



Cohere Medical Policy – Magnetic Resonance Imaging (MRI), Breast

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: August 29, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE’S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

Cohere Health, Inc. (“**Cohere**”) has published these clinical guidelines to determine the medical necessity of services (the “**Guidelines**”) for informational purposes only, and solely for use by Cohere’s authorized “**End Users**”. These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice.

©2024 Cohere Health, Inc. All Rights Reserved.

Other Notices:

HCPCS® and CPT® copyright 2024 American Medical Association. All rights reserved.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS and CPT are registered trademarks of the American Medical Association.

Guideline Information:

Specialty Area: Diagnostic Imaging

Guideline Name: Cohere Medical Policy – Magnetic Resonance Imaging (MRI), Breast

Date of last literature review: 8/27/2024

Document last updated: 8/29/2024

Type: Adult (18+ yo) | Pediatric (0-17 yo)

Table of Contents

Important Notices	2
Table of Contents	3
Medical Necessity Criteria	4
Service: Magnetic Resonance Imaging (MRI), Breast	4
Recommended Clinical Guidelines	4
Medical Necessity Criteria	4
Indications	4
Non-Indications	7
Level of Care Criteria	8
Procedure Codes (CPT/HCPCS)	8
Medical Evidence	10
References	12
Clinical Guideline Revision History/Information	16

Medical Necessity Criteria

Service: Magnetic Resonance Imaging (MRI), Breast

Recommended Clinical Guidelines

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

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^{3,16}:

- 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)⁷; **OR**
- Personal history of atypical ductal hyperplasia, atypical lobular hyperplasia, or lobular carcinoma in situ **AND** dense breasts (heterogeneously dense or extremely dense)⁷; **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 BRCA1 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^{3,21-22}; **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** indications²²:
- Recently diagnosed breast cancer to evaluate tumor extent; **OR**
 - Recently diagnosed breast cancer before and after neoadjuvant chemotherapy⁹; **OR**
 - Recently diagnosed Paget’s disease of the breast; **OR**
 - Recently diagnosed Phyllodes tumor of the breast; **OR**
 - To detect silicone breast implant rupture in symptomatic patients^{3,21-22}; **OR**
 - To detect suspected cancer recurrence in patients with a

history of mastectomy¹⁰; **OR**

- To detect suspected cancer recurrence in patients with a history of breast conservation therapy or lumpectomy¹⁰; **OR**
- To guide biopsy of suspicious MRI findings¹⁵; **OR**
- To guide presurgical localization of MRI findings¹⁵; **OR**
- To identify occult breast cancer in patients with distant or nodal metastasis but benign mammogram or ultrasound;
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 ultrasound¹²; **OR**
- To further evaluate inconclusive or indeterminate findings on mammogram or ultrasound¹²; **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 surgery¹⁰; **OR**
- To follow-up suspicious MRI findings recommended for surgery in patients who are not surgical candidates; **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 of a specific area or structure using the same imaging modality is considered appropriate when **ALL** of the

following is **TRUE**:

- There is documented clinical necessity; **AND**
- No existing follow-up guideline for that indication; **AND**
- Prior imaging results of the specific area or structure, obtained using the same imaging modality, must be documented and available for comparison; **AND**
- **ANY** of the following is **TRUE**:
 - A change in clinical status, such as worsening symptoms or the emergence of new symptoms, that may influence the treatment approach; **OR**
 - The requirement for interval reassessment, which may alter the treatment plan; **OR**
 - One-time follow-up of a prior indeterminate finding to assess for interval change; **OR**
 - The need for re-imaging either before or after performing an invasive procedure.

* 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.³

**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.²³

Non-Indications

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

- ◆ The patient has undergone advanced imaging of the same body

part within 3 months without undergoing treatment or developing new or worsening symptoms; **OR**

- ◆ 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.¹⁹

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.²¹

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.²³

References

1. American College of Radiology (ACR). ACR practice parameter for performing and interpreting magnetic resonance imaging (MRI) – resolution 8. Updated 2022. Accessed August 13, 2024. <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Perf-Interpret.pdf>.
2. Expert Panel on Breast Imaging, Chetlen A, Niell BL, et al. ACR appropriateness criteria – breast implant evaluation: 2023 update. *J Am Coll Radiol*. 2023 Nov;20(11S):S329–S350. doi: 10.1016/j.jacr.2023.08.019. PMID: 38040459.
3. American College of Radiology (ACR). ACR practice parameter for the performance of contrast-enhanced magnetic resonance imaging (MRI) of the breast – resolution 8. Updated 2023. Accessed August 13, 2024. <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/mr-contrast-breast.pdf>.
4. Expert Panel on Breast Imaging, Niell BL, Jochelson MS, et al. ACR appropriateness criteria – female breast cancer screening. Updated 2023. Accessed August 13, 2024. <https://acsearch.acr.org/docs/70910/Narrative/>.
5. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines: Genetic/familial high-risk assessment: Breast, ovarian, and pancreatic (ver. 3.2024). Published February 12, 2024. Accessed August 13, 2024. https://www.nccn.org/professionals/physician_gls/pdf/genetics_bop.pdf.
6. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines: Breast cancer screening and diagnosis (ver. 3.2023). Published October 31, 2023. Accessed August 13, 2024. https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf.
7. Expert Panel on Breast Imaging, Weinstein SP, Slanetz PJ, et al. ACR appropriateness criteria – supplemental breast cancer screening

- based on breast density. *J Am Coll Radiol*. 2021 Nov;18(11S):S456–S473. doi: 10.1016/j.jacr.2021.09.002. PMID: 34794600.
8. Expert Panel on Breast Imaging, McDonald ES, Scheel JR, et al. ACR appropriateness criteria – imaging of invasive breast cancer. Published 2023. Accessed August 13, 2024. <https://acsearch.acr.org/docs/3186697/Narrative>.
 9. Expert Panel on Breast Imaging, Hayward JH, Linden OE, et al. ACR appropriateness criteria – monitoring response to neoadjuvant systemic therapy for breast cancer: 2022 update. *J Am Coll Radiol*. 2023 May;20(5S):S125–S145. doi: 10.1016/j.jacr.2023.02.016. PMID: 37236739.
 10. Expert Panel on Breast Imaging, Mehta TS, Lourenco AP, et al. ACR appropriateness criteria – imaging after breast surgery. *J Am Coll Radiol*. 2022 Nov;19(11S):S341–S356. doi: 10.1016/j.jacr.2022.09.003. PMID: 36436961.
 11. Expert Panel on Breast Imaging, Lewin AA, Moy L, et al. ACR appropriateness criteria – stage I breast cancer: Initial workup and surveillance for local recurrence and distant metastases in asymptomatic women. *J Am Coll Radiol*. 2019 Nov;16(11S):S428–S439. doi: 10.1016/j.jacr.2019.05.024. PMID: 31685110.
 12. Giess CS, Chikarmane SA, Sippo DA, et al. Clinical utility of breast mri in the diagnosis of malignancy after inconclusive or equivocal mammographic diagnostic evaluation. *AJR Am J Roentgenol*. 2017 Jun;208(6):1378–1385. doi: 10.2214/AJR.16.16751. PMID: 28267372.
 13. Bennani-Baiti B, Bennani-Baiti N, Baltzer PA. Diagnostic performance of breast magnetic resonance imaging in non-calcified equivocal breast findings: Results from a systematic review and meta-analysis. *PLoS One*. 2016 Aug 2;11(8):e0160346. doi: 10.1371/journal.pone.0160346. PMID: 27482715; PMCID: PMC4970763.
 14. Berger N, Luparia A, Di Leo G, et al. Diagnostic performance of MRI versus galactography in women with pathologic nipple discharge: A systematic review and meta-analysis. *AJR Am J Roentgenol*. 2017 Aug;209(2):465–471. doi: 10.2214/AJR.16.16682. PMID: 28537847.
 15. American College of Radiology (ACR). ACR practice parameter for the performance of magnetic resonance imaging-guided breast interventional procedures – resolution 29. Updated 2021. Accessed

August 13, 2024.

<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Guided-Breast.pdf>.

16. Expert Panel on Breast Imaging, Le-Petross HT, Slanetz PJ, et al. ACR appropriateness criteria – imaging of the axilla. *J Am Coll Radiol*. 2022 May;19(5S):S87–S113. doi: 10.1016/j.jacr.2022.02.010. PMID: 35550807.
17. Grobner T. Gadolinium – a specific trigger for the development of nephrogenic fibrosing dermopathy and nephrogenic systemic fibrosis? *Nephrol Dial Transplant*. 2006 Apr;21(4):1104–8. doi: 10.1093/ndt/gfk062. PMID: 16431890. Erratum in: *Nephrol Dial Transplant*. 2006 Jun;21(6):1745.
18. Lobig F, Caleyachetty A, Forrester L, et al. Performance of supplemental imaging modalities for breast cancer in women with dense breasts: Findings from an umbrella review and primary studies analysis. *Clin Breast Cancer*. 2023 Jul;23(5):478–490. doi: 10.1016/j.clbc.2023.04.003. PMID: 37202338.
19. Comstock CE, Gatsonis C, Newstead GM, et al. Comparison of abbreviated breast MRI vs digital breast tomosynthesis for breast cancer detection among women with dense breasts undergoing screening. *JAMA*. 2020 Feb 25;323(8):746–756. doi: 10.1001/jama.2020.0572. PMID: 32096852; PMCID: PMC7276668. Erratum in: *JAMA*. 2020 Mar 24;323(12):1194. doi: 10.1001/jama.2020.2991. PMID: 32207778.
20. Yeh JM, Lowry KP, Schechter CB, et al. Clinical benefits, harms, and cost-effectiveness of breast cancer screening for survivors of childhood cancer treated with chest radiation : A comparative modeling study. *Ann Intern Med*. 2020 Sep 1;173(5):331–341. doi: 10.7326/M19–3481. PMID: 32628531; PMCID: PMC7510774.
21. Noreña-Rengifo BD, Sanín-Ramírez MP, Adrada BE, et al. MRI for evaluation of complications of breast augmentation. *Radiographics*. 2022 Jul-Aug;42(4):929–946. doi: 10.1148/rg.210096. PMID: 35559662.
22. United States Food and Drug Administration (FDA). Breast implants – certain labeling recommendations to improve patient communication: guidance for industry and Food and Drug Administration staff. Published September 29, 2020. Accessed August 13, 2024. <https://www.fda.gov/media/131885/download>.

23. Kaneda HJ, Mack J, Kasales CJ, et al. Pediatric and adolescent breast masses: a review of pathophysiology, imaging, diagnosis, and treatment. *AJR Am J Roentgenol*. 2013 Feb;200(2):W204-12. doi: 10.2214/AJR.12.9560. PMID: 23345385.

Clinical Guideline Revision History/Information

Original Date: April 1, 2022

Review History

Version 2	08/29/2024	Annual review and policy restructure.