



## FEP Medical Policy Manual

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### FEP 6.01.29 Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer

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**Effective Policy Date: January 1, 2021**

**Related Policies:**

**Original Policy Date: December 2011**

None

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## Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer

### Description

Magnetic resonance imaging (MRI) of the breast is performed using scanners and intravenous imaging contrast agents in combination with specialized breast coils. This evidence review only addresses the use of breast MRI for clinical indications related to the detection or diagnosis of breast cancer.

Screening uses include screening for breast cancer in patients who are at high genetic risk for breast cancer. Magnetic resonance imaging (MRI) of the breast has been investigated as a screening tool in specific higher-risk subgroups of patients. First, it has been studied in patients considered to be at high genetic risk of breast cancer, such as women with known *BRCA1* or *BRCA2* genetic variants or with a family history consistent with a hereditary pattern of breast cancer. Screening for breast cancer often begins at an earlier age in these patients, and mammography is considered less sensitive in younger patients due to the prevalence of dense breast tissue.

Screening MRI has been suggested for patients who may or may not be at increased risk but who have breast tissue characteristics that limit the sensitivity of mammographic screening (these characteristics are dense breast tissue, breast implants, or scarring after breast-conserving therapy [BCT]). BCT consists of breast-conserving surgery (BCS) followed by radiotherapy.

Breast MRI has been advocated to help detect suspected occult primary breast cancer in patients with adenocarcinoma in the axillary lymph nodes after mammography and physical exam have failed to reveal a breast tumor. Localization of a primary breast tumor might permit BCT instead of presumptive mastectomy.

Patients with a diagnosed breast cancer are at higher risk for a synchronous or subsequent breast cancer in the contralateral breast, and breast MRI has been suggested as a more sensitive screening test compared to mammography.

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Patients with abnormal findings on mammography are categorized according to the level of suspicion of the findings. Patients with low-suspicion findings are often recommended to undergo short-interval follow-up after 3 to 6 months (instead of immediate biopsy). This follow-up may continue for 2 years to demonstrate the stability of benign findings or to detect progression; progression would indicate the need for biopsy. MRI of the breast has been investigated as a more sensitive technique to further characterize low-suspicion breast lesions, so that patients with MRI-negative lesions may be reassured and avoid prolonged follow-up and those with MRI-positive lesions may be referred for early biopsy, possibly leading to earlier diagnosis and treatment.

Breast lesions detected by clinical exam or mammography that are considered suspicious are frequently referred for biopsy; however, only a minority of such biopsies reveal breast cancer due to the relatively low specificity of clinical and radiologic exams. Breast MRI has been investigated as a technique to further characterize suspicious breast lesions so that patients with benign lesions may be spared a biopsy procedure. One infrequent situation (niche use) in which MRI of the breast may be helpful and improve health outcomes is in the management of patients who have a suspicious lesion that can only be seen on one mammographic view (ie, the lesion cannot be seen in other views or on an ultrasound). Patients who fall under this category have a lesion that is not palpable, and therefore, percutaneous biopsy localization cannot be performed. Instead, MRI would be used to localize the suspicious lesion and permit biopsy (this technique would presumably lead to earlier diagnosis of breast cancer as opposed to waiting until the lesion was visible on 2 mammographic views or on ultrasound). The previously described scenario is an infrequent occurrence, so the evidence base addressing this use is mainly anecdotal but the clinical rationale supporting this use is good.

Treatment-related uses addressed here are surgical planning, evaluating tumor response to neoadjuvant therapy, and evaluating residual tumor after BCT. Preoperative planning includes identification of multicentric disease in clinically localized breast cancer; surgical decisions after neoadjuvant chemotherapy; evaluation of suspected chest wall involvement, and localizing lesions prior to biopsy.

Patients with locally advanced breast cancer are usually offered neoadjuvant chemotherapy to reduce tumor size and permit BCT. Evaluation of tumor size and extent using conventional techniques (ie, mammography, clinical examination, ultrasonography) is suboptimal, and breast MRI has been proposed as a means to more accurately determine tumor size for surgical planning. MRI before chemotherapy is used to document tumor location so that the tumor can be optimally evaluated after chemotherapy, especially if the size and degree of contrast enhancement are greatly reduced. Tumors that respond to chemotherapy get smaller and may even disappear; however, the actual reduction in size is a delayed finding, and earlier changes in tumor vascularity have been observed in chemotherapy-responsive tumors. A decline in contrast enhancement on MRI has been noted in tumors relatively early in the course of chemotherapy. This MRI finding as an early predictor of tumor response has been explored as a means to optimize the choice of the chemotherapeutic agent (eg, to alter chemotherapy regimen if the tumor appears unresponsive).

Tumors located near the chest wall may invade the pectoralis major muscle or extend deeper into chest wall tissues. Typically, modified radical mastectomy removes only the fascia of the pectoralis muscle; however, tumor involvement of the muscle would also necessitate the removal of the muscle (or a portion of it). In smaller tumors, it is necessary to determine how closely the tumor abuts the pectoralis muscle and whether it invades the muscle to determine whether there is an adequate margin of normal breast tissue to permit BCT. Breast MRI has been suggested as a means of determining pectoralis muscle/chest wall involvement for surgical planning and to assist in the decision whether to use neoadjuvant chemotherapy.

BCT includes complete removal of the primary tumor along with a rim of normal surrounding tissue. Pathologic assessment of surgical margins is performed on excisional specimens to determine whether the tumor extends to the margins of resection. Surgical specimens are oriented and marked to direct re-excision if margins are shown to contain tumor; however, when the tumor is not grossly visible, the extent of a residual tumor within the breast can only be determined through repeat excision and pathologic assessment. MRI has been proposed to evaluate the presence and extent of the residual tumor as a guide to re-excision when surgical margins are positive for tumor.

## OBJECTIVE

The objective of this evidence review is to determine whether magnetic resonance imaging of the breast improves the net health outcome for individuals undergoing breast cancer screening, breast cancer detection, and/or evaluation for breast cancer before and/or after treatment.

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## POLICY STATEMENT

All policy statements below refer to performing magnetic resonance imaging (MRI) of the breast with contrast agents and a breast coil. MRI of the breast without a breast coil, regardless of the clinical indication, is considered **investigational**. See additional comments in the Policy Guidelines section about the breast imaging team and the need for breast MRI centers to perform MRI-guided biopsy and localization.

### Screening Uses

MRI of the breast may be considered **medically necessary** for breast cancer screening patients with high risk of breast cancer. (For definitions on each of the risk levels, see the Policy Guidelines section.)

MRI of the breast is considered **investigational** as a screening technique in average-risk patients.

MRI of the breast is considered **investigational** as a screening technique for the detection of breast cancer when the sensitivity of mammography (ie, mammography using low-dose x-rays for imaging) is limited (ie, dense breasts, breast implants, scarring after breast cancer treatment).

### Detection Uses

MRI of the breast may be considered **medically necessary** for detection of a suspected occult breast primary tumor in patients with axillary nodal adenocarcinoma (ie, negative mammography and physical exam).

MRI of the breast may be considered **medically necessary** in patients with a new diagnosis of breast cancer to evaluate the contralateral breast when clinical and mammographic findings are normal.

MRI of the breast is considered **investigational** for diagnosis of low-suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow-up.

MRI of the breast is considered **investigational** for the diagnosis of a suspicious breast lesion in order to avoid biopsy.

### Treatment-Related Uses

MRI of the breast may be considered **medically necessary** for preoperative tumor mapping of the involved (ipsilateral) breast to evaluate the presence of multicentric disease in patients with clinically localized breast cancer who are candidates for breast conservation therapy (see the Policy Guidelines section).

MRI of the breast may be considered **medically necessary** for presurgical planning in patients with locally advanced breast cancer (before and after completion of neoadjuvant chemotherapy) to permit tumor localization and characterization.

MRI of the breast may be considered **medically necessary** to determine the presence of pectoralis major muscle/chest wall invasion in patients with posteriorly located tumors.

MRI of the breast may be considered **medically necessary** to evaluate a documented abnormality of the breast before obtaining an MRI-guided biopsy when there is documentation that other methods, such as palpation or ultrasound, are not able to localize the lesion for biopsy.

MRI of the breast is considered **investigational** to determine response during neoadjuvant chemotherapy in patients with locally advanced breast cancer.

MRI of the breast is considered **investigational** for evaluation of residual tumor in patients with positive margins after initial lumpectomy or breast conservation surgery.

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## POLICY GUIDELINES

### High-risk Considerations

High risk is defined in the applicable clinical guidelines. See the Supplemental Information section. Also check the guideline websites for potential updates.

### Considerations for Performing Magnetic Resonance Imaging

Breast magnetic resonance imaging (MRI) exams should be performed and interpreted by an expert breast imaging team working with the multidisciplinary oncology treatment team.

As noted, breast MRI exams require a dedicated breast coil and the use of contrast agents by radiologists familiar with the optimal timing sequences and other technical aspects of image interpretation. The breast MRI center also should have the ability to perform MRI-guided biopsy and/or wire localization of findings detected by MRI.

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

## FDA REGULATORY STATUS

MRI of the breast can be performed using commercially available magnetic resonance scanners and intravenous magnetic resonance contrast agents. Specialized breast coils such as the Access Breast Coil 4/SMS (Confirma) and magnetic resonance-compatible equipment for performing biopsy have been developed and cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that these devices are substantially equivalent to predicate devices for use "in conjunction with a magnetic resonance imager (MRI) to produce diagnostic and interventional images of the breast, chest wall and axillary tissues that can be interpreted by a trained physician."<sup>1</sup>

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## RATIONALE

### Summary of Evidence

#### Screening Uses

For individuals who are asymptomatic with high-risk of breast cancer who receive magnetic resonance imaging (MRI) as an adjunct to screening for breast cancer, the evidence includes systematic reviews (including a TEC Assessment) and diagnostic accuracy studies. Relevant outcomes are overall survival (OS), disease-specific survival, test accuracy and validity, and resource utilization. Studies have found that MRI is more sensitive than mammography or ultrasonography in detecting malignancy. Because of the high likelihood of malignancy among women at high-risk for breast cancer, the benefits of detecting cancer earlier with MRI outweigh the disadvantages of incurring unnecessary workups and biopsies due to false-positive results. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are asymptomatic with average-risk of breast cancer who receive MRI as an adjunct to screening for breast cancer, the evidence includes systematic reviews and clinical validity studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. The systematic reviews did not identify any randomized controlled trials (RCTs) or nonrandomized comparative studies evaluating MRI for screening average-risk women. One comparative observational study has been published since the systematic reviews. The diagnostic accuracy of screening tests would likely be lower in this lower prevalence population, and there would be higher false-positive rates, morbidity, and anxiety. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with characteristics limiting the accuracy of mammography (eg, dense breasts) who receive MRI as an adjunct to screening for breast cancer, the evidence includes a systematic review (TEC Assessment), RCT, and diagnostic accuracy studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. There are limited data on the diagnostic accuracy of MRI vs mammography in patients who have had breast-conserving therapy (BCT) or who have dense breasts. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### Detection Uses

For individuals who have suspected occult breast primary tumor with axillary nodal adenocarcinoma with negative mammography who receive MRI as an adjunct to detect breast cancer eligible for breast-conserving therapy (BCT), the evidence includes a systematic review (TEC Assessment) and meta-analysis. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. The studies found that adjunctive use of breast MRI to guide breast-conserving surgery (BCS) rather than preemptive mastectomy allowed a substantial portion of patients to avoid the morbidity of mastectomy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have breast cancer who receive adjunctive MRI of the contralateral breast, the evidence includes cohort studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. A study of nearly 1000 patients found that MRI could detect contralateral breast cancer with a high degree of accuracy. Although long-term outcomes of these contralateral breast cancers are not fully known, important changes in management will occur (eg, simultaneous treatment of synchronous cancers) as a result of these findings, which should lead to improved outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have low-suspicion findings on conventional mammography who receive MRI as an adjunct to detect breast cancer, the evidence includes a systematic review (TEC Assessment). Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. The TEC Assessment concluded that, although the available studies suggested reasonably high diagnostic accuracy, none of the studies used prospective methods in appropriate study populations or appropriate comparison interventions such as short-interval mammographic follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have suspicious breast lesions who receive MRI as an adjunct to further characterize lesions, the evidence includes systematic reviews (including a TEC Assessment) and cohort studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. Studies have found that MRI for evaluation of suspicious breast lesions has relatively

high sensitivity and a moderately high specificity. However, it has not yet been established that the negative predictive value is sufficient to preclude the need for biopsy. Although 2 recent studies have reported negative predictive values greater than 90% in certain types of breast lesions, these were non-U.S., single-institution studies that require replication in larger, multicenter trials. Therefore, the use of MRI to further characterize suspicious lesions is currently unlikely to alter clinical management. In addition, the moderately high rate of false-positives will lead to substantial numbers of unnecessary biopsies. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Treatment-Related Uses

For individuals who have clinically localized breast cancer who receive MRI for preoperative mapping to identify multicentric disease, the evidence includes RCTs, systematic reviews, and prospective cohort studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. Studies have found that, for patients with clinically localized breast cancer, MRI can detect additional areas of disease in the ipsilateral or contralateral breast beyond that detected by standard imaging; further, MRI is associated with a higher rate of mastectomy. Follow-up studies have reported mixed results including no significant reduction in reoperation rates after MRI while other studies have reported lower odds of reoperation in patients with invasive lobular carcinoma. No significant differences in ipsilateral local or distant recurrence-free survival after MRI-guided treatment were found in meta-analyses. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have locally advanced breast cancer undergoing neoadjuvant chemotherapy who receive an MRI to guide surgical decisions after neoadjuvant chemotherapy, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. Both a 2004 TEC Assessment and a 2015 systematic review found that MRI results were well-correlated with pathologic assessment for measuring residual tumor size after neoadjuvant chemotherapy. The 2015 systematic review also found that MRI performed better than conventional methods. Using breast MRI instead of conventional methods to guide surgical decisions on BCT vs mastectomy after neoadjuvant chemotherapy would be at least as beneficial and may lead to appropriate surgical treatment more often. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have posteriorly located breast tumors who receive an MRI to diagnose chest wall involvement, the evidence includes cohort studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. Only a few small studies were identified but MRI was 100% accurate in identifying chest wall involvement compared with the criterion standard. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a suspicious breast lesion recommended for biopsy but not localizable by mammography or ultrasonography who receive MRI to evaluate and localize the lesion prior to biopsy, the evidence includes a cohort study. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. A small cohort study from Brazil identified malignant tumors in 60% of patients with MRI-detected occult lesions using contrast-enhanced MRI. Although there is little published evidence supporting this indication, improved health outcomes are expected by enabling earlier diagnosis of breast cancer for suspicious lesions where other good options are not available. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have locally advanced breast cancer undergoing neoadjuvant chemotherapy who receive an MRI to evaluate response to chemotherapy, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. Studies, including systematic reviews, have not found that there is sufficient evidence to determine whether breast MRI can reliably predict lack of response to neoadjuvant chemotherapy. There is a large amount of variability in reported performance characteristics of MRI in published studies, leaving uncertainty about the true accuracy of MRI for this purpose. Furthermore, evidence would need to show that any resulting change in patient management (eg, discontinuation of chemotherapy, change to a different regimen) would improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have positive surgical margins after lumpectomy or breast conservation surgery who receive MRI to evaluate residual tumor, the evidence includes cohort studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. The studies, most of which were retrospective and published before 2005, generally reported moderate sensitivity and specificity with MRI for detection of residual disease compared with the criterion standard. Two retrospective studies published since 2015 have an uncertain or high-risk of bias and therefore performance characteristics are unknown. The evidence is insufficient to determine the effects of the technology on health outcomes.

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## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

#### National Comprehensive Cancer Network

NCCN guidelines on breast cancer (v.5.2020),<sup>55</sup> breast cancer screening and diagnosis (v.2.2019),<sup>56</sup> and genetic assessment of those at high-risk of breast, ovarian, and pancreatic cancer (v.1.2020)<sup>57</sup>, list the following indications for breast magnetic resonance imaging (MRI).

Screening (as an adjunct to mammography):

"Recommend Annual MRI Screening (Based on Evidence)

- First-degree relative of *BRCA* carrier, but untested: Encourage genetic testing before MRI.
- Lifetime risk 20% or greater, as defined by models that are largely dependent on family history. Encourage genetic testing for first-degree relatives. If testing declined, recommend MRI.

Recommend Annual MRI Screening (Based on Expert Consensus Opinion):

- Radiation to chest between 10 and 30 years

Consider MRI screening for LCIS [lobular carcinoma in situ] and ALH [atypical lobular hyperplasia]/ADH [atypical ductal hyperplasia] based on emerging evidence if lifetime risk  $\geq 20\%$

Insufficient evidence to Recommend for or Against MRI Screening:

- Lifetime risk 15%-20%, as defined by models that are largely dependent on family history
- Heterogeneously or extremely dense breast on mammography

Recommend Against MRI Screening (Based on Expert Consensus Opinion):

- Women at <15% lifetime risk" <sup>56</sup>.

The NCCN guidelines state that women at "increased risk" of breast cancer include the following groups:

- "women with a prior history of breast cancer;
- women  $\geq 35$  years of age with a 5-year risk of invasive breast cancer  $\geq 1.7\%$  (per Modified Gail Model);
- women who have a lifetime risk  $>20\%$  based on history of LCIS or ADH/ALH;
- women who have a lifetime risk  $>20\%$  as defined by models that are largely dependent on family history;
- women who received prior thoracic irradiation between the ages of 10 and 30 years
- women with "a pedigree suggestive of or with a known genetic predisposition" <sup>56</sup>.

The NCCN guidelines for genetic or familial high-risk assessment for breast cancer recommend MRI screening with contrast for patients with *BRCA* pathogenic or likely pathogenic variants starting at age 25 to 29 years or individualized if the family had breast cancer

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diagnosis before age 30. The guidelines further state that MRI with contrast can be considered for patients with the following genetic variants:

- *ATM*, *CHEK2*, and *NBN*, starting at age 40 years
- *CDH1* and *PALB2*, starting at age 30 years
- *NF1*, from ages 30 to 50 years
- *TP3* pathogenic/likely pathogenic variant who are treated for breast cancer and have not had a bilateral mastectomy, starting at age 20 to 29 years
- *PTEN* pathogenic/likely pathogenic variant who are treated for breast cancer and have not had a bilateral mastectomy, starting at age 30 to 35 years or 5 to 10 years before the earliest breast cancer in the family
- [57](#),

The NCCN guidelines also state there is insufficient evidence for any recommendations for use of breast MRI for patients with the following genetic variants: *BARD1*, *BRIP1*, *MLH1*, *MSH2*, *MSH6*, *PMS2*, *EPCAM*, *RAD51C*, *RAD51D*, *STK11*, *FANCC*, *MRE11A*, *MUTYH heterozygotes*, *RECQL4*, *RAD50*, *RINT1*, *SLX4*, *SMARCA*, or *XRCC2*.

Guidelines on breast cancer screening and diagnosis make the following recommendations on diagnosis [56](#).

- Optional MRI for women with nipple discharge, no palpable mass and a BI-RADS rating of 1-3.
- Guideline discussion update in progress: "For patients with skin changes consistent with serious breast disease, consideration of breast MRI is included in the guidelines for those with benign biopsy of skin or nipple following BI-RADS category 1-3 assessment. Since a benign skin punch biopsy in a patient with clinical suspicion of inflammatory breast cancer (IBC) does not rule out malignancy, further evaluation is recommended...[and] MRI may facilitate diagnosis of IBC."

Guidelines on breast cancer make the following recommendations on pretreatment evaluation [55](#).

- "May be useful for identifying primary cancer in women with axillary nodal adenocarcinoma and occult (unidentified) primary cancer, or with Paget's disease, or with invasive lobular carcinoma poorly (or inadequately) defined on mammography, ultrasound, or physical examination."
- "May be used for staging evaluation to define extent of cancer or presence of multifocal or multicentric cancer in the ipsilateral breast, or as screening of the contralateral breast cancer at time of initial diagnosis."

Guidelines on breast cancer make the following recommendations on treatment [55](#).

- "May be helpful for breast cancer evaluation before and after preoperative systemic therapy to define extent of disease, response to treatment, and potential for breast-conserving therapy."
- "False-positive findings on breast MRI are common. Surgical decisions should not be based solely on MRI findings. Additional tissue sampling of areas of concern identified by breast MRI is recommended."

Guidelines on breast cancer make the following recommendations on surveillance [55](#).

- Utility of MRI in follow-up screening in women with prior breast cancer is undefined. Generally, it should only be considered for women with a greater than 20% lifetime risk of second primary breast cancer.

## American Cancer Society

The American Cancer Society (2017) guide on early detection of breast cancer has recommended the following on MRI [58](#):

"Breast MRI is sometimes used in women who already have been diagnosed with breast cancer, to help measure the size of the cancer, look for other tumors in the breast, and to check for tumors in the opposite breast. For certain women at high-risk for breast

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cancer, a screening MRI is recommended along with a yearly mammogram. MRI is not recommended as a screening tool by itself because it can miss some cancers that a mammogram would find.

Although MRI can find some cancers not seen on a mammogram, it's also more likely to find something that turns out not to be cancer (called a false positive). This can result in a woman getting tests and/or biopsies that end up not being needed. This is why MRI is not recommended as a screening test for women at average risk of breast cancer."

## American College of Radiology

The American College of Radiology has appropriateness criteria for breast imaging, which were developed in 2012 and revised in 2017;<sup>59</sup> palpable breast masses<sup>60</sup>, revised in 2016; initial workup and surveillance for stage I breast cancer, reviewed in 2019<sup>61</sup>; and monitoring response to neoadjuvant therapy, 2017.<sup>62</sup> (see Table 1).

**Table 1. MRI-Related to Criteria for Breast Cancer Screening, Diagnosis, and Monitoring Response**

Specific Indications	MRI Rating
High-risk women: women with a <i>BRCA</i> gene variant and their untested first-degree relatives, women with a history of chest irradiation between the ages of 10 and 30 years, women with 20% or greater lifetime risk of breast cancer	Usually appropriate with and without contrast (with mammography)
Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15%-20% lifetime risk of breast cancer	May be appropriate with and without contrast (with mammography)
Average-risk women: women with <15% lifetime risk of breast cancer, breasts not dense	Usually not appropriate with and without contrast
Evaluating palpable breast mass. All indications reviewed	Usually not appropriate with and without contrast
Initial determination of tumor size and extent within the breast prior to neoadjuvant chemotherapy.	Usually appropriate without and with contrast
Imaging of the breast after initiation or completion of neoadjuvant chemotherapy [if a prechemotherapy MRI was performed].	Usually appropriate without and with contrast
Axillary evaluation prior to neoadjuvant chemotherapy.	May be appropriate without and with contrast
Known breast cancer. Axillary evaluation after completion of neoadjuvant chemotherapy, axilla not previously evaluated.	May be appropriate without and with contrast
Surveillance. Rule out local recurrence.	May be appropriate without and with contrast

MRI: magnetic resonance imaging.

The College (2018) issued recommendations for breast cancer screening in women at higher-than-average risk.<sup>63</sup> The recommendations for MRI are as follows:

- "For women with genetics-based increased risk (and their untested first-degree relatives), history of chest radiation, calculated lifetime risk of 20% or more, breast MRI should be performed annually beginning at age 25 to 30."
- "For women with personal histories of breast cancer and dense breast tissue, or those diagnosed before age 50, annual surveillance with breast MRI is recommended."
- "For women with personal histories of breast cancer not included in the above, or with LCIS or atypia on prior biopsy, MRI should be considered, especially if other risk factors are present."

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## American Society of Clinical Oncology

The American Society of Clinical Oncology (2006) has published guidelines for follow-up and management after primary treatment of breast cancer.<sup>64</sup> In 2013, the guidelines were updated with a systematic review of the literature through March 2012, and no revisions were made.<sup>65</sup> The guidelines recommended against the use of breast MRI "for routine follow-up in an otherwise asymptomatic patient with no specific findings on clinical examination."<sup>65</sup> Furthermore, "The decision to use breast MRI in high-risk patients should be made on an individual basis depending on the complexity of the clinical scenario."<sup>64</sup>

## International Late Effects of Childhood Cancer Guideline Harmonization Group

The International Late Effects of Childhood Cancer Guideline Harmonization Group from 9 countries (2013) published evidence-based recommendations for breast cancer surveillance in female survivors of childhood, adolescent, and young adult cancer who received chest irradiation before age 30 years and have no genetic predisposition to breast cancer.<sup>66</sup> The authors found concordance among previous guidelines to initiate annual breast MRI exams beginning at age 25 or 8 years after radiation. Based on a systematic review of the literature to August 2011 and expert consensus, the authors recommended mammography, breast MRI, or both for surveillance (strong recommendation based on high-quality evidence with a low degree of uncertainty). The authors acknowledged that "no prospective studies have assessed the use of MRI screening in this population." The recommendation was therefore based on extrapolation of evidence from patients with hereditary risk for breast cancer.

## U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task **Force** (2016) updated its recommendations on breast cancer screening. The Task Force concluded the following on breast MRI<sup>67</sup>:

"... the current evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging, DBT [digital breast tomosynthesis], or other methods in women identified to have dense breasts on an otherwise negative screening mammogram."

## Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

## REFERENCES

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2013	Replace policy	Rationale extensively written; References removed, references 8, 9, 18, 31, 44-46, 49 & 54 added. Policy statement amended to clarify that medically necessary statements refer to performing MRI of the breast with a breast coil and the use of contrast.
September 2014	Replace policy	Policy updated with literature review; references 16, 21, 46-49, 56-57, 64-65, and 77-82 added; references 11, 13, and 26-27 updated. No change to policy statements.
September 2015	Replace policy	Policy updated with literature review through March 8, 2015; references 17, 33-34, 53, 70-74, 85-86, and 88-89 added. Policy statements unchanged.

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Date	Action	Description
March 2017	Archive policy	Policy updated with literature review through July 22, 2016. References 10, 15, 41, 49 and 81-82 added. For first policy statement, screening patients at high risk of breast cancer, risk level criteria moved to Policy Guidelines and updated with new NCCN criteria. Title changed to "Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer". Policy archived.
December 2019	Reactivate policy	Policy updated with literature review through July 8, 2019; references added; references on NCCN updated. Policy statements unchanged. Policy reactivated for use with prior approval where applicable.
December 2020	Replace policy	Policy updated with literature review through July 20, 2020; references added. Policy statements unchanged.

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