



<b>*National Imaging Associates, Inc.</b>	
<b>Clinical guidelines BREAST MRI</b>	<b>Original Date: September 1997</b>
<b>CPT Codes: Unilateral without contrast 77046 Bilateral without contrast 77047 Unilateral without and with contrast 77048 Bilateral without and with contrast 77049 +0698T</b>	<b>Last Revised Date: May 2023</b>
<b>Guideline Number: NIA_CG_023</b>	<b>Implementation Date: January 2024</b>

### GENERAL INFORMATION

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

### INDICATIONS FOR BREAST MRI

See [Legislative Requirements](#) for specific mandates in: Commonwealth of Pennsylvania; State of Connecticut; State of Illinois; State of North Carolina, State of Ohio

### NO HISTORY OF KNOWN BREAST CANCER<sup>+</sup>

#### Dense breast tissue on mammography

- Inconclusive screening mammogram when category 0 has been specifically assigned due to breast characteristics limiting the sensitivity of mammography (e.g., extremely or heterogeneously dense breast, implants obscure breast tissue)

#### High risk screening breast MRI

- A Breast Cancer Risk Assessment (including the Breast Cancer Consortium Risk Model (BCSC) which incorporates breast density, the International Breast Cancer Intervention Study (IBIS)/

Tyrer-Cuzick model, the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm model (BOADICEA), the modified Gail (also known as the Breast Cancer Risk assessment tool (BCRAT)) or other validated risk assessment models) that identifies the patient as having a lifetime risk of 20% or greater of developing breast cancer<sup>1</sup>

- Approve annually beginning 10 years prior to youngest family member's age at diagnosis or at age 40, whichever comes first, but not before age 25<sup>2-6</sup>
- Patients with lifetime risk of 20% or greater of developing breast cancer based on history of lobular neoplasia (LCIS/ALH (Lobular Carcinoma in Situ /Atypical Lobular Hyperplasia)) or ADH (atypical ductal hyperplasia)
  - Approve annually beginning at age of diagnosis of LCIS/ALH or ADH but not prior to age 25<sup>2</sup>
- Patients with intermediate lifetime risk (15%-20%) of developing breast cancer based on a history lobular neoplasia (LCIS/ALH (Lobular Carcinoma in Situ /Atypical Lobular Hyperplasia)) or ADH (atypical ductal hyperplasia)) AND have dense breast tissue on mammography
  - Approve annually beginning at age of diagnosis of LCIS/ALH or ADH but not prior to age 25<sup>2, 7, 8</sup>
- Patients with history of extensive chest irradiation (usually as treatment for Hodgkin's or other lymphoma between ages ten and thirty)
  - Begin eight years after radiation, but not prior to age 25<sup>2</sup>
- Patients with known *BRCA 1/2* mutation
  - Approve annually starting at age 25<sup>2, 3</sup>
- Patients not yet tested for *BRCA* gene, but with known *BRCA* mutation in first-degree relative
  - Approve annually starting at age 25<sup>2, 3</sup>
- Personal history of germline mutations known to predispose to a high risk of breast cancer:<sup>1</sup>
  - Li-Fraumeni syndrome (*TP53* mutation)
    - Begin age 20-29 or age at earliest diagnosed breast cancer in family, if younger than age 20
  - Cowden syndrome (*PTEN*) or Bannayan-Riley-Ruvalcaba syndrome (BRRS)
    - Begin age 35 or 10 years before earliest breast cancer diagnosis in family, whichever comes first (NCCN 2022)
  - *ATM*
    - Begin age 30-35 years
  - *BARD1*
    - Begin age 40
  - *CDH1*
    - Begin age 30
  - *CHEK2*
    - Begin age 30-35 years
  - *NF1*
    - Begin age 30, end age 50<sup>2</sup>
  - *PALB2*
    - Begin age 30

- Peutz-Jeghers Syndrome (*STK11*)
  - Begin age 30
- RAD51C
  - Begin age 40
- RAD51D
  - Begin age 40

<sup>+</sup>For screening examination to detect breast cancer in any of the following situations. It is appropriate to perform screening breast MRI at routine intervals in patients at increased risk who are lactating.

Contrast-enhanced MRI is not recommended during pregnancy due to the trans-placental passage of gadolinium and potential concern for the exposure of the fetus to gadolinium.

**For evaluation of identified lesion, mass, or abnormality in breast in any of the following situations**

- Evaluation of suspected breast cancer when other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer, and biopsy could not be performed (e.g., seen only in single view mammogram without ultrasound correlation)
  - Includes skin changes of suspected inflammatory breast cancer if conventional imaging and skin biopsies are first performed and negative<sup>3, 9, 10</sup>
- For evaluation of suspicious mass, lesion, distortion, or abnormality of the breast in patient with history of breast cancer when other imaging is inconclusive
- For cases of new nipple inversion when mammographic and sonographic findings are inconclusive, and a biopsy cannot be performed<sup>11-13</sup>
- Patients diagnosed with biopsy-proven lobular neoplasia, i.e., LCIS/ALH (Lobular Carcinoma in Situ /Atypical Lobular Hyperplasia) or ADH (atypical ductal hyperplasia)<sup>2, 3, 14, 15</sup>
- Spontaneous unilateral serous or bloody nipple discharge when conventional imaging is interpreted as BI-RADS 1-3 and there is no palpable mass thought to be related to the discharge<sup>2, 3, 16</sup>
- Paget’s disease of the nipple: to detect underlying ductal carcinoma when conventional imaging is interpreted as BI-RADS 1-3 and there is no palpable mass<sup>3</sup>
- For a phyllodes tumor diagnosed by biopsy, breast MRI may help determine extent of disease and resectability in selected cases. However routine use for surgical planning is controversial<sup>17-19</sup>
- Follow-up of a probably benign (BI-RADS 3) lesion seen only on prior MRI (when prior mammogram and ultrasound did not show the abnormality)<sup>20-22</sup>

**HISTORY OF KNOWN BREAST CANCER**

- Yearly surveillance for history of breast cancer and dense breast tissue on mammography<sup>4</sup>
- Yearly surveillance for individuals with personal history of breast cancer diagnosed before age 50<sup>4</sup>



- Yearly surveillance in patients with genetic or other risk factors placing them at high risk for a new cancer or recurrence<sup>3, 23</sup>
- Yearly surveillance for individuals with a mammographically occult primary breast cancer<sup>24</sup>.

### Staging, treatment, and surveillance of patients with a known history of Breast Cancer

- Approve for initial staging when conventional imaging is indeterminate in defining the extent of cancer, or presence of multifocal, multicentric, or contralateral cancer, or if there is a discrepancy in estimated tumor size between physical exam and imaging<sup>2, 3, 14</sup>
- For invasive lobular carcinoma that is poorly or inadequately defined by mammography, ultrasound, or physical exam<sup>2, 14</sup>
- To identify primary cancer in a patient with axillary nodal adenocarcinoma and unidentified primary tumor<sup>2</sup>
- Prior to treatment: To serve as a baseline for comparison prior to a patient starting planned neoadjuvant chemotherapy<sup>25</sup>  
During or after treatment: To identify candidates for breast conserving therapy or evaluate response to treatment, including preoperative neoadjuvant therapy [within three (3) months]<sup>3</sup>

### Silicone Implants

MRI is not indicated for evaluation of saline implant complications or for asymptomatic silicone implants.<sup>4, 26</sup>

- Confirmation of suspected silicone gel-filled breast implant ruptures in *asymptomatic* patients, after an abnormal or indeterminate finding on mammography or breast ultrasound
- MRI is considered the gold standard for evaluation of symptomatic silicone implant rupture.<sup>3, 4</sup> Prior imaging is not required in patients with silicone implants and symptoms of possible rupture.
- For postoperative evaluation of silicone breast implant complications when other imaging is inconclusive

### Pre-operative

- For preoperative evaluation for known breast cancer when surgery planned within thirty (30) days to be determined on a case-by-case basis<sup>3, 14, 27, 28</sup>

### Post-operative/procedural evaluation

A follow-up study may be needed to help evaluate a patient's progress after treatment, procedure, intervention, or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested<sup>4</sup>

### Other Indications

Further evaluation of indeterminate findings on prior imaging (unless follow up is otherwise specified within the guideline):

- For initial evaluation of an inconclusive finding on a prior imaging report that requires further clarification
- One follow-up exam of a prior indeterminate MR/CT finding to ensure no suspicious interval change has occurred. (No further surveillance unless specified as highly suspicious or change was found on last follow-up exam.)

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## LEGISLATIVE REQUIREMENTS

- **Commonwealth of Pennsylvania**
  - The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows: Section 632 - Coverage for Mammographic Examinations and [Diagnostic] Breast Imaging and of the act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921.
  - A group or individual health or sickness or accident insurance policy providing hospital or medical/surgical coverage and a group or individual subscriber contract or certificate issued by any entity subject to 40 Pa.C.S. Ch. 61 or 63, this act, the "Health Maintenance Organization Act," the "Fraternal Benefit Society Code" or an employe welfare benefit plan as defined in section 3 of the Employee Retirement Income Security Act of 1974 providing hospital or medical/surgical coverage shall also provide coverage for breast imaging.
    - The minimum coverage required shall include
      - supplemental magnetic resonance imaging or, if such imaging is not possible, ultrasound if recommended by the treating physician
      - all costs associated with one supplemental breast screening every year because the woman is believed to be at an increased risk of breast cancer due to:
        - personal history of atypical breast histologies
        - personal history or family history of breast cancer
        - genetic predisposition for breast cancer
        - prior therapeutic thoracic radiation therapy
        - heterogeneously dense breast tissue based on breast composition categories of the Breast Imaging and Reporting Data System established by the American College of Radiology with any one of the following risk factors
          - lifetime risk of breast cancer of greater than 20%, according to risk assessment tools based on family history;
          - personal history of BRCA1 or BRCA2 gene mutations;

- first-degree relative with a BRCA1 or BRCA2 gene mutation but not having had genetic testing herself;
  - prior therapeutic thoracic radiation therapy between 10 and 30 years of age; or
  - personal history of Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes; or
  - extremely dense breast tissue based on breast composition (categories of the Breast Imaging and Reporting Data System established by the American College of Radiology)
- Nothing in this subsection shall be construed to require an insurer to cover the surgical procedure known as mastectomy or to prevent the application of deductible, copayment or coinsurance provisions contained in the policy or plan.
- Nothing in this subsection shall be construed as to preclude utilization review as provided under Article XXI of this act or to prevent the application of deductible, copayment or coinsurance provisions contained in the policy or plan for breast imaging in excess of the minimum coverage required.
- As used in this section: "Supplemental breast screening" means a medically necessary and clinically appropriate examination of the breast using either standard or abbreviated magnetic resonance imaging or, if such imaging is not possible, ultrasound if recommended by the treating physician to screen for breast cancer when there is no abnormality seen or suspected in the breast.

**Source:** Pennsylvania General Assembly, Senate Bill 8, Amended May 01, 2023<sup>29</sup>

- **State of Connecticut**

- CT ST § 38a-530. Effective: October 1, 2020
  - Coverage for breast MRI is mandated within the State of Connecticut without coinsurance, copay of more than \$20 deductible, or other out of pocket expenses for women with dense breast tissue if the woman is believed to be at increased risk of breast cancer because of family or personal history of breast cancer, positive genetic testing. Coverage is also mandated for other indications determined by a woman's physician, or when screening is recommended by a physician and the woman is over age 40, has a family or prior history of breast cancer or has breast disease diagnosed through biopsy as benign. This applies to high deductible plans unless plans are used to establish an HRA or HSA to the extent permitted by federal law. Though not designated in the original intent of the bill, language includes the above provisions and criteria for breast MRI.
- Source: Connecticut General Assembly<sup>30</sup>

- **State of North Carolina**

- Medicaid and NCHC cover magnetic resonance imaging (MRI) for the detection of:
  - Breast cancer in beneficiaries who are at a high genetic risk for breast cancer:
    - known BRCA 1 or 2 mutation in beneficiary;
    - known BRCA 1 or 2 mutation in relatives; or
    - pattern of breast cancer history in multiple first-degree relatives, often at a young age and bilaterally.
  - Breast cancer in beneficiaries who have breast characteristics limiting the sensitivity of mammography (such as dense breasts, implants, scarring after treatment for breast cancer).
  - A suspected occult breast primary tumor in beneficiaries with axillary nodal adenocarcinoma with negative mammography and clinical breast exam.
  - Breast cancer in beneficiaries with a new diagnosis of breast cancer. It can be used to determine the extent of the known cancer and/or to detect disease in the contralateral breast.
  - To evaluate implant integrity in beneficiaries with breast implants.
- Source: NC Medicaid<sup>31</sup>; amended September 15, 2020

- **State of Illinois**

Commercial, Exchange, and Medicaid

- MRI of the entire breast or breasts is approvable for individuals 35 years or older
  - if a mammogram demonstrates heterogenous or dense breast tissue **OR**
  - when determined medically necessary by a physician licensed to practice medicine in all of its branches
- Screening breast MRI approvable when determined medically necessary by a physician licensed to practice medicine in all of its branches

**Source:** Illinois General Assembly

[Illinois General Assembly - Full Text of SB0162 \(ilga.gov\)](#)<sup>32</sup>

- **State of Ohio**

Medicaid

- Section 1 (A)(3): "Supplemental breast cancer screening" means any additional screening method deemed medically necessary by a treating health care provider for proper breast cancer screening in accordance with applicable American college of radiology guidelines, including magnetic resonance imaging, ultrasound, or molecular breast imaging.
- Section 1 (C)(2) The benefits provided under division (B)(2) of this section shall cover expenses for supplemental breast cancer screening for an adult woman who meets either of the following conditions:

- (a) The woman's screening mammography demonstrates, based on the breast imaging reporting and data system established by the American college of radiology, that the woman has dense breast tissue;
- (b) The woman is at an increased risk of breast cancer due to family history, prior personal history of breast cancer, ancestry, genetic predisposition, or other reasons as determined by the woman's health care provider.

Source: Ohio General Assembly – HB 371<sup>33</sup>  
[AM 134 3269-1 \(state.oh.us\)](#)

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## BACKGROUND

Magnetic resonance imaging (MRI) of the breast is a useful tool for the detection and characterization of breast disease, assessment of local extent of disease, evaluation of treatment response, and guidance for biopsy and localization.<sup>34</sup> Breast MRI should always be bilateral to allow for assessment of symmetry between the breasts. MRI findings should be correlated with clinical history, physical examination, and the results of mammography and any other prior breast imaging.

## OVERVIEW

**MRI and risk evaluation** – The age of a family member’s diagnosis is **only** relevant for patients under the age of 40. Anyone 40 or over should be getting annual mammograms and breast MRIs if their lifetime risk is 20% or greater.

**Nipple discharge** – Nipple discharge is a common complaint with at least 80% of women having at least 1 episode. Discharge that is considered pathologic is unilateral, spontaneous, from one duct orifice and serous or bloody. Physiologic discharge will be bilateral, from multiple ducts, and white, green, or yellow in color. “In general, MRI may be considered in cases in which **mammography and US** have failed to identify an underlying cause of pathologic nipple discharge. The sensitivities of breast MRI for detecting the cause of the pathologic nipple discharge are 86% to 100% for invasive cancer and 40% to 100% for noninvasive disease”.<sup>35</sup> Ductography (galactography) has the ability to demonstrate small lesions in the specific duct that is secreting the pathologic nipple discharge. However, it is invasive and may cause discomfort and pain. It can be time-consuming and technically challenging and the rate of inadequate or incomplete ductography is as high as 15%. The discharge must be present on the day of the study so that a cannula can be placed in the appropriate duct. Failure to cannulate the discharging duct may occur and cannulation of the wrong duct may cause a false-negative ductogram.<sup>35</sup>

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## POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"><li>• Updated background</li><li>• Updated references</li><li>• Added dense breast to indications for breast MRI</li><li>• Change screening ages based on society recommendations for high-risk conditions</li><li>• Added language regarding lactating and pregnant patients</li><li>• General Information moved to beginning of guideline with added statement on clinical indications not addressed in this guideline</li><li>• Added statement regarding further evaluation of indeterminate findings on prior imaging</li></ul>
September 2022	Added mandate language for State of Illinois
June 2022	<ul style="list-style-type: none"><li>• Added criteria for an intermediate lifetime risk of breast cancer</li><li>• Reformatted mandates</li></ul>
April 2022	<ul style="list-style-type: none"><li>• Revised high-risk screening section for germline mutations</li><li>• Updated background section on genetic syndromes</li><li>• Updated citations</li></ul>

## Reviewed / Approved by NIA Clinical Guideline Committee

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