MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Magnetic Resonance Imaging (MRI) of the Breast**
Policy Number	**6.01.35**
Category	**Technology Assessment**
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Current Effective Date	**09/15/23**
Archived Date	**N/A**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, magnetic resonance imaging (MRI) has been medically proven to be effective and, therefore, is considered **medically appropriate** for the following breast indications:
   A. In patients with breast augmentation, breast implants (saline or silicone), breast reconstruction, free injection, and capsular contracture to confirm rupture of breast implants, when necessary, in patients when mammography or ultrasound is nondiagnostic of rupture.
   B. Indeterminate breast imaging when mammography or ultrasound is inconclusive and:
      1. The finding is not a palpable mass; or
      2. Discordance between imaging findings and core needle biopsy findings (the biopsy result does not adequately explain the abnormal findings on mammogram and/or ultrasound); or
      3. Discordance between the imaging findings and histopathologic core need biopsy result, before consideration for surgical management versus observation; or
      4. Inconclusive findings of fat necrosis post lumpectomy or mastectomy with or without reconstruction; or
      5. There is pathologic nipple discharge and the initial diagnostic mammogram and ultrasound is negative or inconclusive.
   C. Initial work-up/staging for the following indications:
      1. Adenocarcinoma in axillary lymph node without a breast primary site identified on mammogram/ultrasound;
      2. Multifocal or multicentric breast cancer;
      3. Before neoadjuvant systemic therapy;
      4. High risk histologies to include:

   a. Atypical ductal hyperplasia (ADH); or
   b. Atypical lobular hyperplasia ALH; or
   c. Lobular carcinoma in situ (LCIS); or
   d. Invasive lobular carcinoma (ILC);
5. Paget's disease of the breast;
6. Inconclusive findings on both mammogram and ultrasound;
7. Extremely dense breast tissue (breast density category D) on mammography.

D. Preoperatively, to establish extent of disease where a diagnosis of malignant phyllode tumor has previously been established by tissue diagnosis.

E. Restaging/Recurrence:
1. After completion of neoadjuvant chemotherapy to determine resectability;
2. Biopsy proven local recurrence;
3. Suspicion of recurrence with inconclusive mammogram and/or ultrasound (BIRADS 0); or
4. Mammogram and ultrasound conflicts with physical exam.

F. Follow-up/Surveillance of women with prior history of breast cancer (not treated with bilateral mastectomy) and **ONE** of the following indications:
1. Positive for a known high risk genetic breast cancer mutation**:** Li-Fraumeni Syndrome/TP53 syndrome, BRCA1/BRCA2, Peutz-Jehgers Syndrome (STK11/LKB1 gene variations), PTEN Mutation/Cowden Syndrome, CDH1, NF1, PALB2, ATM, CHEK2, NBN, BARD1, RAD51C and RAD51D; or
2. Clinical lifetime risk estimated to be greater than or equal to 20% using genetic or clinical risk estimator calculated prior to the initial diagnosis of breast cancer; or
3. Extremely dense breast tissue (breast density Category D) on mammography; or
4. Age at breast cancer diagnosis less than or equal to 50 years; or
5. Individuals with a history of:
   a. Atypical ductal hyperplasia (ADH); or
   b. Atypical lobular hyperplasia ALH; or
   c. Lobular carcinoma in situ (LCIS); or
   d. Invasive lobular carcinoma (ILC).

G. MRI Breast Screening based on the National Comprehensive Cancer Network (NCCN) Guidelines:

High Risk Indications	
1.	*MRI Screening to begin at age 20:*
	a. Li-Fraumeni Syndrome (TP53 mutation) should start annual breast screening MRI starting at age 20 or at the age of the earliest diagnosed breast cancer in the family, whichever comes first.
2.	*MRI screening to begin at diagnosis but not prior to age 25:*
	a. Individuals with a history of : 1. Atypical ductal hyperplasia (ADH); or 2. Atypical lobular hyperplasia (ALH); or 3. Lobular carcinoma in situ (LCIS).
3.	*MRI screening to begin at age determined by gene mutation:*
	a. BRCA 1 or BRCA 2 begin age 25
	b. ATM, CHEK2, STK11, Peutz-Jeghers syndrome (PJS), PTEN Mutation (Cowden Syndrome), CDH1, NF1, PALB2 begin age 30
	c. NBN, BARD1, RAD51C, RAD51D begin age 40
4.	*MRI screening begins at age 40:*

	a. First-degree relative (parent, sibling, child. Half siblings are considered second degree relatives) with BRCA 1 or BRCA 2, if individual has not been tested for BRCA mutation. (If individual has been tested and negative for mutation then annual screening is not indicated.)
5.	*MRI screening begins at age 40, or 10 years before the age of relative (lineage as described below) when first diagnosed with breast cancer, but not prior to the age of 25:*
	a. Two or more first-degree relatives with breast or ovarian cancer.
	b. One first-degree relative with breast cancer or ovarian cancer that was diagnosed ≤age 50.
	c. One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer.
	d. A first or second-degree male relative (father, brother, uncle, grandfather) diagnosed with breast cancer.
6.	*MRI screening begins at age 40:*
	a. Clinical lifetime risk estimated at greater than or equal to 20% using genetic risk or clinical risk estimator, acceptable models are Gail (NCI), Claus, Tyrer-Cuzick (IBIS) or BRCAPRO.
7.	*MRI screening to begin at age 25 or 8 years after completion of radiotherapy (whichever occurs later - screening MRI Breast is not supported prior to age 25)*
	a. Annual MRI Breast and annual mammogram is recommended for individuals who received therapeutic radiation exposure in the following fields while they were under 30 years of age: 1. Chest (thorax) 2. Whole lung 3. Mediastinal 4. Axilla 5. Mini-mantle, mantle, or extended mantle 6. Total (TLI) or subtotal (SLTI) lymphoid irradiation 7. Total body irradiation (TBI)

II. Based upon our criteria and assessment of the peer-reviewed literature, supplemental MRI breast screening after an inconclusive mammogram is considered **medically appropriate** for the following transgender individual:
   A. Transmasculine (female-to-male) with **ALL** the following risk factors:
      1. Reduction mammoplasty or no chest surgery; and
      2. Age greater than or equal to 25 years; and
      3. High-risk (greater than or equal to 20% lifetime risk) using genetic risk or clinical risk estimator, acceptable models are Gail (NCI), Claus, Tyrer-Cuzick (IBIS) or BRCAPRO.

III. Based upon our criteria and assessment of the peer-reviewed literature, MRI of the breast has not been medically proven to be effective and, therefore, is considered **investigational** for indications including, but not limited to, the following:
   A. Screening for the detection of breast cancer when the sensitivity of mammography is limited (e.g., dense breasts, breast implants). Breast ultrasound should be considered before MRI for this population of women.
   B. Screening in average-risk patients (15-20 percent lifetime risk based on one of the accepted risk assessment tools that utilize family history and other factors).
   C. Screening in individuals with MSH2, MLH1, MSH6, PMS2, EPCAM genetic variants of unknown significance, genetic variants favoring polymorphism, or genetic variants of moderate penetrance.
   D. For further evaluation of an otherwise suspicious breast lesion on mammogram and/or ultrasound.
   E. For further evaluation of low-suspicion findings on conventional testing not indicated for immediate biopsy and referred for short-interval follow-up.
   F. To evaluate breasts before biopsy in an effort to reduce the number of surgical biopsies for benign lesions.
   G. To confirm silent/asymptomatic rupture of silicone/saline implants.

H. To differentiate benign from malignant breast disease, especially clustered microcalcifications.
I. To diagnose a suspicious breast lesion in order to avoid biopsy.
J. For routine surveillance following bilateral mastectomy.

Refer to Corporate Medical Policy #2.02.06 Genetic Testing for Hereditary BRCA Mutation

Refer to Corporate Medical Policy #2.02.44 Genetic Testing for Susceptibility to Hereditary Cancers

Refer to Corporate Medical Policy #7.01.109 Gender Reassignment/Gender Affirming Surgery and Treatments for Medicaid and HARP Members

Refer to Corporate Medical Policy #7.01.84 Gender Reassignment Surgery

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

Refer to Corporate Medical Policy #11.01.10 Clinical Trials

POLICY GUIDELINE

Use of computer-aided detection (CAD) or 3D Imaging is considered inclusive when performed as part of the Breast MRI.

DESCRIPTION

Magnetic resonance imaging (MRI) is a diagnostic imaging modality that uses magnetic and radiofrequency fields to produce a non-invasive, two-dimensional view of an internal organ or structure. Through radiofrequency emissions, a tomographic image can be constructed that will represent the tissue being analyzed and the environment surrounding it. MRI is designed to identify anatomical abnormalities and to provide information on characteristics of the tissue. Breast MRI generally requires a high field strength system and a dedicated breast surface coil.

Computer-Aided Detection (CAD) for MRI (also referred to as computer-aided evaluation or CAE), unlike CAD systems used with mammography, is not aimed primarily at identifying lesions for consideration by a radiologist. CAD systems for MRI propose to provide easier ways of interpreting the patterns of contrast enhancement and washout across a series of images, which may help identify lesions and their likelihood of being malignant.

Lesions on mammography have a subtle appearance; however, most cancers enhance on MRI. The challenge is determining which lesions are benign and which are malignant. A large number of images are produced during MRI of the breast. Images are taken at varying depths throughout each breast, multiplied by the number of times the breast is imaged to capture different time points in the enhancement process, which can produce hundreds of images. Radiologists view the images to detect suspicious areas, and then may choose a region of interest and look at the enhancement pattern; however, there may be variations across radiologists in the regions of interest selected and in the precise definition of the region of interest. CAE systems use color-coding and differences in hue to indicate the patterns of enhancement for each pixel in the breast image, which may allow radiologists to analyze the enhancement patterns systematically.

RATIONALE

A number of magnetic resonance scanners have received 510(k) premarket clearance by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) for use in the United States. Low-field MRI systems have also received 510(k) premarket clearance by the FDA CDRH, such as the ARTOSCAN (0.2 Tesla magnet) and MAGNA SL (0.3 Tesla magnet). Specialized breast coils such as the OBC-300 Breast Array Coil (MRI Devices Corp., Waukesha, WI) and MR-compatible equipment for performing biopsy have received FDA 510(k) clearance. Computer-aided detection (CAD) systems for use with MRI of the breast have received 510(k) marketing clearance from the FDA, e.g., CADstream (Confirma, Kirkland, WA) and 3TP Software Option (CAD Sciences, White Plains, NY).

Safety Alert: On May 10, 2005, the FDA issued a Public Health Notification reminding radiology personnel and physicians that serious injury or death can occur when patients with implanted neurological stimulators undergo MRI procedures, even if the device has been turned off.

MRI before and after Neoadjuvant Chemotherapy to Guide Decisions to use Breast Conservation Therapy (BCT)

Available studies consistently show that breast MRI appears to be better than conventional presurgical clinical staging methods at determining extent and size of residual tumor. Compared with histopathology, the reference standard, MRI demonstrated the presence of residual tumor with estimated sensitivity ranging from 90-100% and specificity from 50-100%. MRI estimated the size and extent of tumor correctly in comparison with pathologic evaluation in 57%-97% of cases among five studies. As MRI appears to provide a more accurate determination of tumor size and extent compared with clinical staging, it is likely that MRI would be more accurate in determining eligibility for BCT. Using staging results instead of clinical staging for presurgical planning would lead to an improvement in net health outcome by increasing the use of BCT when appropriate and avoiding the need for re-excision surgery when BCT is not appropriate.

A prospective study of 118 women evaluated the accuracy of contrast-enhanced MRI (CE-MRI) mammography for depiction of synchronous contralateral breast cancer in patients with newly diagnosed unilateral breast cancer or high-risk lesions, with histologic analysis or follow-up as a reference. Patients had negative findings in the contralateral breast at physical examination, ultrasound and conventional mammography. CE-MRI showed contralateral lesions in 28 (24%) of 118 patients. Twenty-four of the 28 lesions were detected in patients with dense breasts (BI-RADS breast density category 3 or 4). At histologic analysis, 22 lesions were confirmed as malignant; six were fibroadenomas.

MRI for Early Prediction of Response to Neoadjuvant Chemotherapy

There is insufficient evidence to permit conclusions on the effect on health outcomes of using breast MRI to provide an early prediction of the response to neoadjuvant chemotherapy. Available evidence is limited to a few small studies with inconsistencies in outcome measures, reporting, and use of statistical comparison. Results are not consistent.

MRI for Patients with Personal History of Breast Cancer

Current studies are small and retrospective but suggest some benefit for surveillance MRI after breast cancer treatment. Although MRI may demonstrate new or recurrent cancers earlier than routine mammographic and/or ultrasonographic imaging, the low yield may not be cost-effective in counter-balancing its inherent low specificity and subsequent need for additional imaging and/or tissue biopsy. Many of the articles indicate that prospective studies are necessary to determine which subset of patients, if any, may benefit from MRI surveillance in the setting of previous breast cancer, and whether this early identification translates to improved disease-specific survival.

MRI for Screening High Genetic-risk Patients

Asymptomatic women thought to be at high risk of breast cancer due to genetic risk have a lifetime risk of cancer that is much higher than average. In addition, breast cancer often occurs at a much younger age than average. Traditional screening using mammography is thought to be less sensitive in younger versus older women because of a higher prevalence of dense breast tissue. Clinical evidence shows at least equivalent performance for MRI in terms of sensitivity in detecting breast cancer, compared to mammography. In two published studies, MRI detected 100% of cancer cases, while mammography detected 33%. In one study, the difference between MRI and mammography sensitivity was statistically significant, but not in the other. Presently, there are no studies that adequately define the age of initiation or the appropriate frequency of testing with MRI in high-risk women. The American Cancer Society (ACS) recommends annual screening with MRI as an adjunct to mammography for those at high risk for breast cancer (lifetime risk of 20-25% or greater), for those who received radiation to the chest between 10 to 30 years of age, for those with Li-Fraumeni syndrome and first-degree relatives, and for those with Cowden and Bannayan-Rile-Ruvalcaba syndromes and first-degree relatives. The ACS states that there is insufficient evidence to recommend for or against annual MRI screening for those with a lifetime risk for breast cancer of 15-20%, lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH), atypical ductal hyperplasia (ADH), heterogeneously or extremely dense breast n mammography, or a personal history of breast cancer, including ductal carcinoma in situ (DCIS). The ACS recommends against annual MRI screening for those with a less than 15% lifetime risk of breast cancer.

Lifetime risk of breast cancer may be calculated using the Gail, Claus or the Tyrer-Cuzick model. The Gail model bases its risk estimates on personal risk factors such as current age, age at menarche (first menstrual period), and history of prior breast biopsies, along with any history of breast cancer in first-degree relatives. The Claus model estimates risk based on family history of breast cancer in both first- and second-degree relatives. The Tyrer-Cuzick model takes into account the person's history (age, extended family history of breast and ovarian cancer, childbirth history, history of breast biopsy and its pathology, age of menarche and menopause, exposure to post-menopausal hormones, and Ashkenazi Jewish heritage), as well as the person’s height/weight (higher BMI-body mass index=increased risk). These two models could easily give

different estimates using the same data. Results from any of the risk assessment tools should be discussed by a patient and doctor when being used to decide whether to start MRI screening.

The American College of Radiology Appropriateness Criteria for Breast Cancer (2018) considers Breast MRI for the surveillance of women with greater than or equal to 20% lifetime risk of breast cancer (for example, individuals with genetic predisposition to breast cancer as determined by either gene testing or family pedigree, or individuals with a history of mantle radiation for Hodgkin lymphoma). High-risk patients may be referred for annual screening breast MRI in addition to mammography, preferably after risk assessment and counseling either by personnel trained in the assessment of hereditary breast cancer or by a referring physician who has used a breast cancer risk assessment model. Although there is no direct evidence that MRI reduces mortality, supplementing annual screening with MRI facilitates early disease detection in high-risk patients.

MRI Screening for Detection of Breast Cancer in Patients who have Breast Characteristics Limiting the Sensitivity of Mammography
The American College of Radiology Appropriateness Criteria for Breast Cancer Screening (2017) has indicated that MRI screening may be appropriate for intermediate-risk women, including women with a history of breast cancer, lobular neoplasia, or atypical ductal hyperplasia, or a 15% to 20% lifetime risk of breast cancer.

MRI Screening for Average-risk Patients
Evidence for routine use of MRI in breast cancer screening is limited to studies that compare the sensitivity and specificity of MRI screening to other methods, such as mammography. Such evidence is limited because it does not evaluate the impact on patient outcomes. The American College of Radiology Appropriateness Criteria for Breast Cancer Screening (2017) considers MRI for screening average-risk women with less than 15% lifetime risk of breast cancer usually not appropriate.

Computer-aided Detection (CAD) with MRI/Computer-aided Evaluation (CAE)
There is insufficient evidence to assess whether the use of CAD with MRI of the breast improves intermediate and long-term outcomes. There are no high-quality published studies of the impact of commercially available CAD systems on the sensitivity and specificity of MRI of the breast. Literature is not clear on how CAD systems are to be used. Because CAD is not 100% sensitive, potentially malignant lesions detected on original films are followed up, as well as additional lesions identified by CAD that the radiologist determines should be worked up. In this way, CAD can add to the sensitivity but not the specificity of MRI. With MRI of the breast, the issue is trying to increase the specificity, not the sensitivity, which is already high. Additionally, there is insufficient evidence to assess whether the use of CAD systems would maintain or increase the sensitivity, specificity and recall rates of breast MRI used to screen women at high genetic risk of breast cancer.

Prospective, well-designed, and executed studies that look specifically at the addition of CAD with MRI are needed to determine whether or not the use of CAD provides a positive clinical benefit to patients. Small studies propose the use of CAD to identify lesions that would not need to be biopsied. However, there were false negative findings. The risk of missing cancers and delaying treatment has to be weighed against the opportunity for reducing the number of unnecessary biopsies. The magnitude of this risk cannot be estimated reliably from available studies. Further research is needed that focuses on the incremental value of CAD in large samples and in a variety of settings.

The American College of Radiology Appropriateness Criteria Transgender Breast Cancer Screening (2021)
ACR breast cancer screening recommendations for transgender and gender nonconforming individuals are based on the sex assigned at birth, risk factors, and use of exogenous hormones. There is currently insufficient evidence to determine whether transgender people undergoing hormone therapy have an overall lower, average, or higher risk of developing breast cancer compared to birth-sex controls and there are no long-term studies evaluating the efficacy of breast cancer screening in the transgender population. Therefore, current evidence is based on data extrapolated from cisgender studies and a limited number of cohort studies and case reports published on the transgender community.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN)*

CPT Codes

Code	Description
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	requiring image postprocessing on an independent workstation
76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)
77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral

HCPCS Codes

Code	Description
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral
C8937	Computer-aided detection, including computer algorithm analysis of breast MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)

ICD10 Codes

Code	Description
C50.011-C50.929	Malignant neoplasm of breast, female or male (code range)
C79.81	Secondary malignant neoplasm of breast
D05.00-D05.92	Carcinoma in situ of breast (code range)

Code	Description
L59.9	Disorder of the skin and subcutaneous tissue related to radiation, unspecified
N63.0	Unspecified lump in unspecified breast
Z12.39	Encounter for other screening for malignant neoplasm of breast
Z15.01	Genetic susceptibility to malignant neoplasm of breast
Z80.3	Family history of malignant neoplasm of breast
Z85.3	Personal history of malignant neoplasm of breast
Z92.3	Personal history of irradiation

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*Key Article

KEY WORDS

Breast MRI, CAD MRI.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD# L33585) for Breast Imaging: Mammography/Breast Echography (Sonography)/Breast MRI/Dictograph. Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33585&ver=33&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=All&bc=AggAAAIAgAAA&] accessed 08/04/23.