Cohere Medicare Advantage Policy - Magnetic Resonance Imaging (MRI), Breast

Clinical Guidelines for Medical Necessity Review

Version: 1.1
Revision Date: March 18, 2025

Important Notices

Notices & Disclaimers:

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Other Notices:

Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Magnetic Resonance Imaging (MRI), Breast

Date of last literature review: 10/2/2024
Document last updated: 3/18/2025
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Breast

Benefit Category

Not Applicable

Recommended Clinical Approach

Findings from magnetic resonance imaging (MRI) of the breast should be correlated with the patient's clinical history, physical examination findings, and results from previous imaging (e.g., mammography, ultrasound). MRI may yield findings that are not evident clinically or on mammography or ultrasound; the additional abnormalities detected on MRI may result in a follow-up examination or recommendation for biopsy.[1]

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[2-5]

- Breast Imaging: Breast Echography (Sonography)/Breast MRI/Ductography (L33585)
- Billing and Coding: Breast Imaging: Breast Echography (Sonography)/Breast MRI/Ductography (A52849)
- Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography (L33950)
- Billing and Coding: Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography (A56448)

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of magnetic resonance imaging (MRI), breast. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- There is a risk of malfunction of implanted medical devices (e.g., implanted pacemakers, cochlear implants).
- A potential exists for allergic reactions to contrast material, if used in the study. The MRI department staff will monitor the patient for an allergic reaction and treat as recommended by a physician.[1-3]
- Use of gadolinium-based contrast is not recommended during pregnancy or in patients with acute or chronic kidney injury or disease.[1,6]
- If sedation is used for the study (for anxiety or claustrophobia), there is a risk of over-sedation. The patient will be monitored during the procedure to reduce this risk.
- There is uncertain risk for MR imaging in pregnant patients. The decision to image in a pregnant patient should be made on an individual basis in consultation with the patient's obstetric provider.
- There is a risk of increased healthcare costs and complications from the inappropriate use of additional interventions.[7]

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. Cancer detection rates are improved in high-risk patients compared to use of mammgoraphy alone.[8]
- Reduction in complications and adverse effects from unnecessary procedures. Breast MRI is particularly effective in evaluating complications of breast augmentation.[9]
- Enhanced diagnostic accuracy for complex medical conditions. MRI is stated to be the most sensitive examination for detecting breast cancer, particularly in high-risk screening.[10]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Magnetic resonance imaging (MRI), breast** is considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ **MRI, breast with or without IV contrast,** may be used as a supplement to mammogram or ultrasound for **screening** for **ANY** of the following[11-12]:
    - Personal history of chest radiation treatment between age 10 and 30 years; **OR**
    - Personal history of breast cancer diagnosed before age 50; **OR**
    - Personal history of breast cancer diagnosed after age 50 **AND** dense breasts (heterogeneously dense or extremely dense)[13]; **OR**
    - Personal history of atypical ductal hyperplasia, atypical lobular hyperplasia, or lobular carcinoma in situ **AND** dense breasts (heterogeneously dense or extremely dense)[13]; **OR**
    - Personal history of BRCA1 gene, BRCA2 gene, or TP53 gene mutation (Li-Fraumeni syndrome) **AND** at least 25 years of age; **OR**
    - Personal history of PTEN gene mutation (Cowden and Bannayan-Riley-Ruvalcaba syndromes), STK11/LKB1 gene mutation (Puetz-Jaeger syndrome), PALB2 gene mutation, CDH1 gene mutation, or NF1 gene mutation **AND** at least 30 years of age; **OR**
    - Personal history of ATM gene mutation, CHEK2 gene mutation, NBN gene, BARD1 gene, RAD51C gene, or RAD51D gene mutation AND at least 40 years of age; **OR**
    - First-degree family relative (parent, sibling, child) with BRCA 1 or BRCA2 mutation; **OR**
    - Lifetime breast cancer risk of greater than or equal to 20% using standard risk assessment models; **OR**
    - To detect silicone implant rupture in asymptomatic patients, beginning 3 years after implant, then every 2

years[9,11,15]; **OR**
- To detect suspected breast implant-associated anaplastic large cell lymphoma; **OR**

◆ **MRI, breast with or without IV contrast,** may be used for **ANY** of the following **diagnostic** indications[2,4]:
- When diagnosis is inconclusive, even after standard work-up; **OR**
- Evaluation of the post-operative patient when scar tissue cannot be differentiated from tumors; **OR**
- Patients with positive axillary nodes but no known primary; **OR**
- Patients with known or suspected leak or rupture of a breast implant; **OR**
- Recently diagnosed breast cancer to evaluate tumor extent, including possible chest wall invasion; **OR**
- Recently diagnosed breast cancer before and after neoadjuvant chemotherapy[16]; **OR**
- Recently diagnosed Paget's disease of the breast; **OR**
- Recently diagnosed Phyllodes tumor of the breast; **OR**
- To detect suspected cancer recurrence in patients with a history of mastectomy[17]; **OR**
- To detect suspected cancer recurrence in patients with a history of breast conservation therapy or lumpectomy[17]; **OR**
- To guide biopsy of suspicious MRI findings[18]; **OR**
- To guide presurgical localization of MRI findings[18]; **OR**
- To further evaluate suspicious breast symptoms such as bloody or clear nipple discharge, nipple retraction, or palpable breast mass following a benign or inconclusive mammogram or ultrasound[19]; **OR**
- To follow-up a probably benign finding (BI-RADS 3) seen on prior MRI, every 6 months for up to 2 years total; **OR**
- To further evaluate positive or close surgical margins following breast surgery[17]; **OR**
- To evaluate the extent of disease of newly diagnosed high-risk benign findings, including lobular carcinoma in situ, atypical lobular hyperplasia, atypical ductal hyperplasia, papillary neoplasm, radial scar, or complex sclerosing lesion; **OR**

- One-time follow-up after a benign MRI-guided biopsy in 6 months; **OR**
- Family history of first-degree male relative (father, brother) with breast cancer; **OR**

◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

* NOTE: Inappropriate uses of MRI of the breast: MRI should not supplant careful problem-solving mammographic views or ultrasound in the diagnostic setting. MRI should not be used in lieu of a biopsy of a suspicious finding identifiable by mammography, ultrasound, or clinical examination.[1]
**NOTE: Ultrasound is generally the primary imaging modality used in young patients, aiding in the initial diagnosis, assisting in imaging-guided biopsy when indicated, and offering a safe method of follow-up. In the pediatric patient, MRI of the breast is rarely used, though in select cases, it may be useful for surgical planning or assessing the extent of disease.[20]

Non-Indications

➔ **Magnetic resonance imaging (MRI), breast** is not considered appropriate if **ANY** of the following is **TRUE**:

◆ If contrast is used, history of anaphylactic allergic reaction to gadolinium contrast media with detailed guidelines for use in patients with renal insufficiency; **OR**

◆ The patient has metallic clips on vascular aneurysms; **OR**

◆ Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**

◆ Metallic foreign body in orbits/other critical area(s) or within the field of view and obscuring area of concern.

*NOTE: MRI in patients with claustrophobia should be requested at the discretion of the ordering provider.
**NOTE: MRI in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
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
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

Medical Evidence

Lobig et al. (2023) conducted a systematic review to evaluate the evidence surrounding supplemental screening methods among asymptomatic women with dense breasts, stratified by their breast cancer risk. Research comparing functional imaging methods like MRI and contrast-enhanced mammography (CEM) to conventional ultrasound for supplemental breast cancer screening in women with dense breasts remains limited. The sole randomized controlled trial (RCT) on MRI indicated its superior screening efficacy compared to other modalities in dense breast populations with an average risk of breast cancer. However, evidence regarding the effectiveness of MRI in women with intermediate breast cancer risk is minimal. A single study examined CEM as an alternative to MRI due to its high cancer detection and low interval cancer rates. Regardless of the screening modality, all women with dense breasts may derive benefits from supplemental screening following mammography or digital breast tomosynthesis (DBT). Additional research on women with average breast cancer risk and dense breasts is needed.[21]

Yeh et al. (2020) conducted a comparative modeling study on the clinical benefits and harms of breast cancer screening for survivors of childhood cancer treated with chest radiation. The study, funded by the American Cancer Society and National Institutes of Health, utilized data from the Childhood Cancer Survivor Study and existing published literature. The target population was females at least 20 years of age with a history of chest radiotherapy. Implementing annual MRI screenings, with or without mammography (commencing at ages 25, 30, or 35 years), shows the potential to reduce breast cancer mortality by 50% or more among survivors of childhood cancer.[22]

Kaneda and colleagues (2013) reviewed the literature regarding pediatric breast masses and stated that most are benign lesions, often secondary to normal developmental changes. Obtaining family history is important in treating these patients. MRI is less frequently used than ultrasound in pediatric patients; however, it may be found to be useful in surgical planning or assessing extent of disease. MRI screening is recommended in women who have received radiation to the chest, as this patient group is at increased risk for development of breast cancer.[20]

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Clinical Guideline Revision History/Information

Original Date: October 3, 2024		
Review History		
Version 1.1	3/18/2025	• Updated policy per CMS revisions for 12/5/2024 • Updated Effective date • Updated Links and Bookmarks