Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer

Policy #  00084
Original Effective Date: 03/25/2002
Current Effective Date: 04/09/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

• Benefits are available in the member’s contract/certificate, and
• Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider the use of magnetic resonance imaging (MRI) of the breast with a breast coil and with contrast to be eligible for coverage** for the following indications:

Screening Uses
• Annual MRI for screening of breast cancer in high-risk patients, starting at age twenty-five (25). The following list includes individual risk factors known to indicate a high risk of breast cancer by themselves:
  o History of lobular carcinoma in situ (LCIS), atypical lobular hyperplasia (ALH) or atypical ductal hyperplasia (ADH) on biopsy; or
  o Individuals with a genetic predisposition to breast cancer, in either themselves or a first-degree relative, which may include ANY of the following pathogenic or likely pathogenic gene variants:
    ▪ BRCA1 and BRCA2
    ▪ TP53 (Li-Fraumeni syndrome)

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- PTEN (Cowden syndrome/PTEN Hamartoma Tumor Syndrome); or
  - Individuals known to have ANY of the following established genetic mutations (pathogenic or likely pathogenic variants):
    - ATM, BARD1, or CHEK2
    - CDH1 or PALB2
    - NF-1
    - STK11; or
  - Lifetime risk of 20% or greater as defined by the GAIL model, BOADICEA, BRCAPRO, Claus, Tyrer-Cuzick or other validated models that are largely dependent on family history; or
  - Individuals who received radiation therapy to the chest between ages of 10 and 30 years

- Annual screening for breast cancer following a bilateral mastectomy in any woman who was previously diagnosed with breast cancer, completed active treatment, and was subsequently determined to be cancer free.

Detection Uses

- Detection of a suspected occult breast primary tumor in patients with axillary nodal adenocarcinoma (i.e., negative mammography and physical exam).
- A new diagnosis of breast cancer to evaluate the contralateral breast when clinical and mammographic findings are normal
- Detection of suspected breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in patients with textured breast implants when ultrasound report is nondiagnostic and when breast implant was eligible for coverage under breast reconstructions benefits
- Evaluation of pathologic nipple discharge (e.g. persistent and reproducible on exam, spontaneous, unilateral, single duct, and clear or bloody) after nondiagnostic mammography and ultrasound
- Metastatic cancer suspected to be of breast origin by histology when no mammographic findings of primary breast carcinoma
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Treatment-Related Uses

- Preoperative tumor mapping of the involved (ipsilateral) breast to evaluate the presence of multi-centric disease in patients with clinically localized breast cancer who are candidates for breast-conservation therapy
- Pre-surgical planning in patients with locally advanced breast cancer before and after completion of neoadjuvant chemotherapy to permit tumor localization and characterization
- To determine the presence of pectoralis major muscle/chest wall invasion in patients with posteriorly located tumors
- 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
- Detection of suspected recurrence in women with a prior history of breast cancer when clinical, mammographic, and/or sonographic report findings are inconclusive

Other

Based on review of available data, the Company may consider the use of magnetic resonance imaging (MRI) of the breast to be eligible for coverage** when used to assess breast implant rupture in symptomatic women who have undergone breast reconstruction for breast cancer, and the diagnosis of implant rupture cannot be confirmed by mammography or ultrasound.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers magnetic resonance imaging (MRI) of the breast without a breast coil for any clinical indication to be investigational*

Based on review of available data, the Company considers all other uses of magnetic resonance imaging (MRI) of the breast to be investigational* including but not limited to the following:

Screening Uses
- As a screening technique in average-risk patients
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- 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 treatment for breast cancer)

Detection Uses
- For diagnosis of low-suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow-up
- For diagnosis of a suspicious breast lesion in order to avoid biopsy

Treatment-Related Uses
- To determine response during neoadjuvant chemotherapy in patients with locally advanced breast cancer
- For evaluation of residual tumor in patients with positive margins after initial lumpectomy or breast conservation surgery.

When Services Are Not Covered
The use of magnetic resonance imaging (MRI) of the breast to assess breast implant rupture following cosmetic, non-covered breast surgery is not eligible for coverage.**

The use of magnetic resonance imaging (MRI) of the breast for detection of suspected breast implant associated anaplastic large cell lymphoma (BIA-ALCC) following cosmetic, non-covered breast surgery is not eligible for coverage.**

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

**Background/Overview**

Magnetic Resonance Imaging

MRI of the breast can be used to screen, detect, and/or diagnosis of breast cancer. MRI can be used as a replacement for mammography screening, or as an additional imaging test alone, or in combination with other imaging modalities. Each potential use is described below.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

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. FDA through the 510(k) process. The Food and Drug Administration determined that these devices are substantially equivalent to predicate devices for use "in conjunction with a MRI to produce diagnostic and interventional images of the breast, chest wall and axillary tissues that can be interpreted by a trained physician."

**Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Magnetic resonance imaging 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
For individuals who are asymptomatic with high-risk of breast cancer who receive MRI as an adjunct to screening for breast cancer, the evidence includes systematic reviews (including a TEC Assessment) and diagnostic accuracy studies. The 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. The systematic reviews did not identify any randomized controlled trials 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) and diagnostic accuracy studies. There are limited data on the diagnostic accuracy of MRI vs mammography in patients who have had breast-conserving therapy 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, the evidence includes a systematic review (TEC Assessment) and meta-analysis. The relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization.
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resource utilization. The studies found that adjunctive use of breast MRI to guide breast-conserving surgery 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. The 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). The 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. The 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
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numbers of unnecessary biopsies. The evidence is insufficient to determine the effects of the technology on health outcomes.

Breast implant-associated anaplastic large cell lymphoma is a rare condition that has been documented in patients with a history of textured-surface breast implants. Guidelines recommend ultrasound for initial evaluation in patients with clinically suspected BIA-ALCL due to its ability to detect a mass, effusion, and enlarged regional lymph nodes. Ultrasound is also useful for guidance of biopsy or aspiration. In cases where ultrasound is equivocal, MRI without and with contrast may be considered.

In the setting of nipple discharge, breast imaging is not generally indicated for evaluation of a physiologic discharge such as galactorrhea. Pathologic nipple discharge, such as persistent and reproducible on exam, spontaneous, unilateral, single duct, and bloody or clear, may be evaluated by MRI if further evaluation is warranted following initial standard imaging. The American College of Radiology states that MRI should be considered when other approaches have failed to identify an underlying cause of pathologic nipple discharge. MRI has a sensitivity for invasive cancer of 86% to 100% and a sensitivity of 40% to 100% for noninvasive disease in the setting of a pathologic nipple discharge. A systematic review and meta-analysis showed that MRI has a superior diagnostic accuracy compared to galactography/ductography in detecting lesions in patients with nipple discharge and states that if mammography and ultrasound are negative, MRI should be preferred over galactography for further evaluation.

Treatment-Related Uses
For individuals who have clinically localized breast cancer who receive MRI for preoperative mapping to identify multicentric disease, the evidence includes randomized controlled trials, systematic reviews, and prospective cohort studies. The 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
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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. The 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 breast-conserving therapy 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. The 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. The 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...
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accuracy studies and systematic reviews. The 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. The 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.

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 NCCN guidelines on breast cancer (v.4.2022), breast cancer screening and diagnosis (v.1.2022), and genetic assessment of those at high-risk of breast, ovarian, and pancreatic cancer (v.2.2022) list the following indications for breast MRI.

Screening (as an adjunct to mammography):

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"Recommend Annual MRI Screening

- For individuals with a genetic mutation, or a 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 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"

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 ≥ 35 years of age with a 5-year risk of invasive breast cancer ≥ 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"

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:
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- **ATM, BARD1,** and **CHEK2** starting at age 40 years
- **CDH1** 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
- **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, 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:

- Optional MRI for women with nipple discharge, no palpable mass and a BI-RADS rating of 1-3.
- 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 1-3 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:

- “May be useful for 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.”
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- "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 on treatment:
- "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 MRI related to surveillance:
- The utility of MRI in follow-up screening of patients with prior breast cancer is undefined. It should generally be considered only in 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:

"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"
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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 imaging, which were developed in 2012 and revised in 2017; palpable breast masses, revised in 2016; initial workup and surveillance for stage I breast cancer, reviewed in 2019; and monitoring response to neoadjuvant therapy, 2017, transgender breast cancer screening, 2021; and supplemental breast cancer screening based on breast density (see Table 1).

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

<table>
<thead>
<tr>
<th>Specific Indications</th>
<th>MRI Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>Usually appropriate with and without contrast (with mammography)</td>
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### Specific Indications

<table>
<thead>
<tr>
<th>Specific Indications</th>
<th>MRI Rating</th>
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<tbody>
<tr>
<td>Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15% to 20% lifetime risk of breast cancer</td>
<td>May be appropriate with and without contrast (with mammography)</td>
</tr>
<tr>
<td>Average-risk women: women with &lt;15% lifetime risk of breast cancer, breasts not dense</td>
<td>Usually not appropriate with and without contrast</td>
</tr>
<tr>
<td>Evaluating palpable breast mass. All indications reviewed</td>
<td>Usually not appropriate with and without contrast</td>
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<tr>
<td>Initial determination of tumor size and extent within the breast prior to neoadjuvant chemotherapy.</td>
<td>Usually appropriate without and with contrast</td>
</tr>
<tr>
<td>Imaging of the breast after initiation or completion of neoadjuvant chemotherapy [if a prechemotherapy MRI was performed].</td>
<td>Usually appropriate without and with contrast</td>
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<tr>
<td>Axillary evaluation prior to neoadjuvant chemotherapy.</td>
<td>May be appropriate without and with contrast</td>
</tr>
<tr>
<td>Known breast cancer. Axillary evaluation after completion of neoadjuvant chemotherapy, axilla not previously evaluated.</td>
<td>May be appropriate without and with contrast</td>
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<tr>
<td>Surveillance. Rule out local recurrence.</td>
<td>May be appropriate without and with contrast</td>
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<tr>
<td>Transfeminine (male-to-female) patient, 40 years of age or older with past or current hormone use ≥5 years; average risk patient.</td>
<td>Usually not appropriate without and with contrast</td>
</tr>
<tr>
<td>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.</td>
<td>Usually not appropriate without and with contrast</td>
</tr>
<tr>
<td>Transfeminine (male-to-female) patient with no hormone use (or hormone use &lt;5 years) at any age; average-risk patient</td>
<td>Usually not appropriate without and with contrast</td>
</tr>
<tr>
<td>Transfeminine (male-to-female) patient, 25 to 30 years of age or older with no hormone use (or hormone use &lt;5 years); higher-than-average risk.</td>
<td>Usually not appropriate without and with contrast</td>
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### Specific Indications

<table>
<thead>
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<th>Specific Indications</th>
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<tbody>
<tr>
<td>Transmasculine (female-to-male) patient with bilateral mastectomies (“top surgery”) at any age and any risk.</td>
<td>Usually not appropriate without and with contrast</td>
</tr>
<tr>
<td>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).</td>
<td>Usually not appropriate without and with contrast</td>
</tr>
<tr>
<td>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).</td>
<td>May be appropriate without and with contrast; usually not appropriate without contrast</td>
</tr>
<tr>
<td>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 of chest irradiation between 10 to 30 years of age, patient with 20% or greater lifetime risk of breast cancer).</td>
<td>Usually appropriate without and with contrast; usually not appropriate without contrast</td>
</tr>
<tr>
<td>Average-risk females with nondense breasts</td>
<td>Usually not appropriate without and with contrast</td>
</tr>
<tr>
<td>Intermediate-risk females with nondense breasts</td>
<td>Usually not appropriate without and with contrast</td>
</tr>
<tr>
<td>High-risk females with nondense breasts</td>
<td>Usually not appropriate without and with contrast</td>
</tr>
<tr>
<td>Average-risk females with dense breasts</td>
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Specific Indications | MRI Rating
--- | ---
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. 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. In 2013, the guidelines were updated with a systematic review of the literature through March 2012, and no revisions were made. 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." 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."

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. 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:
"... 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.

**Ongoing and Unpublished Clinical Trials**
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.
Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01805076</td>
<td>Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women With Breast Cancer</td>
<td>317</td>
<td>Feb 2025</td>
</tr>
<tr>
<td>NCT01035112</td>
<td>Magnetic Resonance Imaging of Breast Cancer</td>
<td>445</td>
<td>May 2022</td>
</tr>
<tr>
<td>NCT00474604</td>
<td>MRI Evaluation of Breast Tumor Growth and Treatment Response</td>
<td>209</td>
<td>Dec 2025</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01716247</td>
<td>Comparison of Contrast Enhanced Mammography to Breast MRI in Screening Patients at Increased Risk for Breast Cancer</td>
<td>1000</td>
<td>Jun 2018</td>
</tr>
<tr>
<td>NCT01929395</td>
<td>A Study to Evaluate the Use of Supine MRI Images in Breast Conserving Surgery</td>
<td>159</td>
<td>Jul 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

**References**

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03/06/2002  Medical Director review
03/21/2002  Medical Policy Committee review
03/25/2002  Managed Care Advisory Council approval
06/24/2002  Format revision. No substance change to policy
05/07/2004  Medical Director review
06/28/2004  Managed Care Advisory Council approval
10/05/2004  Medical Director review
11/16/2004  Medical Policy Committee review. Format revision. Policy revised to include statement requiring use of a breast coil. Coverage Eligibility Revision. Added coverage eligibility for presurgical planning in patients with locally advanced breast cancer, and to determine presence of pectoralis major muscle/chest wall invasion. Added investigational status for screening technique of the contralateral
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breast and average risk patients, preoperative tumor mapping, to determine response to neoadjuvant chemotherapy and evaluation of residual tumor.

11/29/2004 Managed Care Advisory Council approval
10/05/2005 Medical Director review
10/27/2005 Quality Care Advisory Council approval
07/07/2006 Format revision; addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/02/2006 Medical Director review
08/09/2006 Medical Policy Committee approval. MRI of the breast for preoperative tumor mapping to evaluate the presence of multicentric disease in patients with clinically localized breast cancer who are candidates for breast-conservation therapy was changed from investigational to eligible for coverage.
12/06/2006 Medical Director review
12/20/2006 Medical Policy Committee approval. Coverage eligibility changed to allow coverage for the following indications:

- To assess response during neoadjuvant chemotherapy: magnetic resonance mammography may be performed before, during and after chemotherapy, to assess response to treatment and extent of residual disease, prior to surgery.
- To evaluate multi-centric disease in newly diagnosed breast carcinomas - in the contralateral breast, to interrogate for lesions not suspected by mammography and physical exam.
- To evaluate lesion, when primary screening test results (mammography, breast ultrasound, biopsy) and physical examination are inconclusive for breast carcinoma or when these studies cannot be performed.
- To detect residual disease post-lumpectomy with close or positive pathological margins, particularly when breast conservation and local re-excision are planned.
- To detect local recurrence of breast carcinoma post-mastectomy breast reconstruction, with implant or tissue transfer flap.
- To detect breast cancer in patients with personal history of infiltrating ductal carcinoma, particularly among candidates for breast conservation.
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- To assess the extent and multicentricity of disease in invasive lobular carcinoma, particularly when primary screening tests are inconclusive or when breast conservation is considered.
- To differentiate palpable mass(es) from surgical scar tissue following breast surgery, breast reconstruction or radiation therapy.

12/05/2007 Medical Director review
12/19/2007 Policy Committee approval. Coverage eligibility unchanged.
12/03/2008 Medical Director review
12/17/2008 Policy Committee approval. Added the phrase “with a breast coil” for clarity of coverage statement.
12/04/2009 Medical Policy Committee approval
08/05/2010 Medical Policy Committee approval
08/18/2010 Medical Policy Implementation Committee approval. Added a Patient Selection Criteria bullet indicating that the use of MRI of the breast with a breast coil may be considered eligible for coverage to detect breast cancer in an individual with a personal history of breast cancer.
11/04/2010 Medical Policy Committee review
11/16/2010 Medical Policy Implementation Committee approval. Defined high-risk in the Background/Overview section. Deleted the following statement from the first bullet in the coverage section: “(Genetic counseling in hereditary breast cancer should precede surveillance for breast carcinoma with MRI mammography)”.
11/03/2011 Medical Policy Committee approval
11/16/2011 Medical Policy Implementation Committee approval. No change to coverage.
11/01/2012 Medical Policy Committee review
11/07/2013 Medical Policy Committee review
11/06/2014 Medical Policy Committee review
11/21/2014 Medical Policy Implementation Committee approval. No change to coverage.
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08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015 Medical Policy Committee review
11/16/2015 Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016 Medical Policy Committee review
11/16/2016 Medical Policy Implementation Committee approval. Modification of coverage indications, high risk definition modified and moved from Background section to policy statements. Guidelines section added.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017 Medical Policy Committee review
08/09/2018 Medical Policy Committee review
08/15/2018 Medical Policy Implementation Committee approval. Added “Screening for breast cancer in any person previously diagnosed with breast cancer who has completed treatment, including a bilateral mastectomy, and was subsequently determined to be cancer free” as eligible under the Screening uses section.
01/10/2019 Medical Policy Committee review
01/23/2019 Medical Policy Implementation Committee approval. Screening uses criteria revised. Removed ATM and CHEK2 genes from covered criteria.
01/03/2020 Medical Policy Committee review
01/08/2020 Medical Policy Implementation Committee approval. No change to coverage.
07/02/2020 Medical Policy Committee review
07/08/2020 Medical Policy Implementation Committee approval. Added under Detection Uses as eligible for coverage:
• Detection of suspected breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in patients with textured breast implants when ultrasound is nondiagnostic and when breast implant was eligible for coverage under breast reconstructions benefits
• Evaluation of pathologic nipple discharge (e.g. unilateral discharge or one that is bloody or clear) after nondiagnostic mammography and ultrasound

Added under Treatment Related Uses as eligible for coverage:

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- Detection of suspected recurrence in women with a prior history of breast cancer when clinical, mammographic, and/or sonographic findings are inconclusive.

Added When Services Are Not Covered:
The use of magnetic resonance imaging (MRI) of the breast for detection of suspected breast implant associated anaplastic large cell lymphoma (BIA-ALCC) following cosmetic, non-covered breast surgery is not eligible for coverage.

10/07/2021 Medical Policy Committee review
10/13/2021 Medical Policy Implementation Committee approval. Screening criteria revised due to state law. See below.

- Annual MRI for screening of breast cancer in high-risk patients, starting at age twenty-five (25). The following list includes individual risk factors known to indicate a high risk of breast cancer by themselves:
  - History of lobular carcinoma in situ (LCIS), atypical lobular hyperplasia (ALH) or atypical ductal hyperplasia (ADH) on biopsy; or
  - Individuals with a genetic predisposition to breast cancer, in either themselves or a first-degree relative, which may include ANY of the following pathogenic or likely pathogenic gene variants:
    - BRCA1 and BRCA2
    - TP53 (Li-Fraumeni syndrome)
    - PTEN (Cowden syndrome/ PTEN Hamartoma Tumor Syndrome); or
  - Individuals known to have ANY of the following established genetic mutations (pathogenic or likely pathogenic variants):
    - ATM, BARD1, or CHEK2
    - CDH1 or PALB2
    - NF-1
    - STK11; or
  - Lifetime risk of 20% or greater as defined by the GAIL model, BOADICEA, BRCAPro, Claus, Tyrer-Cuzick or other validated models that are largely dependent on family history; or
  - Individuals who received radiation therapy to the chest between ages of 10 and 30 years.
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Detection uses changes:

- Evaluation of pathologic nipple discharge (e.g. persistent and reproducible on exam, spontaneous, unilateral, single duct, and clear or bloody) after nondiagnostic mammography and ultrasound
- Metastatic cancer of unknown primary and suspected to be of breast origin by histology when no mammographic findings of primary breast carcinoma

12/01/2022  Medical Policy Committee review
12/14/2022  Medical Policy Implementation Committee approval. Made the following change under detection uses: Removed “of unknown primary” from this statement. Metastatic cancer of unknown primary and suspected to be of breast origin by histology when no mammographic findings of primary breast carcinoma.”

Next Scheduled Review Date:  12/2023

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<th>Code Type</th>
<th>Code</th>
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</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,
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would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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