Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer

Policy # 00084
Original Effective Date: 03/25/2002
Current Effective Date: 09/26/2020

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. The following list includes individual risk factors known to indicate a high risk of breast cancer by themselves:
    - Lobular carcinoma in situ (LCIS), atypical lobular hyperplasia (ALH) or atypical ductal hyperplasia (ADH) on biopsy; or
    - A known BRCA1 or BRCA2 pathogenic or likely pathogenic variants in patient or first-degree relative of BRCA carrier if patient is untested; or
    - Another gene variant associated with high risk or increased risk of breast cancer, e.g. TP53 (Li-Fraumeni syndrome), PTEN (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), CDH1, STK11, NF1, NBN, and PALB2 mutation; or

  - High risk (lifetime risk 20% or greater) of developing breast cancer as identified by models that are largely defined by family history, e.g. BRCA PRO, BOADICEA, Gail, Claus, Tyrer-Cuzick.; or
  - Received radiation therapy to the chest between 10 and 30 years of age
- 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

Detection Uses

- Detection of a suspected occult breast primary tumor in patients with axillary nodal adenocarcinoma (ie, 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. unilateral discharge or one that is bloody or clear) after nondiagnostic mammography and ultrasound report

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
- 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.

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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
There is no standardized method for determining a woman's risk of breast cancer that incorporates all possible risk factors. Clinical practice guidelines offer guidance on factors known to individually indicate a high risk of breast cancer.

A number of factors may increase the risk of breast cancer but do not by themselves indicate high risk. It is possible that combinations of factors may be indicative of high risk, but it is not possible to quantitate estimates of risk. As a result, it may be necessary to individualize the estimate of risk, whereby one would need to take into account the numerous risk factors. A number of risk factors, not individually indicating high risk, are included in the National Cancer Institute Breast Cancer Risk Assessment Tool (also called the Gail model). Risk factors in the model can be accessed online (http://www.cancer.gov/bcrisktool/Default.aspx).

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

As noted, breast MRI exams require a dedicated breast coil and the use of contrast 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.

CONSIDERATIONS FOR PREOPERATIVE MRI
Preoperative MRI in patients with localized disease results in higher rates of mastectomy and lower rates of breast-conserving therapy. There is uncertainty from the available evidence on whether outcomes are improved by changing to a more extensive operation. If biopsies are performed on all MRI-identified lesions, and if shared patient decision making is used for altering the surgical approach, then the probability of improved outcomes is increased.

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. Food and Drug Administration 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 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."

Rationale/Source

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

Screening Uses

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 relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. 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. The relevant outcomes are OS, disease-specific survival, test accuracy and validity, and resource utilization. There are limited data on the diagnostic accuracy of MRI vs mammography in patients who have had breast-conserving therapy 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. 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

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 a unilateral discharge or one that is 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

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

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

National Comprehensive Cancer Network

Current NCCN guidelines on breast cancer (v.1.2019), breast cancer screening and diagnosis (v.2.2019), and genetic assessment of those at high-risk of breast and/or ovarian cancer (v.3.2019) list the following indications for breast magnetic resonance imaging (MRI).

Screening (as an adjunct to mammography):

"Recommend Annual MRI Screening (Based on Evidence)

- First-degree relative of *BRCA* carrier, but untested: commence at age 25-29 y
- Lifetime risk 20% or greater, as defined by models that are largely dependent on family history .Encourage genetic testing for first-degree relatives. If testing declined, recommend MRI.

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

- Radiation to chest between 10 and 30 years

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

Insufficient evidence to recommend for or Against MRI Screening:

- Lifetime risk 15%-20%, as defined by models that are largely dependent on family history
- Heterogeneously or extremely dense breast on mammography
- Women with a personal history of breast cancer, including ductal carcinoma in situ (DCIS)

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 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 between the ages of 10 and 30 years with prior thoracic RT [radiotherapy]

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 25-29 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:

- *ATM, CHEK2,* and *NBN*, starting at age 40
- *CDH1* and *PALB2*, starting at age 30
- *NF1*, from ages 30 to 50.

The NCCN guidelines also state there is insufficient evidence for any recommendations for use of breast MRI for patients with the following genetic variants: *BARD1*, *BRIP1*,*MLH1*, *MSH2*, *MSH6*, *PMS2*, *EPCAM*, *RAD51C*, *RAD51D*, *STK11*, *TP53*, *PTEN*,*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.

ï‚Guideline discussion update in progress: "For patients with skin changes consistent with serious breast disease, consideration of breast MRI is included in the guidelines for those with benign biopsy of skin or nipple following BI-RADS category 1-2 assessment. Since a benign skin punch biopsy in a patient with clinical suspicion of inflammatory breast cancer (IBC) does not rule out malignancy, further evaluation is recommended [and] MRI may facilitate diagnosis of IBC."

Guidelines on breast cancer make the following recommendations on pretreatment evaluation:

- ï‚"May be useful for identifying primary cancer in women with axillary nodal adenocarcinoma and occult (unidentified) primary cancer, or with Paget's disease, or with invasive lobular carcinoma poorly (or inadequately) defined on mammography, ultrasound, or physical examination."

Guidelines on breast cancer make the following recommendations on treatment

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

Guidelines on breast cancer make the following recommendations on surveillance

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

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

"A breast MRI is mainly used for women who have been diagnosed with breast cancer, to help measure the size of the cancer, look for other tumors in the breast, and to check for tumors in the opposite breast. For certain women at high-risk for breast cancer, a screening MRI is recommended along with a yearly mammogram. MRI is not recommended as a screening tool by itself because it can miss some cancers that a mammogram would find.

Although MRI can find some cancers not seen on a mammogram, it's also more likely to find something that turns out not to be cancer (called a false positive). False-positive findings have to be checked out to know that cancer isn't present. This means more tests and/or biopsies. This is why MRI is not recommended as a screening test for women at average risk of breast cancer, because it would mean unneeded biopsies and other tests for many of these women."

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 (see Table 1).

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

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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%-20% lifetime risk of breast cancer	May be appropriate with and without contrast (with mammography)
Average-risk women: women with <15% lifetime risk of breast cancer, breasts not dense	Usually not appropriate with and without contrast
Evaluating palpable breast mass. All indications reviewed	Usually not appropriate with and without contrast
Initial determination of tumor size and extent within the breast prior to neoadjuvant chemotherapy.	Usually appropriate without and with contrast
Imaging of the breast after initiation or completion of neoadjuvant chemotherapy [if a prechemotherapy MRI was performed].	Usually appropriate without and with contrast
Axillary evaluation prior to neoadjuvant chemotherapy.	May be appropriate without and with contrast

Specific Indications	MRI Rating
Known breast cancer. Axillary evaluation after completion of neoadjuvant chemotherapy, axilla not previously evaluated.	May be appropriate without and with contrast
Surveillance. Rule out local recurrence.	May be appropriate without and with contrast

MRI: magnetic resonance imaging.

The College (2018) issued recommendations for breast cancer screening in women at higher-than-average risk. 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 (2013) published evidence-based recommendations for breast cancer surveillance in female survivors of childhood, adolescent, and young adult cancer who received chest irradiation before age 30 years and have no genetic predisposition to breast cancer. The authors found concordance among previous guidelines to initiate annual breast MRI exams beginning at age 25 or 8 years after radiation. Based on a systematic review of the literature to August 2011 and expert consensus, the authors recommended mammography, breast MRI, or both for surveillance (strong recommendation based on high-quality evidence with a low degree of uncertainty). The authors acknowledged that "no prospective studies have assessed the use of MRI screening in this population." The recommendation was therefore based on extrapolation of evidence from patients with hereditary risk for breast cancer.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (2016) updated its recommendations on breast cancer screening. The Task Force concluded the following on breast MRI:
"… the current evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging, DBT [digital breast tomosynthesis], or other methods in women identified to have dense breasts on an otherwise negative screening mammogram."

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

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02933489	Comparison of Abbreviated Breast MRI and Digital Breast Tomosynthesis in Breast Cancer Screening in Women With Dense Breasts	1450	Dec 2018
NCT02244593	FAST MRI Study in Breast Cancer Survivors	300	May 2020
NCT01805076	Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women With Breast Cancer	536	Sep 2019
Unpublished			
NCT02798796	Brazilian Randomized Study - Impact of MRI for Breast Cancer (BREAST-MRI)	372	Nov 2016 (unknown)
NCT01716247	Comparison of Contrast Enhanced Mammography to Breast MRI in	1000	Jun 2018

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Screening Patients at Increased Risk for Breast Cancer		
NCT01929395	A Study to Evaluate the Use of Supine MRI Images in Breast Conserving Surgery	138	Jul 2018

NCT: national clinical trial.

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Policy History

Original Effective Date: 03/25/2002
Current Effective Date: 09/26/2020

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
05/18/2004	Medical Policy Committee review. Format revision. Clinical criteria revision.
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 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
10/18/2005	Medical Policy Committee review. Format revision. FDA approval information added. Coverage eligibility unchanged.
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.
- 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

12/16/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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
11/28/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. No change to coverage.
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
11/15/2017	Medical Policy Implementation Committee approval. "Breast conservation surgery" added to policy statement on evaluation of residual tumor.

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:

- 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.

Next Scheduled Review Date: 07/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of

descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

Code Type	Code
CPT	77046, 77047, 77048, 77049
HCPCS	C8903, C8905, C8906, C8908
ICD-10 Diagnosis	C50.011-C50.029, C50.111-C50.129, C50.211-C50.229, C50.311-C50.329, C50.411-C50.429, C50.511-C50.529, C50.611-C50.629, C50.811-C50.829, C50.911-C50.929, C79.81, D05.00-D05.02, D05.10-D05.12, D05.80-D05.82, D05.90-D05.92, N63, Z15.01, Z80.3, Z85.3

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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, 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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Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer

Policy # 00084
Original Effective Date: 03/25/2002
Current Effective Date: 09/26/2020

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.