI) of the Breast

Number: 0105

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

I. Aetna considers magnetic resonance imaging (MRI), with or without contrast materials, of the breast medically necessary for members who have had a recent (within the past year) conventional mammogram and/or breast sonogram, in any of the following circumstances where MRI of the breast may affect their clinical management:

A. For individuals who received radiation treatment to the chest between ages 10 and 30 years, such as for Hodgkin disease, Wilm’s tumors; or
B. To assess tumor location, size, and extent before and/or after neoadjuvant chemotherapy in persons with locally advanced breast cancer, for determination of eligibility for breast conservation therapy; or
C. To detect implant rupture in symptomatic members; or
D. To detect suspected local tumor recurrence in members with breast cancer who have undergone mastectomy and breast reconstruction with an implant; or

Policy History

Last Review 03/30/2018
Effective: 03/22/1996
Next Review: 01/24/2019

Definitions

Additional Information

Clinical Policy Bulletin Notes
E. To detect local tumor recurrence in individuals with breast cancer who have radiographically dense breasts or old scar tissue from previous breast surgery that compromises the ability of combined mammography and ultrasonography; or
F. To detect the extent of residual cancer in the recently post-operative breast with positive pathological margins after incomplete lumpectomy when the member still desires breast conservation and local re-excision is planned; or
G. To evaluate persons with lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS); or
H. To guide localization of breast lesions to perform needle biopsy when suspicious lesions exclusively detected by contrast-enhanced MRI can not be visualized with mammography or ultrasonography; or
I. To localize the site of primary occult breast cancer in individuals with adenocarcinoma suggestive of breast cancer discovered as axillary node metastasis or distant metastasis without focal findings on physical examination or on mammography/ultrasonography; or
J. To map the extent of primary tumors and identify multicentric disease in persons with localized breast cancer (stage I or II, T0-1 N0-1 M0) prior to surgery (lumpectomy versus mastectomy); or
K. Contralateral breast examination for members with breast malignancy; or
L. Lesion characterization (nipple retraction, Unilateral drainage from the nipple that is bloody or clear) when all other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer; or
M. After breast conservation therapy in women who exhibit suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations

II. Aetna considers breast MRI a medically necessary adjunct to mammography for screening of women considered to be at
high genetic risk of breast cancer because of any of the following:

A. 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); or
B. Confirmed presence of BRCA1 or BRCA2 mutation; or
C. First degree blood relative with BRCA1 or BRCA2 mutation and are untested; or
D. Have a lifetime risk of breast cancer of 20 to 25 % or more using standard risk assessment models (BRCAPRO, Claus model, Gail model, or Tyrer-Cuzick).

III. Aetna considers breast MRI medically necessary to detect intra-capsular (silent) rupture of silicone gel-filled breast implants. Screening for silent intra-capsular rupture more frequently than every 2 years is not considered medically necessary.

IV. Aetna considers breast MRI experimental and investigational for all other indications, including any of the following, because there is insufficient scientific evidence to support its use:
A. To confirm implant rupture in symptomatic individuals whose ultrasonography shows rupture, especially with implants more than 10 years old (ultrasound sufficient to proceed with removal); or
B. To diagnose fat necrosis post-breast reduction surgery; or
C. To differentiate benign from malignant breast disease, especially clustered micro-calcifications; or
D. To differentiate cysts from solid lesions (ultrasound indicated); or
E. To evaluate breasts before biopsy in an effort to reduce the number of surgical biopsies for benign lesions; or
F. Surveillance of asymptomatic individuals with breast cancer who have completed primary therapy and who are not at high genetic risk of breast cancer; or
G. To provide an early prediction of response to adjuvant
breast cancer chemotherapy in guiding choice of chemotherapy regimen; or

H. Dermatomyositis as an indication for use of MRI for breast cancer screening; or

I. To screen for breast cancer in members with average risk of breast cancer; or

J. To screen BRCA-positive men.

V. Aetna considers computer-aided detection of malignancy with MRI of the breast experimental and investigational because its clinical value has not been established.

VI. Aetna considers post-surgical intra-operative breast MRI for quantifying tumor deformation and detecting residual breast cancer experimental and investigational because its clinical value has not been established.

VII. Aetna considers quantitative breast MRI for predicting the risk of breast cancer recurrence experimental and investigational because its clinical value has not been established.

See also CPB 0584 - Mammography (../500_599/0584.html).

**Background**

Mammography is the only screening test proven to lower breast cancer morbidity and mortality. Although mammography is an effective screening tool, it does have limitations, especially in women with dense breasts. New imaging techniques are being developed to overcome these limitations, enhance cancer detection, and improve patient outcome. Digital mammography, computer-aided detection (CAD), breast ultrasound, and breast magnetic resonance imaging (MRI) are frequently used adjuncts to mammography in today's clinical practice.

An expert panel convened by the American Cancer Society
recommended the use of MRI for screening women at a 20 to 25% or greater lifetime risk for breast cancer (Saslow et al, 2007). The panel states that, in addition to mammography, annual screening using MRI is recommended for women who:

- 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)
- 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 to 25% or more using standard risk assessment models
- Received radiation treatment to the chest between ages 10 and 30, such as for Hodgkin Disease

The ACS guidelines recommend use of MRI in addition to, not in place of, mammography for screening high-risk women (Saslow et al, 2007). The guidelines explain that all of the clinical trials screened participants with both MRI and mammography at the same time. The guidelines state that 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."

The guideline provides information about 3 risk assessment models available for calculating breast cancer risk (BRCAPRO, Claus model, and Tyrer-Cuzick). Software for each model is available online (see Appendix below). The 3 risk models utilize different combinations of risk factors, are derived from different data sets, and vary in the age to which they calculate cumulative breast cancer risk. As a result, they may generate different risk estimates for a given patient. This variability is an indicator that the risk models provide approximate, rather than precise, estimates of breast cancer risk. According to ACS guidelines, each of the risk models can be used for the purpose of identifying patients who would benefit from breast MRI
screening (Saslow et al, 2007). In addition, the Gail model is widely used in research studies and clinical counseling to predict a woman's lifetime risk of developing breast cancer. Calculation of a 5-year and lifetime breast cancer risk according to the Gail model can be performed by accessing the National Cancer Institute's website and searching for information on breast cancer risk.

The ACS panel also identified several risk subgroups for which the available data are insufficient to recommend either for or against MRI screening (Saslow et al, 2007). They include women with a personal history of breast cancer, carcinoma in situ, atypical hyperplasia, and extremely dense breasts on mammography.

Although ultrasound is sufficient to confirm rupture of breast implants in women with symptoms, MRI may be necessary to detect intra-capsular rupture of silicone gel-filled breast implants in asymptomatic women. The sensitivity of plastic surgeons familiar with implants to diagnose rupture is 30% compared to 89% for MRI (Holmich et al, 2005). The FDA therefore recommends that women with silicone gel-filled breast implants have regular breast MRIs over their lifetime to screen for silent rupture. The FDA-approved labeling of silicone gel-filled breast implants recommends that the first MRI be performed 3 years post-operatively, then every 2 years thereafter. The FDA recommends that the MRI have at least a 1.5 Tesla magnet, a dedicated breast coil, and a radiologist experienced with breast implant MRI films for signs of rupture.

Houssami et al (2008) reviewed the evidence on MRI in staging the affected breast to determine its accuracy and impact on treatment. These researchers estimated summary receiver operating characteristic curves, positive predictive value (PPV), true-positive (TP) to false-positive (FP) ratio, and examined their variability according to quality criteria. Pooled estimates of the proportion of women whose surgery was altered were calculated. Data from 19 studies showed MRI detects additional disease in 16% of women with breast cancer (n =
Magnetic resonance imaging incremental accuracy differed according to the reference standard (RS; p = 0.016) decreasing from 99% to 86% as the quality of the RS increased. Positive predictive value was 66% (95% confidence interval [CI]: 52% to 77%) and TP:FP ratio was 1.91 (95% CI: 1.09 to 3.34). Conversion from wide local excision (WLE) to mastectomy was 8.1% (95% CI: 5.9 to 11.3), from WLE to more extensive surgery was 11.3% in multi-focal/multi-centric disease (95% CI: 6.8 to 18.3). Due to MRI-detected lesions (in women who did not have additional malignancy on histology) conversion from WLE to mastectomy was 1.1% (95% CI: 0.3 to 3.6) and from WLE to more extensive surgery was 5.5% (95% CI: 3.1 to 9.5). The authors concluded that MRI staging causes more extensive breast surgery in an important proportion of women by identifying additional cancer, however there is a need to reduce FP MRI detection. They stated that randomized trials are needed to determine the clinical value of detecting additional disease which changes surgical treatment in women with apparently localized breast cancer.

In a review on the utility of MRI for the screening and staging of breast cancer, Patani and Mokbel (2008) stated that while MRI can facilitate local staging, especially the evaluation of ipsilateral multi-centric or multi-focal lesions as well as synchronous contralateral disease that may be missed by conventional imaging; however, efficacy with respect to clinically relevant and patient oriented end-points has yet to be addressed in the context of clinical trials.

Computer-aided detection has been used to aid radiologists’ interpretation of contrast-enhanced MRI of the breast, which is sometimes used as an alternative to mammography or other screening and diagnostic tests because of its high sensitivity in detecting breast lesions, even among those in whom mammography is less accurate (e.g., younger women and those with denser breasts). However, MRI has a high FP rate because of the difficulty in differentiating between benign and malignant lesions. The use of CAD may also reduce the time needed to interpret breast MRI images, which currently takes
much longer than reading mammograms.

The BlueCross and BlueShield Association’s Technology Evaluation Center (TEC) Medical Advisory Panel (2006) assessed the evidence on the use of CAD with MRI of the breast by comparing the sensitivity, specificity, and recall rate (percentage of patients asked to come back for further evaluation) of MRI with and without the use of commercially available CAD systems in detecting malignant lesions, evaluating the extent of disease in women with cancer, or gauging the impact of treatment. According to this assessment, many of the studies on the use of CAD with MRI of the breast mainly reported on the development of CAD systems, or testing new CAD approaches. The assessment noted that few of them evaluated commercially available CAD systems. Several of those that did, reported on the development and testing of approaches that underlie one of the commercially available systems (3TP); the assessment stated that it is not clear to what degree the current 3TP system has or has not been modified compared to these earlier approaches. Although the studies had to have separate testing data sets to be included in the TEC assessment, these data sets often were enriched with more cancer cases or consisted exclusively of cases in which lesions had been found. The TEC assessment found, as a result, the range of sensitivities and specificities cannot be applied to the populations usually found in a clinical setting. The TEC assessment also found that many of the studies of CAD systems were retrospective, and reported primarily on their development and testing; thus, these studies lacked the rigor and generalizability of a large, prospective, well-designed study.

The TEC assessment stated that the literature is unclear on how CAD systems are to be used. In the case of CAD with mammography, the radiologist reads the original films first, makes a diagnosis, and then reviews the CAD results. The TEC assessment explained that, because CAD is not 100% sensitive, lesions detected by mammography both before the use of CAD and after viewing the CAD results may be worked up. Thus, CAD can add to the sensitivity of mammography, but not its
specificity. The TEC assessment noted, however, with MRI of the breast, the sensitivity is already high, and the focus is mainly on enhancing the specificity. In some studies, it appears that CAD was intended as an adjunct to the initial MRI reading, just as with CAD and mammography. In other studies, it was proposed as a way of speeding up the MRI reading process, and the precise protocol to be followed in reading the MRI images is unclear. In addition, unlike in the case of CAD with mammography, in the documents regarding the FDA clearance it did not specify that CAD must be added only after an initial reading of the images alone, although it did say for one system that “patient management decisions should not be made based solely on the results of the CADstream analysis”. The TEC assessment observed that the impact of CAD on the accuracy of MRI of the breast may depend partly on how the CAD results are incorporated into the reading and diagnostic process.

Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel concluded that there is insufficient evidence to evaluate if the use of CAD systems would maintain or increase the sensitivity, specificity, and recall rates of MRI of the breast. The TEC assessment concluded that, given the inability to evaluate these intermediate outcomes, it is impossible to evaluate the impact of CAD on health outcomes such as treatment success and survival of patients with breast cancer.

There is limited evidence on the predictive value of preoperative MRI in persons who are newly diagnosed with early stage breast cancer, and no consistent evidence that a pre-operative breast MRI confers a benefit to the patient by improving clinical outcomes or surgical procedures. Lehman et al (2009) stated that use of breast MRI in the pre-operative evaluation of patients recently diagnosed with breast cancer has increased significantly over the past 10 years because of its well-documented high sensitivity for detecting otherwise occult breast cancer in the affected and contralateral breasts. However, published research reports on the impact of this improved cancer detection are limited. Equally important are
growing concerns that the quality of breast MRI may vary significantly across practice sites, and therefore the published value of MRI may not be achieved for many patients. These researchers described the peer-reviewed, published clinical research trials evaluating breast MRI in patients with newly diagnosed breast cancer on which the National Comprehensive Cancer Network (NCCN) practice guidelines on breast cancer were based. The current NCCN guidelines (2011) recommend that breast MRI be considered for patients with a newly diagnosed breast cancer to evaluate the extent of cancer or presence of multi-focal or multi-centric cancer in the ipsilateral breast; and for screening of the contralateral breast cancer at the time of initial diagnosis (category 2B).

Lehman and colleagues (2007) conducted a study to examine if MRI could improve on clinical breast examination and mammography in detecting contralateral breast cancer soon after the initial diagnosis of unilateral breast cancer. A total of 969 women with a recent diagnosis of unilateral breast cancer and no abnormalities on mammographic and clinical examination of the contralateral breast underwent breast MRI. The diagnosis of MRI-detected cancer was confirmed by means of biopsy within 12 months after study entry. The absence of breast cancer was determined by means of biopsy, the absence of positive findings on repeat imaging and clinical examination, or both at 1 year of follow-up. MRI detected clinically and mammographically occult breast cancer in the contralateral breast in 30 of 969 women who were enrolled in the study (3.1 %). The sensitivity of MRI in the contralateral breast was 91 %, and the specificity was 88 %. The negative predictive value of MRI was 99 %. A biopsy was performed on the basis of a positive MRI finding in 121 of the 969 women (12.5 %), 30 of whom had specimens that were positive for cancer (24.8 %); 18 of the 30 specimens were positive for invasive cancer. The mean diameter of the invasive tumors detected was 10.9 mm. The additional number of cancers detected was not influenced by breast density, menopausal status, or the histologic features of the primary tumor. The authors concluded that MRI can detect cancer in the contralateral breast that is missed by
mammography and clinical examination at the time of the initial breast-cancer diagnosis.

Bernard and associates (2010) evaluated the prevalence of synchronous, occult contralateral breast cancer detected by MRI but not by mammography or clinical breast examination in women with newly diagnosed breast cancer, including those aged 70 years or older. These investigators reviewed MRI results for women with newly diagnosed breast cancer who underwent bilateral breast MRI after negative mammography and clinical examination. The prevalence of pathologically confirmed contralateral carcinoma diagnosed solely by MRI was determined and analyzed in the context of age, breast density, family history, menopausal status, and primary-tumor characteristics. Logistic regression was used to explore the association between contralateral carcinoma and potential patient risk factors. A total of 425 women were evaluated, of whom 129 (30 %) were aged 70 years or older. A contralateral biopsy was recommended and performed solely on the basis of MRI in 72 of the 425 women (17 %). Sixteen of these 72 women (22 %) had pathologically confirmed carcinoma, including 7 in the older subgroup. The prevalence of clinically and mammographically occult contralateral carcinoma detected by MRI was 3.8 % (16/425) overall and 5.4 % (7/129) in the group of older women. When potential risk factors for contralateral breast cancer were evaluated, post-menopausal status was the only significant predictor of contralateral cancer detected by MRI (p = 0.016). The authors concluded that contralateral breast screening with MRI should be considered in post-menopausal women with newly diagnosed breast cancer, even those aged 70 years or older at diagnosis.

On the other hand, Houssami and Hayes (2009) noted that randomized controlled trials (RCTs) have shown equivalent survival for women with early stage breast cancer who are treated with breast-conservation therapy (local excision and radiotherapy) or mastectomy. Decades of experience have shown that breast-conservation therapy provides excellent local control based on defined standards of care. Magnetic
resonance imaging has been introduced in pre-operative staging of the affected breast in women with newly diagnosed breast cancer because it detects additional foci of cancer that are occult on conventional imaging. The median incremental (additional) detection for MRI has been estimated as 16% in meta-analysis. In the absence of consensus on the role of pre-operative MRI, these investigators reviewed data on its detection capability and its impact on treatment. They outlined that the assumptions behind the adoption of MRI, namely that it will improve surgical planning and will lead to a reduction in re-excision surgery and in local recurrences, have not been substantiated by trials. Evidence consistently shows that MRI changes surgical management, usually from breast conservation to more radical surgery; however, there is no evidence that it improves surgical care or prognosis. Emerging data indicate that MRI does not reduce re-excision rates and that it causes FPs in terms of detection and unnecessary surgery; overall there is little high-quality evidence at present to support the routine use of pre-operative MRI. The authors concluded that RCTs are needed to establish the clinical, psychosocial, and long-term effects of MRI and to show a related change in treatment from standard care in women newly affected by breast cancer.

Furthermore, Solin (2010) stated that for the woman with a newly diagnosed early stage breast cancer, the routine use of pre-operative breast MRI is not indicated beyond conventional breast imaging (i.e., mammography with correlation ultrasound as indicated). There is no consistent evidence that a pre-operative breast MRI confers a benefit to the patient by improving clinical outcomes or surgical procedures. In a meta-analysis of studies reporting on the use of pre-operative breast MRI for the patient with an established index cancer, multi-focal or multi-centric disease was found on breast MRI in 16% of the patients, a rate substantially higher than the rate of local recurrence after breast conserving surgery plus definitive radiation treatment. In the largest retrospective study of patients treated with breast conserving surgery plus radiation, no gain was found for adding a breast MRI to conventional
breast imaging. No randomized clinical trial has been designed to evaluate long-term clinical outcomes associated with adding a pre-operative breast MRI. Adding pre-operative breast MRI can alter clinical management in ways that are potentially harmful to patients (e.g., increased ipsilateral mastectomies, increased contralateral prophylactic mastectomies, increased work-ups, and delay to definitive surgery). The authors concluded that the routine use of pre-operative breast MRI is not warranted for the typical patient with a newly diagnosed early stage breast cancer.

There are no clinical studies of breast MRI in BRCA-positive men. Neither the American Cancer Society guidelines nor the National Comprehensive Cancer Network (NCCN) guidelines recommend breast MRI screening for men.

Wurdinger et al (2005) evaluated the MRI appearance of phyllodes breast tumors and to differentiate them from fibro-adenomas. MR images were obtained on a 1.5-T imager. T1- and T2-weighted sequences and dynamic 2D fast-field echo T1-weighted sequences were performed. MR images of 23 patients with 24 phyllodes breast tumors (1 malignant, 23 benign) were analyzed with respect to morphology and contrast enhancement. The tumors were compared with the MRI appearance of 81 fibro-adenomas of 75 patients. Well-defined margins were seen in 87.5 % of the phyllodes tumors and 70.4 % of the fibro-adenomas, and a round or lobulated shape in 100 % and 90.1 %, respectively. A heterogeneous internal structure was observed in 70.8 % of phyllodes tumors and in 49.4 % of fibro-adenomas. Non-enhancing internal septations were found in 45.8 % of phyllodes tumors and 27.2 % of fibro-adenomas. A significantly greater increase in signal was seen on T2-weighted images in the tissue surrounding phyllodes tumors (21 %) compared with fibro-adenomas (1.2 %). Most of both lesions appeared with low signal intensity on T1- and T2-weighted images. After the administration of contrast material, 33.3 % of phyllodes tumors and 22.2 % of fibro-adenomas showed a suspicious signal intensity-time course. The authors concluded that phyllodes breast tumors and other fibro-
adenomas can not be precisely differentiated on breast MRI. Phyllodes tumors have benign morphologic features and contrast enhancement characteristics suggestive of malignancy in 33 % of cases.

Biondi et al (2009) stated that phyllodes tumors are unusual biphasic fibro-epithelial neoplasms of the breast, accounting for less than 1 % of all breast tumors and raising issues of diagnosis and therapeutic choice. They can grow quickly and when the maximum diameter is greater than 10 cm, they are known as giant phyllodes tumors. Ultrasound, mammography and fine needle aspiration are not effective. A potentially useful diagnostic modality is MRI. Core tissue biopsy or incisional biopsy represent the preferred means of pre-operative diagnosis. Conservative treatment can be effective also in giant tumors depending upon the size of the tumor and the breast if a complete excision with an adequate margin of normal breast tissue can be achieved, so avoiding local recurrence often accompanied by worse histopathology. The authors reported the case of a giant benign phyllode tumor of the breast treated with conservative surgery, quadrantectomy and oncoplasty. No local recurrence at 4 years follow-up.

An UpToDate review on "Phyllodes tumors of the breast" (Grau et al, 2011) states that the role of MRI in the diagnosis and management of phyllodes tumors is not clear. A retrospective study of 30 patients with biopsy confirmed phyllodes tumors showed that malignant phyllodes tumors are seen as well-circumscribed tumors with irregular walls, high signal intensity on T1-weighted images and low signal intensity on T2-weighted images. Cystic change may be seen as well. Interestingly, a rapid enhancement pattern is seen more commonly with benign rather than malignant phyllodes tumors, which is the opposite of the pattern seen with adenocarcinomas of the breast. When the diagnosis of a phyllodes tumor has been made on core biopsy, breast MRI may prove helpful in determining the extent of disease and facilitating pre-operative planning. However, the use of breast MRI in surgical planning for phyllodes tumors is controversial as there are very little data
on its role in this setting as they are so rare.

Furthermore, the NCCN Clinical Practice Guideline on breast cancer (2011) mentions the use of ultrasonography and mammography for the work-up of patients with phyllodes tumor; but does not mention the use of MRI in the management of these patients.

In a retrospective cohort study, Weber and colleagues (2012) examined the effect of pre-operative MRI on the reoperation rate in women with operable breast cancer. Women with operable breast cancer treated by a single surgeon between January 1, 2006, and December 31, 2010 were included in this study; selective pre-operative MRI based on breast density and histologic findings were carried out. Main outcome measures were reoperation rate and pathologically avoidable mastectomy at initial operation. Of 313 patients in the study, 120 underwent pre-operative MRI. Patients undergoing MRI were younger (mean age, 53.6 versus 59.5 years; p < 0.001), were more often of non-Hispanic white race/ethnicity (61.7 % versus 52.3 %, p < 0.05), and more likely had heterogeneously dense or very dense breasts (68.4 % versus 22.3 %, p < 0.001). The incidence of lobular carcinoma (8.3 % in the MRI group versus 5.2 % in the no MRI group, p = 0.27) and the type of surgery performed (mastectomy versus partial mastectomy, p = 0.67) were similar in both groups. The mean pathological size of the index tumor in the MR imaging group was larger than that in the no MRI group (2.02 versus 1.72 cm, p = 0.009), but the extent of disease was comparable (75.8 % in the MR imaging group versus 82.9 % in the no MRI group had pathologically localized disease, p = 0.26). The reoperation rate was similar between the 2 groups (19.1 % in the MRI group versus 17.6 % in the no MRI group, p = 0.91) even when stratified by breast density (p = 0.76), pT2 tumor size (p = 0.35), or lobular carcinoma histologic findings (p = 0.26). Pathologically avoidable mastectomy (multi-focal or multi-centric MRI and uni-focal histopathological findings) was observed in 12 of 47 patients (25.5 %) with pre-operative MRI who underwent mastectomy. The authors concluded that the selective use of
pre-operative MRI to decrease reoperation in women with breast cancer is not supported by these data. In a considerable number of patients, MRI over-estimated the extent of disease.

Plana et al (2012) estimated the diagnostic accuracy of MRI in detecting additional lesions and contralateral cancer not identified using conventional imaging in primary breast cancer. These investigators conducted a systematic review and meta-analyses to estimate diagnostic accuracy indices and the impact of MRI on surgical management. A total of 50 articles were included (n = 10,811 women). MRI detected additional disease in 20 % of women and in the contralateral breast in 5.5 %. The summary PPV of ipsilateral additional disease was 67 % (95 % CI: 59 to 74 %). For contralateral breast, the PPV was 37 % (95 % CI: 27 to 47 %). For ipsilateral lesions, MRI devices greater than or equal to 1.5 Tesla (T) had higher PPV (75 %, 95 % CI: 64 to 83 %) than MRI with less than 1.5 T (59 %, 95 % CI: 53 to 71 %). Similar results were found for contralateral cancer, PPV 40 % (95 % CI: 29 to 53 %) and 19 % (95 % CI: 8 to 39 %) for high- and low-field equipments, respectively. True-positive MRI findings prompted conversion from wide local excision (WLE) to more extensive surgery in 12.8 % of women while in 6.3 % this conversion was inappropriate. The authors concluded that MRI shows high diagnostic accuracy, but MRI findings should be pathologically verified because of the high FP rate. They stated that future research on this emerging technology should focus on patient outcome as the primary end-point.

Prevos et al (2012) examined if MRI can identify pre-treatment differences or monitor early response in breast cancer patients receiving neoadjuvant chemotherapy. PubMed, Cochrane library, Medline and Embase databases were searched for publications until January 1, 2012. After primary selection, studies were selected based on pre-defined inclusion/exclusion criteria. Two reviewers assessed study contents using an extraction form. In 15 studies, which were mainly under-powered and of heterogeneous study design, 31 different parameters were studied. Most frequently studied parameters were tumor diameter or volume, K(trans), K(ep), V(e), and
apparent diffusion coefficient (ADC). Other parameters were analyzed in only 2 or less studies. Tumor diameter, volume, and kinetic parameters did not show any pre-treatment differences between responders and non-responders. In 2 studies, pre-treatment differences in ADC were observed between study groups. At early response monitoring significant and non-significant changes for all parameters were observed for most of the imaging parameters. The authors concluded that evidence on distinguishing responders and non-responders to neoadjuvant chemotherapy using pre-treatment MRI, as well as using MRI for early response monitoring, is weak and based on under-powered study results and heterogeneous study design. Thus, the value of breast MRI for response evaluation has not yet been established.

The American Society of Clinical Oncology’s clinical practice guideline update on “Breast cancer follow-up and management after primary treatment” (Khatcheressian et al, 2013) provided recommendations on the follow-up and management of patients with breast cancer who have completed primary therapy with curative intent. A systematic review of the literature published from March 2006 through March 2012 was completed using Medline and the Cochrane Collaboration Library. An Update Committee reviewed the evidence to determine whether the recommendations were in need of updating. There were 14 new publications that met inclusion criteria: 9 systematic reviews (3 included meta-analyses) and 5 RCTs. After its review and analysis of the evidence, the Update Committee concluded that no revisions to the existing ASCO recommendations were warranted. Regular history, physical examination, and mammography are recommended for breast cancer follow-up. Physical examinations should be performed every 3 to 6 months for the first 3 years, every 6 to 12 months for years 4 and 5, and annually thereafter. For women who have undergone breast-conserving surgery, a post-treatment mammogram should be obtained 1 year after the initial mammogram and at least 6 months after completion of radiation therapy. Thereafter, unless otherwise indicated, a yearly mammographic evaluation should be performed. The
use of complete blood counts, chemistry panels, bone scans, chest radiographs, liver ultrasounds, pelvic ultrasounds, computed tomography scans, $[(18)F]fluorodeoxyglucose$-positron emission tomography scans, MRI, and/or tumor markers (carcinoembryonic antigen, CA 15-3, and CA 27.29) is not recommended for routine follow-up in an otherwise asymptomatic patient with no specific findings on clinical examination.

Korteweg et al (2011) evaluated the feasibility of 7-T breast MRI by determining the intrinsic sensitivity gain compared with 3-T in healthy volunteers and explored clinical application of 7-T MRI in breast cancer patients receiving neoadjuvant chemotherapy (NAC). In 5 volunteers, the signal-to-noise ratio (SNR) was determined on proton density MRI at 3-T using a conventional 4-channel bilateral breast coil and at 7-T using a dedicated 2-channel unilateral breast coil, both obtained at identical scan parameters. Subsequently, consecutive breast cancer patients on NAC were included. The 7-T breast MRI protocol consisted of diffusion-weighted imaging, 3-D high-resolution (450 μm isotropic) T1-weighted fat-suppressed gradient-echo sequences and quantified single voxel (1)H-magnetic resonance spectroscopy. Morphology was scored according to the MRI Breast Imaging-Reporting and Data System (BI-RADS)-lexicon, and the images were compared with 3-T and histopathologic findings. Image quality was evaluated using a 5-point scale. A 5.7-fold higher SNR was measured at 7-T than at 3-T, which reflected the advantages of a higher field strength and the use of optimized radiofrequency coils. Three breast cancer patients were included and received a total of 13 7-T MRI examinations. The image quality of the high-resolution examinations was at least satisfactory, and good to excellent in 9 of the 13 examinations performed. More anatomic detail was depicted at 7-T than at 3-T. In 1 case, a fat plane between the muscle and tumor was visible at 7-T, but not at the clinically performed 3-T examination, suggesting that there was no muscle invasion, which was confirmed by pathology. Changes in tumor apparent diffusion coefficient values could be monitored in 2 patients and were found to increase during NAC,
consistent with published results from studies at lower field strengths. Apparent diffusion coefficient values increased respectively from $0.33 \times 10^{-3}$ mm$^2$/s to $1.78 \times 10^{-3}$ mm$^2$/s after NAC and from $1.20 \times 10^{-3}$ mm$^2$/s to $1.44 \times 10^{-3}$ mm$^2$/s during NAC. Choline concentrations as low as 0.77 mM/kg(water) could be detected. In 1 patient, choline levels showed an overall decrease from 4.2 mM/kg(water) to 2.6 mM/kg(water) after NAC and the tumor size decreased correspondingly from $3.9 \times 4.1 \times 5.6$ cm$^3$ to $2.0 \times 2.7 \times 2.4$ cm$^3$. All 7-T MRI findings were consistent with pathology analysis. The authors concluded that dedicated 7-T breast MRI is technically feasible, can provide more SNR than at 3-T, and has diagnostic potential.

An UpToDate review on “MRI of the breast and emerging technologies” (Slanetz, 2014) states that “High field strength MRI -- High field strength magnets (3-Tesla and 7-Tesla) provide higher signal to noise ratios than conventional breast MRI, performed with 1.5-Tesla field strength magnets. The high field strength magnets result in higher spatial resolution and improved detection of breast cancers <5 mm in size than conventional techniques. However, there are no large prospective trials that show clinical advantage for high field strength MRI. In addition, the lack of widespread availability of higher field magnets limits applicability to clinical practice”.

**Diagnosis of Fat Necrosis Post-Breast Reduction Surgery:**

Tunçbilek et al (2011) stated that non-traumatic rapid growing giant fat necrosis of the breast mimicking breast tumors is a rare clinical manifestation. The imaging features of the fat necrosis that range from benign to malignant findings may be better explained with associated etiology. These researchers reported the case of a 54-year old woman with a rapid growing, fibrous, and hard giant mass originating in the sub-areolar region of the left breast. Mammography and MRI demonstrated a heterogeneous, well circumscribed mass in 12 × 12 cm size in the left breast. The lesion was suspected as a malignant tumor and underwent core biopsy. The
histopathology examination of the biopsy revealed mononuclear cells, foamy, vacuolated, and bubbly cells containing fat. Excision biopsy of the mass was performed and the final pathological diagnosis was confirmed as fat necrosis. The authors concluded that the wide clinical and radiologic manifestations of fat necrosis are still difficult to diagnose even with the new diagnostic modalities and a great proportion of these lesions need a biopsy to diagnose.

The American College of Radiology (ACR)’s Appropriateness Criteria on “Nonpalpable mammographic findings (excluding calcifications)” (2012) suggested considering “Return to screening mammography if the area can be confidently determined to be related to prior surgery (i.e., by scar marker) or the sequelae of trauma (e.g., presence of fat necrosis)”. This was rendered a “4” rating (4, 5, 6 ratings denote “May be appropriate”). The ACR’s Appropriateness Criteria on “Nonpalpable mammographic findings (excluding calcifications)” does not mention the use of MRI.

Kerridge et al (2015) stated that “Fat necrosis of the breast is a challenging diagnosis due to the various appearances on mammography, ultrasound, CT, positron emission tomography-computed tomography (PET-CT), and MRI. Although mammography is more specific, ultrasound is a very important tool in making the diagnosis of fat necrosis. MRI has a wide spectrum of findings for fat necrosis and the appearance is the result of the amount of the inflammatory reaction, the amount of liquefied fat, and the degree of fibrosis”. In fact, specificity of post-operative MRI may be lowered by enhancing granulation tissue or fat necrosis at the surgical site.

An eMedicine’s review on “Postsurgical Breast Imaging” (Ackerman, 2015) did not mention breast MRI as a diagnostic tool for fat necrosis of the breast.

Furthermore, Radiopaedia.org’s Information Sheet on “Fat Necrosis of the Breast” (2015) stated that “Fat necrosis within the breast is a pathological process that occurs when there is
saponification of local fat. It is a benign inflammatory process and is becoming increasingly common with greater use of breast conserving surgery and mammoplasty procedures”. It mentions mammography and breast ultrasound for the diagnosis of fat necrosis; but not breast MRI.

**Routine Screening/Evaluation of Individuals with Nipple Discharge:**

The Institute for Clinical Systems Improvement’s clinical guideline on “Diagnosis of breast disease” (ICSI, 2012) provided the following information:

- Patients with a bloody or clear discharge should be referred to a radiologist and/or surgeon for further evaluation.
- A mammogram and ultrasound should be obtained with presence of bloody or clear discharge to rule out malignancy.
- Most pathologic nipple discharges should be treated with duct excision. The use of ductography and/or MRI ductography is dependent on the decision of the surgeon and radiologist.

The Alberta Provincial Breast Tumor Team’s clinical guideline on “Magnetic resonance imaging for breast cancer screening, preoperative assessment, and follow-up” (2012) stated that:

- MRI is not recommended for the routine screening of patients with nipple discharge.

van Gelder et al (2015) noted that unilateral bloody nipple discharge (UBND) is mostly caused by benign conditions such as papilloma or ductal ectasia. However, in 7 to 33% of all nipple discharge, it is caused by breast cancer. Conventional diagnostic imaging like mammography (MMG) and ultrasonography (US) is performed to exclude malignancy. Preliminary investigations of breast magnetic resonance imaging (MRI) assume that it has additional value. With an increasing availability of MRI, it is of clinical importance to evaluate this. These investigators evaluated the additional diagnostic value of MRI in patients with UBND in the absence of
a palpable mass, with normal conventional imaging. All women with UBND in the period November 2007 to July 2012 were included. In addition to the standard work-up (patient's history, physical examination, MMG, and US), MRI was performed. Data from these examinations and treatment were collected retrospectively. A total of 111 women (mean age 52 years; range of 23 to 80) were included. In 9 (8 %) patients, malignancy was suspected on MRI while conventional imaging was normal. In 8 (89 %) of these patients, histology was obtained, 2 by core biopsy and 6 by terminal duct excision. Benign conditions were found in 6 patients (86 %) and a (pre)malignant lesion in 2 patients. In both cases, it concerned a ductal carcinoma in-situ, which was treated with breast-conserving therapy. Moreover, in 2 cases of (pre)malignancy, the MRI was interpreted as negative. The authors concluded that in patients with UBND who showed no signs of a malignancy on conventional diagnostic examinations, the added value of a breast MRI is limited, since a malignancy can be demonstrated in less than 2 %.

An UpToDate review on “Nipple discharge” (Golshan and Iglehart, 2015) states that “Magnetic resonance imaging -- MRI is a relatively sensitive imaging modality with low to moderate specificity. The role of MRI in the evaluation of nipple discharge is evolving. In 52 patients with suspicious nipple discharge who were studied with a breast MRI; the sensitivity and specificity for malignancy were 77 and 62 %, respectively, with a median follow-up of 14 months. The positive predictive value of MRI in this series was 56 %. The significant false positive rate and somewhat limited availability of MR-guided biopsy limits the utility of this modality. If MR is going to be used in this setting, it should be done in a facility that has MR biopsy capabilities. MR ductography -- MR ductography is a different technique than standard breast MRI. It utilizes heavy T2 weighting, which accentuates the visibility of fluid containing structures. No directly instilled or intravenous contrast material is necessary. MR ductography provides a 3D image and can show the precise shape and location of the abnormal duct and lesion in the breast. However, this technique will not reveal ducts that are
not dilated or those with low signal intensity on heavily T2-weighted images, due to hemorrhage or the presence of proteinaceous contents within the duct. The workup of suspicious nipple discharge should include ultrasound and mammography. The role of imaging is to determine whether there are any underlying lesions that may account for the symptom of nipple discharge and to target the area for surgical localization. However, imaging studies do not reliably identify cancer or high-risk lesions in patients with nipple discharge. Other diagnostic testing, including ductography, breast magnetic resonance imaging, magnetic resonance ductography, and ductoscopy can be helpful in selected women but are not routinely necessary for the work-up of nipple discharge.

Furthermore, an UpToDate review on “MRI of the breast and emerging technologies” (Slanetz, 2015) states that “Although some have proposed breast MRI imaging for the evaluation of spontaneous nipple discharge when mammography and ultrasound of the periareolar area fail to identify a focal finding, we do not feel there is a role for MRI for this purpose. A negative MRI does not preclude disease and pathologic nipple discharge should be managed with a terminal duct excision”.

Post-Surgical Intra-Operative Breast MRI for Quantifying Tumor Deformation and Detecting Residual Breast Cancer:

Gombos and associates (2016) employed intra-operative supine MRI to quantify breast tumor deformation and displacement secondary to the change in patient positioning from imaging (prone) to surgery (supine) and evaluated residual tumor immediately after breast-conserving surgery (BCS). A total of 15 women gave informed written consent to participate in this prospective HIPAA-compliant, institutional review board-approved study between April 2012 and November 2014; 12 patients underwent lumpectomy and post-surgical intra-operative supine MRI; 6 of 12 patients underwent both pre- and post-surgical supine MRI. Geometric, structural, and heterogeneity metrics of the cancer and distances of the tumor from the nipple, chest wall, and skin were computed. Mean
and standard deviations (SDs) of the changes in volume, surface area, compactness, spherical disproportion, sphericity, and distances from key landmarks were computed from tumor models. Imaging duration was recorded. The mean differences in tumor deformation metrics between prone and supine imaging were as follows: volume, 23.8 % (range of -30 % to 103.95 %); surface area, 6.5 % (range of -13.24 % to 63 %); compactness, 16.2 % (range of -23 % to 47.3 %); sphericity, 6.8 % (range of -9.10 % to 20.78 %); and decrease in spherical disproportion, -11.3 % (range of -60.81 % to 76.95 %). All tumors were closer to the chest wall on supine images than on prone images. No evidence of residual tumor was seen on MRI obtained after the procedures. Mean duration of pre- and post-operative supine MRI was 25 minutes (range of 18.4 to 31.6 minutes) and 19 minutes (range of 15.1 to 22.9 minutes), respectively. The authors concluded that intra-operative supine breast MRI, when performed in conjunction with standard prone breast MI, enabled quantification of breast tumor deformation and displacement secondary to changes in patient positioning from standard imaging (prone) to surgery (supine) and may help clinicians evaluate for residual tumor immediately after BCS. These preliminary findings need to be validated by well-designed studies.

Quantitative Breast MRI Predicting the Risk of Breast Cancer Recurrence:

Li and colleagues (2016) examined the relationships between computer-extracted breast MRI phenotypes with multi-gene assays of MammaPrint, Oncotype DX, and PAM50 to assess the role of radiomics in evaluating the risk of breast cancer recurrence. Analysis was conducted on an institutional review board-approved retrospective data set of 84 de-identified, multi-institutional breast MR examinations from the National Cancer Institute Cancer Imaging Archive, along with clinical, histopathological, and genomic data from the Cancer Genome Atlas. The data set of biopsy-proven invasive breast cancers included 74 (88 %) ductal, 8 (10 %) lobular, and 2 (2 %) mixed cancers. Of these, 73 (87 %) were estrogen receptor (ER)-
positive, 67 (80 %) were progesterone receptor (PR)-positive, and 19 (23 %) were human epidermal growth factor receptor (EGFR)2-positive. For each case, computerized radiomics of the MRI yielded computer-extracted tumor phenotypes of size, shape, margin morphology, enhancement texture, and kinetic assessment. Regression and receiver operating characteristic analysis were conducted to assess the predictive ability of the MR radiomics features relative to the multigene assay classifications. Results Multiple linear regression analyses demonstrated significant associations ($R^2 = 0.25$ to $0.32$, $r = 0.5$ to $0.56$, $p < 0.0001$) between radiomics signatures and multigene assay recurrence scores. Important radiomics features included tumor size and enhancement texture, which indicated tumor heterogeneity. Use of radiomics in the task of distinguishing between good and poor prognosis yielded area under the receiver operating characteristic curve values of 0.88 (standard error [SE], 0.05), 0.76 (SE, 0.06), 0.68 (SE, 0.08), and 0.55 (SE, 0.09) for MammaPrint, Oncotype DX, PAM50 risk of relapse based on subtype, and PAM50 risk of relapse based on subtype and proliferation, respectively, with all but the latter showing statistical difference from chance. The authors concluded that quantitative breast MRI radiomics showed promise for image-based phenotyping in assessing the risk of breast cancer recurrence.

**Surveillance in Women after Breast Conservation Therapy**

In a prospective study, Kim and colleagues (2017) examined the diagnostic performance and tissue changes in early (1 year or less) breast MRI surveillance in women who underwent BCS for breast cancer. Between April 2014 and June 2016, a total of 414 women (mean age of 51.5 years; range of 21 to 81 years) who underwent 422 early surveillance breast MRI examinations (median of 6.0 months; range of 2 to 12 months) after BCS were studied. The cancer detection rate, PPV of biopsy, sensitivity, specificity, accuracy, and area under the curve (AUC) of surveillance MRI, mammography, and US were assessed. Follow-up was also obtained in 95 women by using PET/CT. Background parenchymal enhancement (BPE) changes in the
contralateral breast were assessed according to adjuvant therapy by using the McNemar test. Of 11 detected cancers, 6 were seen at MRI only, 1 was seen at MRI and mammography, 2 were seen at MRI and US, 1 was seen at mammography only, and 1 was seen at PET/CT only; 3 MRI-depicted cancers were observed at the original tumor bed, and 2 MRI-depicted cancers were observed adjacent to the original tumor. Among 2 false-negative MRI diagnoses (2 cases of ductal carcinoma in-situ [DCIS]), 1 cancer had manifested as calcifications at mammography without differentiated enhancement at MRI, and the other cancer was detected at PET/CT, but MRI results were negative because of marked BPE, which resulted in focal lesion masking. The PPV of biopsy and the sensitivity, specificity, accuracy, and AUC for MR imaging were 32.1 % (9 of 28), 81.8 % (9 of 11), 95.1 % (391 of 411), 94.7 % (400 of 422), and 0.88, respectively. The sensitivity of surveillance MRI (81.8 %; 95 % CI: 48.2 % to 97.7 %) was higher than that of mammography (18.2 %; 95 % CI: 2.3 % to 51.8 %) and US (18.2 %; 95 % CI: 2.3 % to 51.8 %), with an overlap in CIs. The BPE showed a significant decrease in the group of patients who received adjuvant chemotherapy (43 BPE decreases and 4 BPE increases) and the group of patients who received hormone therapy (55 BPE decreases and 2 BPE increases) (p < 0.0001 for both). The authors concluded that early MRI surveillance after BCS can be useful in patients who have breast cancer, with superior sensitivity compared with that of mammography and US. The BPE tends to be decreased at short-term follow-up MRI in patients who receive adjuvant therapy.

Cho and co-workers (2017) noted that younger women (aged less than or equal to 50 years) who underwent BCS may benefit from breast MRI screening as an adjunct to mammography. In a prospective, multi-center, non-randomized study, these researchers ascertained the cancer yield and tumor characteristics of combined mammography with MRI or US screening in women who underwent BCS for breast cancers and who were 50 years or younger at initial diagnosis. This trial was conducted from December 1, 2010, to January 31, 2016, at 6 academic institutions. A total of 754 women who were 50
years or younger at initial diagnosis and who had undergone BCS for breast cancer were recruited to participate in the study. Reference standard was defined as a combination of pathology and 12-month follow-up. Participants underwent 3 annual MRI screenings of the conserved and contralateral breasts in addition to mammography and US, with independent readings. Main outcomes measures were cancer detection rate (CDR), sensitivity, specificity, interval cancer rate, and characteristics of detected cancers. Subjects underwent a total of 2,065 mammograms, US, and MRI screenings; 17 cancers were diagnosed, and most of the detected cancers (13 of 17 [76%]) were stage 0 or stage 1. Overall cancer detection rate (8.2 versus 4.4 per 1,000; \( p = 0.003 \)) or sensitivity (100% versus 53%; \( p = 0.01 \)) of mammography with MRI was higher than that of mammography alone. After the addition of US, the cancer detection rate was higher than that by mammography alone (6.8 versus 4.4 per 1,000; \( p = 0.03 \)). The specificity of mammography with MRI or US was lower than that by mammography alone (87% or 88% versus 96%; \( p < 0.001 \)). No interval cancer was found. The authors concluded that the findings of this study suggested that the addition of MRI to mammography screening improved the detection of early-stage breast cancers at acceptable specificity in women who had BCS at 50 years or younger. They stated that these results can be used not only to inform patient and clinician decision-making regarding the best methods of screening after BCS but also to develop more personalized screening guidelines and recommendations for women at increased risk for breast cancer.

The National Cancer Institute’s Breast cancer screening (PDQ) (2017) stated that breast MRI is used in women for diagnostic evaluation, including evaluating the integrity of silicone breast implants, assessing palpable masses after surgery or radiation therapy, detecting mammographically and sonographically occult breast cancer in patients with axillary nodal metastasis, and pre-operative planning for some patients with known breast cancer.
Furthermore, the American Society of Breast Surgeons’ “Consensus Guideline on Diagnostic and Screening Magnetic Resonance Imaging of the Breast” (2017) support the use of breast MRI for the further evaluation of suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations.

**Appendix**

**Breast Cancer Staging:**

Information about breast cancer staging is available from the National Cancer Institute at the following website: Breast Cancer Treatment (http://www.cancer.gov/cancertopics/pdq/treatment/breast/HealthProfessional/page3).

**Breast Cancer Risk Assessment Models:**

Software for each of the breast cancer models referenced the American Cancer Society guidelines (Saslow et al, 2007) is available via the internet:

- **BRCAPRO Version 4.3.** Available at: U.T. Southwestern CancerGene Software (http://www4.utsouthwestern.edu/breasthealth/cagene/default.asp).
- **Tyrer-Cuzick (IBIS Breast Cancer Risk Evaluation Tool, RiskFileCalc version 1.0, copyright 2004).** Available by contacting IBIS: ibis@cancer.org.uk (mailto:ibis@cancer.org.uk).

Breast cancer risk can also be estimated online using the Gail Model Breast Cancer Risk Assessment Tool available from the
National Cancer Institute's website:
Breast Cancer Risk Assessment Tool (http://www.cancer.gov/bcrisktool/)

### CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>CPT codes covered if selection criteria are met:</strong></td>
</tr>
<tr>
<td>19085</td>
<td>Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance</td>
</tr>
<tr>
<td>19086</td>
<td>each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>19287</td>
<td>Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance</td>
</tr>
<tr>
<td>19288</td>
<td>each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>77058</td>
<td>Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral [not covered for screening of BRCA-positive men]</td>
</tr>
<tr>
<td>77059</td>
<td>bilateral [not covered for screening of BRCA-positive men]</td>
</tr>
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</table>

**CPT codes not covered for indications listed in the CPB:**
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>+ 0159T</td>
<td>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)</td>
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**Other CPT codes related to the CPB:**

<table>
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<th>Code</th>
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<tr>
<td>19100 - 19103</td>
<td>Breast biopsy</td>
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<tr>
<td>19120 - 19126</td>
<td>Excision breast lesion</td>
</tr>
<tr>
<td>19300 - 19307</td>
<td>Mastectomy procedures</td>
</tr>
<tr>
<td>19357 - 19369</td>
<td>Breast reconstruction</td>
</tr>
<tr>
<td>76641</td>
<td>Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete</td>
</tr>
<tr>
<td>76642</td>
<td>limited</td>
</tr>
<tr>
<td>77065 - 77067</td>
<td>Diagnostic mammography, including computer-aided detection (CAD) when performed</td>
</tr>
<tr>
<td>88245 - 88269</td>
<td>Chromosome analysis</td>
</tr>
<tr>
<td>88271 - 88275</td>
<td>Molecular cytogenetics</td>
</tr>
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</table>

**HCPCS codes covered if selection criteria are met:**

<table>
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<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C8903</td>
<td>Magnetic resonance imaging with contrast, breast; unilateral</td>
</tr>
<tr>
<td>C8904</td>
<td>Magnetic resonance imaging without contrast, breast; unilateral</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>C8905</td>
<td>Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral</td>
</tr>
<tr>
<td>C8906</td>
<td>Magnetic resonance imaging with contrast, breast; bilateral</td>
</tr>
<tr>
<td>C8907</td>
<td>Magnetic resonance imaging without contrast, breast; bilateral</td>
</tr>
<tr>
<td>C8908</td>
<td>Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral</td>
</tr>
</tbody>
</table>

Other HCPCS codes related to the CPB:

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<th>Code</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>G0202 -</td>
<td>Mammography</td>
</tr>
<tr>
<td>G0206</td>
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</tr>
<tr>
<td>L8600</td>
<td>Implantable breast prosthesis, silicone or equal</td>
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</table>

ICD-10 codes covered if selection criteria are met:

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<tr>
<th>Code</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>C50.011 - C50.929</td>
<td>Malignant neoplasm of breast</td>
</tr>
<tr>
<td>C77.3</td>
<td>Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes</td>
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<tr>
<td>C79.81</td>
<td>Secondary malignant neoplasm of breast</td>
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<tr>
<td>D05.00 - D05.92</td>
<td>Carcinoma in situ of breast</td>
</tr>
<tr>
<td>N64.52</td>
<td>Nipple Discharge</td>
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<tr>
<td>N64.53</td>
<td>Retraction of nipple</td>
</tr>
<tr>
<td>Q85.8</td>
<td>Other phakomatoses, not elsewhere classified [Cowden syndrome]</td>
</tr>
<tr>
<td>R92.8</td>
<td>Other abnormal and inconclusive findings on diagnostic imaging of breast</td>
</tr>
<tr>
<td>T85.41+ - T85.49+</td>
<td>Mechanical complications of breast prosthesis and implant</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>T85.690+</td>
<td>Other mechanical complications of other specified internal prosthetic devices, implants and grafts</td>
</tr>
<tr>
<td>T85.698+</td>
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<tr>
<td>Z12.31</td>
<td>Encounter for screening for malignant neoplasm breast</td>
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<td>Z12.39</td>
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<tr>
<td>Z15.01</td>
<td>Genetic susceptibility to malignant neoplasm of breast [not covered for BRCA-positive men]</td>
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<td>Z15.02</td>
<td>Genetic susceptibility to malignant neoplasm of ovary</td>
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<td>Z40.01</td>
<td>Prophylactic breast removal</td>
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<td>Z40.02</td>
<td>Prophylactic ovary removal</td>
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<td>Z80.3</td>
<td>Family history of malignant neoplasm of breast</td>
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<td>Z80.41</td>
<td>Family history of malignant neoplasm of ovary</td>
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<tr>
<td>Z85.3</td>
<td>Personal history of malignant neoplasm of breast</td>
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<tr>
<td>Z85.43</td>
<td>Personal history of malignant neoplasm of ovary</td>
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<tr>
<td>Z90.10</td>
<td>Acquired absence of breast and nipple</td>
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<td>Z90.13</td>
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<tr>
<td>Z92.3</td>
<td>Personal history of irradiation [to chest]</td>
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</table>

**ICD-10 codes not covered for indications listed in the CPB:**

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<th>Code</th>
<th>Code Description</th>
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<td>D24.1</td>
<td>Benign neoplasm of breast</td>
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<td>D48.60</td>
<td>Neoplasm of uncertain behavior of breast</td>
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<td>D48.69</td>
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<td>M33.00</td>
<td>Dermatopolymyositis</td>
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<td>M33.99</td>
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<td>N60.01</td>
<td>Solitary cyst of breast</td>
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<td>N60.09</td>
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<td>Code</td>
<td>Code Description</td>
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<td>N60.11</td>
<td>Diffuse cystic mastopathy</td>
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<td>N60.19</td>
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<td>N60.21</td>
<td>Fibroadenosis of breast</td>
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<td>N60.29</td>
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<td>N60.81</td>
<td>Other benign mammary dysplasias</td>
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<td>N60.89</td>
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<tr>
<td>N64.1</td>
<td>Fat necrosis of breast</td>
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<tr>
<td>N64.9</td>
<td>Disorder of breast, unspecified</td>
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<tr>
<td>R92.0</td>
<td>Mammographic microcalcification found on diagnostic imaging of breast</td>
</tr>
<tr>
<td>R99</td>
<td>Ill-defined and unknown cause of mortality</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


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imaging of the breast as a screening tool remains uncertain. BMJ. 1997;314(7079):521.


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100. Slanetz PJ. MRI of the breast and emerging technologies. UpToDate Inc., Waltham, MA. Last reviewed September 2014.


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Amendment to
Aetna Clinical Policy Bulletin Number: 0105 Magnetic Resonance Imaging (MRI) of the Breast

There are no amendments for Medicaid.