BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

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

Annual Effective Policy Date: January 1, 2024

Original Policy Date: December 2011

Related Policies:

None

Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer

Description

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.

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.

POLICY STATEMENT

All policy statements below refer to performing magnetic resonance imaging (MRI) of the breast with contrast agents and a breast coil. An 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 individuals undergoing breast cancer screening with a 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 individuals.

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 individuals with axillary nodal adenocarcinoma (ie, negative mammography and physical exam).

MRI of the breast may be considered **medically necessary** in individuals 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 individuals 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 individuals 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 individuals 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 individuals with locally advanced breast cancer.

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

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

An 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."[3,]

RATIONALE

Summary of Evidence

Screening Uses

For individuals who are asymptomatic with a high-risk of breast cancer who receive magnetic resonance imaging (MRI) as an adjunct to screening for breast cancer, the evidence includes systematic reviews 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 an improvement in the net health outcome.

For individuals who are asymptomatic with an 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 that the technology results in an improvement in the net health outcome.

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 an 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 versus mammography in patients who have had breast-conserving therapy (BCT) or who have dense breasts. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 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 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 an 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 an 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, current direct evidence is lacking. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. Well-designed prospective studies would be necessary to permit conclusions about the effect of this adjunctive use of breast MRI on health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspicious breast lesions who receive MRI as an adjunct to further characterize lesions, the evidence includes systematic reviews 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 3 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 that the technology results in an improvement in the net health outcome.

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 an 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. 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 versus 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 an 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 an 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. A retrospective study found that MRI could reduce the need for unnecessary biopsy. 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 an 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network (NCCN) guidelines on breast cancer (v. 4.2023),[60,] breast cancer screening and diagnosis (v. 1.2023),[61,] and genetic assessment of those at high-risk of breast, ovarian, and pancreatic cancer (v. 3.2023)[62,] list the following indications for breast magnetic resonance imaging (MRI).

Screening (as an adjunct to mammography):[61,]

"Recommend Annual MRI Screening

- For individuals with a genetic mutation, or an untested first-degree relative of gene mutation carrier
- For individuals who received thoracic RT [radiation therapy] between the ages of 10 and 30 years
- For individuals with a residual lifetime risk >20% as defined by models that are largely dependent on family history; based on the extent of family history, consider referral for genetic testing.
- Consider annual MRI screening for individuals with ADH [atypical ductal hyperplasia] or lobular neoplasia (LCIS [lobular carcinoma in situ]/ALH [atypical lobular hyperplasia]) and ≥20% lifetime risk

Insufficient Evidence to Recommend for or Against Routine Population-Based MRI Screening:

- Residual 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):

- Individuals at <15% residual lifetime risk"

The NCCN guidelines for breast cancer screening and diagnosis also state that individuals assigned female at birth at "increased risk" of breast cancer include the following groups:[61,]

- " those with a prior history of breast cancer;
- those ≥ 35 years of age with a 5-year risk of invasive breast carcinoma ≥1.7% (per the Modified Gail Model);

- those who have a lifetime risk >20% based on history of LCIS or ADH/ALH;
- those who have a lifetime risk >20% as defined by models that are largely dependent on family history;
- those who received prior thoracic irradiation between the ages of 10 and 30 years
- those with a pedigree suggestive of or with a known genetic predisposition"

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 diagnosis before age 30. The guidelines further state that MRI with contrast can be considered for patients with the following genetic variants:[62,]

- *ATM, BARD1,* and *CHEK2* starting at age 30 to 35 years
- *CDH1, STK11,* and *PALB2*, starting at age 30 years
- *NF1*, from ages 30 to 50 years
- *TP53* pathogenic/likely pathogenic variant who are treated for breast cancer and have not had a bilateral mastectomy, starting at age 20 to 29 years
- *RAD51C and RAD51D*, starting at age 40 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

The NCCN guidelines for genetic or familial high-risk assessment for breast cancer also state there is insufficient evidence for any recommendations for use of breast MRI for patients with the following genetic variants: *BRIP1*, *MLH1*, *MSH2*, *MSH6*, *PMS2*, *EPCAM, FANCC*, *MRE11A*, *MUTYH* heterozygotes, , *RECQL* , *RAD50*, *RINT1*, *SLX4*, *SMARCA4*, or *XRCC2*.

Guidelines on breast cancer screening and diagnosis make the following recommendations on diagnosis:[61,]

- Optional MRI for women with nipple discharge, no palpable mass, and a Breast Imaging Reporting and Data System (BI-RADS) rating of 1 to 3.
- 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 to 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 be used for suspicious nipple discharge when mammography and ultrasound are not diagnostic.

Guidelines on breast cancer make the following recommendations on pretreatment evaluation with breast MRI:[60,]

- "May be useful in identifying otherwise clinically occult disease in patients presenting with axillary nodal metastases (cT0, cN+), with Paget 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 related to MRI surrounding treatment:[60,]

- "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- conservation therapy."
- "False-positive findings on breast MRI are common. Surgical decisions should not be based solely on the MRI findings. Additional tissue sampling of areas of concern identified by breast MRI is recommended."

Guidelines on breast cancer make the following recommendations on MRI related to surveillance:[60,]

- "The utility of MRI in follow-up screening of patients with prior breast cancer is undefined. It should generally be considered for: patients with dense breasts treated with breast-conserving surgery and radiation therapy, those diagnosed before the age of 50, and those whose lifetime risk of a second primary breast cancer is >20% based on models largely dependent on family history, such as in those with the risk associated with inherited susceptibility to breast cancer."

American Cancer Society

The American Cancer Society recommendations for the early detection of breast cancer, most recently updated in 2022, has recommended the following on MRI:[63,]

"Women who are high risk for breast cancer based on certain factors should get a breast MRI and a mammogram every year, typically starting at age 30. This includes women who:

- Have a lifetime risk of breast cancer of about 20% to 25% or greater, according to risk assessment tools that are based mainly on family history
- Have a known *BRCA1* or *BRCA2* gene mutation (based on having had genetic testing)
- Have a first-degree relative (parent, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation, and have not had genetic testing themselves
- Had radiation therapy to the chest when they were between the ages of 10 and 30 years
- Have Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or have first-degree relatives with one of these syndromes

The American Cancer Society recommends against MRI screening for women whose lifetime risk of breast cancer is less than 15%.

There's not enough evidence to make a recommendation for or against yearly MRI screening for women who have a higher lifetime risk based on certain factors, such as:

- Having a personal history of breast cancer, ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), atypical ductal hyperplasia (ADH), or atypical lobular hyperplasia (ALH)
- Having 'extremely' or 'heterogeneously' dense breasts as seen on a mammogram

If MRI is used, it should be in addition to, not instead of, a screening mammogram. This is because although an MRI is more likely to find cancer than a mammogram, it may still miss some cancers that a mammogram would find.

Most women at high risk should begin screening with MRI and mammograms when they are 30 and continue for as long as they are in good health. But this is a decision that should be made with a woman's health care providers, taking into account her personal circumstances and preferences."

American College of Radiology

The American College of Radiology has appropriateness criteria for breast cancer screening, which were developed in 2012 and revised in 2017;[64,] palpable breast masses[65,], revised in 2022 ; initial workup and surveillance for stage I breast cancer, reviewed in 2019[66,]; monitoring response to neoadjuvant therapy, revised 2022 ;[67,] transgender breast cancer screening, 2021[68,]; and supplemental breast cancer screening based on breast density, 2021[69,] (see Table 1).

Table 1. Magnetic Resonance Imaging-Related Criteria for Breast Cancer Screening, Diagnosis, and Monitoring Response

Specific Indications	**MRI Rating**
High-risk women: women with a *BRCA* 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% to 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
Known breast cancer. Initial determination of tumor size and extent within the breast prior to neoadjuvant chemotherapy.	Usually appropriate without and with contrast
Known breast cancer. Imaging of the breast after initiation or completion of neoadjuvant chemotherapy.	Usually appropriate without and with contrast
Known breast cancer, clinically node-negative. Axillary evaluation prior to neoadjuvant chemotherapy.	Usually not appropriate
Known breast cancer, clinically node-positive. Axillary evaluation prior to neoadjuvant chemotherapy.	May be appropriate without and with contrast
Known breast cancer, clinically node-negative. Axillary evaluation after completion of neoadjuvant chemotherapy, axilla not previously evaluated.	Usually not appropriate
Known breast cancer, clinical suspicion of metastatic disease. Staging or assessment of response to neoadjuvant chemotherapy.	Usually not appropriate
Known axillary lymph node-positive breast cancer on prior mammography, ultrasound, or MRI. Axillary evaluation after completion of neoadjuvant chemotherapy, axilla previously evaluated.	Usually not appropriate
Known breast cancer. Axillary imaging suspicious for metastatic disease on mammography, ultrasound, or MRI during initial evaluation.	Usually not appropriate
Surveillance. Rule out local recurrence.	May be appropriate without and with contrast
Transfeminine (male-to-female) patient, 40 years of age or older with past or current hormone use ≥5 years; average risk patient.	Usually not appropriate without and with contrast
Transfeminine (male-to-female) patient, 25 to 30 years of age or older with past or current hormone use ≥5 years; higher-than-average risk.	Usually not appropriate without and with contrast
Transfeminine (male-to-female) patient with no hormone use (or hormone use <5 years) at any age; average-risk patient	Usually not appropriate without and with contrast
Transfeminine (male-to-female) patient, 25 to 30 years of age or older with no hormone use (or hormone use <5 years); higher-than-average risk.	Usually not appropriate without and with contrast
Transmasculine (female-to-male) patient with bilateral mastectomies ("top surgery") at any age and any risk.	Usually not appropriate without and with contrast
Transmasculine (female-to-male) patient with reduction mammoplasty or no chest surgery, 40 years of age or older; average-risk patient (less than 15% lifetime risk of breast cancer).	Usually not appropriate without and with contrast
Transmasculine (female-to-male) patient with reduction mammoplasty or no chest surgery, ≥30 years of age. Intermediate risk (patient with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15% to 20% lifetime risk of breast cancer).	May be appropriate without and with contrast; usually not appropriate without contrast
Transmasculine (female-to-male) patient with reduction mammoplasty or no chest surgery, 25 to 30 years of age or older. High risk (with genetic predisposition to breast cancer or untested patient with a first-degree relative with genetic predisposition to breast cancer, patient with a history	Usually appropriate without and with contrast; usually not appropriate without contrast

of chest irradiation between 10 to 30 years of age, patient with 20% or greater lifetime risk of breast cancer).	
Average-risk females with nondense breasts	Usually not appropriate without and with contrast
Intermediate-risk females with nondense breasts	Usually not appropriate without and with contrast
High-risk females with nondense breasts	Usually not appropriate without and with contrast
Average-risk females with dense breasts	May be appropriate without and with contrast; usually not appropriate without contrast
Intermediate-risk females with dense breasts	May be appropriate without and with contrast; usually not appropriate without contrast
High-risk females with dense breasts	Usually appropriate without and with contrast; usually not appropriate without contrast

MRI: magnetic resonance imaging.

The College (2018) issued recommendations for breast cancer screening in women at higher-than-average risk.[70,] 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."

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.[71,] In 2013, the guidelines were updated with a systematic review of the literature through March 2012, and no revisions were made.[72,] 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."[72,] 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."[71,]

International Late Effects of Childhood Cancer Guideline Harmonization Group

The International Late Effects of Childhood Cancer Guideline Harmonization Group from 9 countries (2020) 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.[73,] The guideline recommends to initiate annual breast MRI exams beginning at age 25 or 8 years after radiation. Based on a systematic review of the literature to June 2019 , the authors recommended mammography and breast MRI for surveillance (strong recommendation based on high-quality evidence with a low degree of uncertainty). The authors acknowledged that "there are no studies of survivors of [childhood, adolescent, and young adult] cancer that investigated whether early detection by MRI or mammography results in better prognosis." However, the panel concluded that the benefits of initiating early annual mammography and MRI are expected to outweigh the harms.

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:[74,]

"... 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."

These guidelines are currently undergoing an update and updated recommendations may be forthcoming.

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

1. Jatoi I, Sung H, Jemal A. The Emergence of the Racial Disparity in U.S. Breast-Cancer Mortality. N Engl J Med. Jun 23 2022; 386(25): 2349-2352. PMID 35713541
2. Yedjou CG, Sims JN, Miele L, et al. Health and Racial Disparity in Breast Cancer. Adv Exp Med Biol. 2019; 1152: 31-49. PMID 31456178
3. Food and Drug Administration (FDA). 510(k) Summary of Safety and Effectiveness: Access Breast Coil 4/SMS. 2006; https://www.accessdata.fda.gov/cdrh_docs/pdf6/K060547.pdf. Accessed July 19, 2023.
4. Warner E, Messersmith H, Causer P, et al. Systematic review: using magnetic resonance imaging to screen women at high risk for breast cancer. Ann Intern Med. May 06 2008; 148(9): 671-9. PMID 18458280
5. Phi XA, Houssami N, Obdeijn IM, et al. Magnetic resonance imaging improves breast screening sensitivity in BRCA mutation carriers age ≥ 50 years: evidence from an individual patient data meta-analysis. J Clin Oncol. Feb 01 2015; 33(4): 349-56. PMID 25534390
6. Phi XA, Houssami N, Hooning MJ, et al. Accuracy of screening women at familial risk of breast cancer without a known gene mutation: Individual patient data meta-analysis. Eur J Cancer. Nov 2017; 85: 31-38. PMID 28886475
7. Ding W, Fan Z, Xu Y, et al. Magnetic resonance imaging in screening women at high risk of breast cancer: A meta-analysis. Medicine (Baltimore). Mar 10 2023; 102(10): e33146. PMID 36897691
8. Nelson HD, Fu R, Cantor A, et al. Effectiveness of Breast Cancer Screening: Systematic Review and Meta-analysis to Update the 2009 U.S. Preventive Services Task Force Recommendation. Ann Intern Med. Feb 16 2016; 164(4): 244-55. PMID 26756588
9. Nikitovic-Jokic M, Holubowich C. Magnetic Resonance Imaging as an Adjunct to Mammography for Breast Cancer Screening in Women at Less Than High Risk for Breast Cancer: A Health Technology Assessment. Ont Health Technol Assess Ser. 2016; 16(20): 1-30. PMID 27990198
10. Bakker MF, de Lange SV, Pijnappel RM, et al. Supplemental MRI Screening for Women with Extremely Dense Breast Tissue. N Engl J Med. Nov 28 2019; 381(22): 2091-2102. PMID 31774954
11. Berg WA, Zhang Z, Lehrer D, et al. Detection of breast cancer with addition of annual screening ultrasound or a single screening MRI to mammography in women with elevated breast cancer risk. JAMA. Apr 04 2012; 307(13): 1394-404. PMID 22474203
12. Cho N, Han W, Han BK, et al. Breast Cancer Screening With Mammography Plus Ultrasonography or Magnetic Resonance Imaging in Women 50 Years or Younger at Diagnosis and Treated With Breast Conservation Therapy. JAMA Oncol. Nov 01 2017; 3(11): 1495-1502. PMID 28655029
13. Kim EJ, Kang BJ, Kim SH, et al. Diagnostic Performance of and Breast Tissue Changes at Early Breast MR Imaging Surveillance in Women after Breast Conservation Therapy. Radiology. Sep 2017; 284(3): 656-666. PMID 28419815
14. de Bresser J, de Vos B, van der Ent F, et al. Breast MRI in clinically and mammographically occult breast cancer presenting with an axillary metastasis: a systematic review. Eur J Surg Oncol. Feb 2010; 36(2): 114-9. PMID 19822403
15. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Breast magnetic resonance imaging (MRI) for detection or diagnosis of primary or recurrent breast cancer TEC Assessments. 2004;Volume 19:Tab 1.
16. Lehman CD, Gatsonis C, Kuhl CK, et al. MRI evaluation of the contralateral breast in women with recently diagnosed breast cancer. N Engl J Med. Mar 29 2007; 356(13): 1295-303. PMID 17392300
17. Liberman L, Morris EA, Kim CM, et al. MR imaging findings in the contralateral breast of women with recently diagnosed breast cancer. AJR Am J Roentgenol. Feb 2003; 180(2): 333-41. PMID 12540428
18. Lehman CD, Blume JD, Thickman D, et al. Added cancer yield of MRI in screening the contralateral breast of women recently diagnosed with breast cancer: results from the International Breast Magnetic Resonance Consortium (IBMC) trial. J Surg Oncol. Oct 01 2005; 92(1): 9-15; discussion 15-6. PMID 16180217
19. Medeiros LR, Duarte CS, Rosa DD, et al. Accuracy of magnetic resonance in suspicious breast lesions: a systematic quantitative review and meta-analysis. Breast Cancer Res Treat. Apr 2011; 126(2): 273-85. PMID 21221772
20. Zhang J, Wang L, Liu HF. Imaging Features Derived From Dynamic Contrast-Enhanced Magnetic Resonance Imaging to Differentiate Malignant From Benign Breast Lesions: A Systematic Review and Meta-Analysis. J Comput Assist Tomogr. May-Jun 2022; 46(3): 383-391.

PMID 35575651
21. Strobel K, Schrading S, Hansen NL, et al. Assessment of BI-RADS category 4 lesions detected with screening mammography and screening US: utility of MR imaging. Radiology. Feb 2015; 274(2): 343-51. PMID 25271857
22. Li E, Li J, Song Y, et al. A comparative study of the diagnostic value of contrast-enhanced breast MR imaging and mammography on patients with BI-RADS 3-5 microcalcifications. PLoS One. 2014; 9(11): e111217. PMID 25365327
23. Pereira RO, Luz LAD, Chagas DC, et al. Evaluation of the accuracy of mammography, ultrasound and magnetic resonance imaging in suspect breast lesions. Clinics (Sao Paulo). 2020; 75: e1805. PMID 32725074
24. Houssami N, Ciatto S, Macaskill P, et al. Accuracy and surgical impact of magnetic resonance imaging in breast cancer staging: systematic review and meta-analysis in detection of multifocal and multicentric cancer. J Clin Oncol. Jul 01 2008; 26(19): 3248-58. PMID 18474876
25. Houssami N, Turner R, Morrow M. Preoperative magnetic resonance imaging in breast cancer: meta-analysis of surgical outcomes. Ann Surg. Feb 2013; 257(2): 249-55. PMID 23187751
26. Houssami N, Turner RM, Morrow M. Meta-analysis of pre-operative magnetic resonance imaging (MRI) and surgical treatment for breast cancer. Breast Cancer Res Treat. Sep 2017; 165(2): 273-283. PMID 28589366
27. Plana MN, Carreira C, Muriel A, et al. Magnetic resonance imaging in the preoperative assessment of patients with primary breast cancer: systematic review of diagnostic accuracy and meta-analysis. Eur Radiol. Jan 2012; 22(1): 26-38. PMID 21847541
28. Houssami N, Turner R, Macaskill P, et al. An individual person data meta-analysis of preoperative magnetic resonance imaging and breast cancer recurrence. J Clin Oncol. Feb 10 2014; 32(5): 392-401. PMID 24395846
29. Li L, Zhang Q, Qian C, et al. Impact of Preoperative Magnetic Resonance Imaging on Surgical Outcomes in Women with Invasive Breast Cancer: A Systematic Review and Meta-Analysis. Int J Clin Pract. 2022; 2022: 6440952. PMID 36081810
30. Brck N, Koskivuo I, Bostrm P, et al. Preoperative Magnetic Resonance Imaging in Patients With Stage I Invasive Ductal Breast Cancer: A Prospective Randomized Study. Scand J Surg. Mar 2018; 107(1): 14-22. PMID 28401771
31. Mota BS, Reis YN, de Barros N, et al. Effects of preoperative magnetic resonance image on survival rates and surgical planning in breast cancer conservative surgery: randomized controlled trial (BREAST-MRI trial). Breast Cancer Res Treat. Apr 2023; 198(3): 447-461. PMID 36786946
32. Gonzalez V, Sandelin K, Karlsson A, et al. Preoperative MRI of the breast (POMB) influences primary treatment in breast cancer: a prospective, randomized, multicenter study. World J Surg. Jul 2014; 38(7): 1685-93. PMID 24817517
33. Peters NH, van Esser S, van den Bosch MA, et al. Preoperative MRI and surgical management in patients with nonpalpable breast cancer: the MONET - randomised controlled trial. Eur J Cancer. Apr 2011; 47(6): 879-86. PMID 21195605
34. Turnbull L, Brown S, Harvey I, et al. Comparative effectiveness of MRI in breast cancer (COMICE) trial: a randomised controlled trial. Lancet. Feb 13 2010; 375(9714): 563-71. PMID 20159292
35. Onega T, Zhu W, Weiss JE, et al. Preoperative breast MRI and mortality in older women with breast cancer. Breast Cancer Res Treat. Jul 2018; 170(1): 149-157. PMID 29516372
36. Fortune-Greeley AK, Wheeler SB, Meyer AM, et al. Preoperative breast MRI and surgical outcomes in elderly women with invasive ductal and lobular carcinoma: a population-based study. Breast Cancer Res Treat. Jan 2014; 143(1): 203-12. PMID 24305978
37. Zeng Z, Amin A, Roy A, et al. Preoperative magnetic resonance imaging use and oncologic outcomes in premenopausal breast cancer patients. NPJ Breast Cancer. 2020; 6: 49. PMID 33083528
38. Drew PJ, Kerin MJ, Mahapatra T, et al. Evaluation of response to neoadjuvant chemoradiotherapy for locally advanced breast cancer with dynamic contrast-enhanced MRI of the breast. Eur J Surg Oncol. Nov 2001; 27(7): 617-20. PMID 11669587
39. Partridge SC, Gibbs JE, Lu Y, et al. Accuracy of MR imaging for revealing residual breast cancer in patients who have undergone neoadjuvant chemotherapy. AJR Am J Roentgenol. Nov 2002; 179(5): 1193-9. PMID 12388497
40. Marinovich ML, Macaskill P, Irwig L, et al. Agreement between MRI and pathologic breast tumor size after neoadjuvant chemotherapy, and comparison with alternative tests: individual patient data meta-analysis. BMC Cancer. Oct 08 2015; 15: 662. PMID 26449630
41. Lobbes MB, Prevos R, Smidt M, et al. The role of magnetic resonance imaging in assessing residual disease and pathologic complete response in breast cancer patients receiving neoadjuvant chemotherapy: a systematic review. Insights Imaging. Apr 2013; 4(2): 163-75. PMID 23359240
42. Morris EA, Schwartz LH, Drotman MB, et al. Evaluation of pectoralis major muscle in patients with posterior breast tumors on breast MR images: early experience. Radiology. Jan 2000; 214(1): 67-72. PMID 10644103
43. Kerslake RW, Carleton PJ, Fox JN, et al. Dynamic gradient-echo and fat-suppressed spin-echo contrast-enhanced MRI of the breast. Clin Radiol. Jul 1995; 50(7): 440-54. PMID 7614789
44. Rodenko GN, Harms SE, Pruneda JM, et al. MR imaging in the management before surgery of lobular carcinoma of the breast: correlation with pathology. AJR Am J Roentgenol. Dec 1996; 167(6): 1415-9. PMID 8956569
45. Xie Z, Xu W, Zhang H, et al. The value of MRI for downgrading of breast suspicious lesions detected on ultrasound. BMC Med Imaging. Jun 05 2023; 23(1): 72. PMID 37271827
46. de Lima Docema MF, Costa PA, de Andrade FE, et al. Magnetic resonance imaging-guided occult breast lesion localization and simultaneous sentinel lymph node mapping. World J Surg Oncol. Oct 23 2014; 12: 320. PMID 25341393
47. Marinovich ML, Houssami N, Macaskill P, et al. Meta-analysis of magnetic resonance imaging in detecting residual breast cancer after neoadjuvant therapy. J Natl Cancer Inst. Mar 06 2013; 105(5): 321-33. PMID 23297042
48. Li H, Yao L, Jin P, et al. MRI and PET/CT for evaluation of the pathological response to neoadjuvant chemotherapy in breast cancer: A systematic review and meta-analysis. Breast. Aug 2018; 40: 106-115. PMID 29758503
49. Janssen LM, den Dekker BM, Gilhuijs KGA, et al. MRI to assess response after neoadjuvant chemotherapy in breast cancer subtypes: a systematic review and meta-analysis. NPJ Breast Cancer. Sep 19 2022; 8(1): 107. PMID 36123365

50. Hylton NM, Blume JD, Bernreuter WK, et al. Locally advanced breast cancer: MR imaging for prediction of response to neoadjuvant chemotherapy--results from ACRIN 6657/I-SPY TRIAL. Radiology. Jun 2012; 263(3): 663-72. PMID 22623692
51. Lee JM, Orel SG, Czerniecki BJ, et al. MRI before reexcision surgery in patients with breast cancer. AJR Am J Roentgenol. Feb 2004; 182(2): 473-80. PMID 14736685
52. Bedrosian I, Mick R, Orel SG, et al. Changes in the surgical management of patients with breast carcinoma based on preoperative magnetic resonance imaging. Cancer. Aug 01 2003; 98(3): 468-73. PMID 12879462
53. Kawashima H, Tawara M, Suzuki M, et al. Effectiveness of dynamic MRI for diagnosing pericicatricial minimal residual breast cancer following excisional biopsy. Eur J Radiol. Oct 2001; 40(1): 2-9. PMID 11673001
54. Orel SG, Reynolds C, Schnall MD, et al. Breast carcinoma: MR imaging before re-excisional biopsy. Radiology. Nov 1997; 205(2): 429-36. PMID 9356624
55. Weinstein SP, Orel SG, Heller R, et al. MR imaging of the breast in patients with invasive lobular carcinoma. AJR Am J Roentgenol. Feb 2001; 176(2): 399-406. PMID 11159081
56. Krammer J, Price ER, Jochelson MS, et al. Breast MR imaging for the assessment of residual disease following initial surgery for breast cancer with positive margins. Eur Radiol. Nov 2017; 27(11): 4812-4818. PMID 28567547
57. Lee RK, Kim HJ, Lee J. Role of breast magnetic resonance imaging in predicting residual lobular carcinoma in situ after initial excision. Asian J Surg. May 2018; 41(3): 279-284. PMID 28286021
58. Frei KA, Kinkel K, Bonel HM, et al. MR imaging of the breast in patients with positive margins after lumpectomy: influence of the time interval between lumpectomy and MR imaging. AJR Am J Roentgenol. Dec 2000; 175(6): 1577-84. PMID 11090379
59. Soderstrom CE, Harms SE, Farrell RS, et al. Detection with MR imaging of residual tumor in the breast soon after surgery. AJR Am J Roentgenol. Feb 1997; 168(2): 485-8. PMID 9016232
60. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology (NCCN guidelines): breast cancer. Version 4.2023. Updated March 23, 2023. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed July 20, 2023.
61. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology (NCCN guidelines): breast cancer screening and diagnosis. Version 1.2023. Updated June 19, 2023. https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf. Accessed July 19, 2023.
62. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology (NCCN guidelines): genetic/familial high-risk assessment: breast, ovarian, and pancreatic. Version 3.2023. Updated February 13, 2023. https://www.nccn.org/professionals/physician_gls/pdf/genetics_bop.pdf. Accessed July 21, 2023.
63. American Cancer Society. Breast MRI. Updated January 14, 2022; https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/american-cancer-society-recommendations-for-the-early-detection-of-breast-cancer.html. Accessed July 19, 2023.
64. American College of Radiology. Appropriateness criteria - breast cancer screening, revised 2017. https://acsearch.acr.org/docs/70910/Narrative/. Accessed July 24, 2023.
65. American College of Radiology. Appropriateness criteria - Palpable Breast Masses, revised 2022. https://acsearch.acr.org/docs/69495/Narrative/. Accessed July 23, 2023.
66. American College of Radiology. ACR Appropriateness Criteria stage I breast cancer: initial workup and surveillance for local recurrence and distant metastases in asymptomatic women. Revised 2019. https://acsearch.acr.org/docs/69496/Narrative/ Accessed July 19, 2023.
67. American College of Radiology. Appropriateness criteria - Monitoring Response to Neoadjuvant Systemic Therapy for Breast Cancer, 2022. https://acsearch.acr.org/docs/3099208/Narrative/. Accessed July 22, 2023.
68. American College of Radiology. ACR Appropriateness Criteria - Transgender breast cancer screening. American College of Radiology. Published 2021. https://acsearch.acr.org/docs/3155692/Narrative/ Accessed July 21, 2023.
69. American College of Radiology. ACR Appropriateness Criteria - Supplemental breast cancer screening based on breast density. American College of Radiology. Published 2021. https://acsearch.acr.org/docs/3158166/Narrative/ Accessed July 20, 2023.
70. Monticciolo DL, Newell MS, Moy L, et al. Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR. J Am Coll Radiol. Mar 2018; 15(3 Pt A): 408-414. PMID 29371086
71. Khatcheressian JL, Wolff AC, Smith TJ, et al. American Society of Clinical Oncology 2006 update of the breast cancer follow-up and management guidelines in the adjuvant setting. J Clin Oncol. Nov 01 2006; 24(31): 5091-7. PMID 17033037
72. Khatcheressian JL, Hurley P, Bantug E, et al. Breast cancer follow-up and management after primary treatment: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. Mar 01 2013; 31(7): 961-5. PMID 23129741
73. Mulder RL, Hudson MM, Bhatia S, et al. Updated Breast Cancer Surveillance Recommendations for Female Survivors of Childhood, Adolescent, and Young Adult Cancer From the International Guideline Harmonization Group. J Clin Oncol. Dec 10 2020; 38(35): 4194-4207. PMID 33078972
74. U.S. Preventive Services Task Force. Final Recommendation Statement. Breast Cancer: Screening. 2016; https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening. Accessed July 19, 2023.

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.
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.
December 2021	Replace policy	Policy updated with literature review through July 22, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through August 9, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
December 2023	Replace policy	Policy updated with literature review through July 21, 2023; references added. Policy statements unchanged.