

Evolent Clinical Guideline ~~023-2014~~ for Breast Magnetic Resonance Imaging (MRI)

Guideline or Policy Number: Evolent_CG_ 023 <u>2014</u>	<u>Applicable Codes</u>		
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STATEMENT

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.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

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. Breast MRI is typically 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.

~~NOTE: 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.~~

Special Note

Legislative Language

See Legislative Language for specific mandates in: ~~State of Connecticut~~, State of Illinois, State of North Carolina, State of Ohio, Commonwealth of Pennsylvania, State of Washington.

INDICATIONS

For screening examination to detect breast cancer in any of the following situations.

NOTE: It is appropriate to perform screening breast MRI at routine intervals in patients at increased risk who are lactating but not during pregnancy.-

~~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.~~

No History of Known Breast Cancer

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 Breast Cancer Screening ^(1,2)

Annual screening with Breast MRI for any **ONE** of the following:

NOTE: Screening occurs annually. The age at which to start screening is specific to the reason the individual qualifies for screening with Breast MRI. For **ALL** of the indications below, screening may start 10 years prior to the earliest family member's age at diagnosis.

- Lifetime risk of developing breast cancer $\geq 20\%$ based on a validated risk assessment model (e.g., Tyrer-Cuzick, BRCAPro, CanRisk/BOADICEA) starting at age 40
- Personal history of atypical hyperplasia (AH) (ductal or lobular) or lobular carcinoma in situ (LCIS) AND $\geq 20\%$ lifetime risk of breast cancer starting at diagnosis of AH/LCIS but not prior to age 25 ⁽³⁾ 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 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 ^(2,3,4,5)
- 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 ⁽²⁾
- 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 mammogram
- Approve annually beginning at age of diagnosis of LCIS/ALH or ADH but not prior to age 25 ^(2,6) Begin eight years after radiation, but not prior to age 25 ⁽²⁾
- Patients with history of extensive chest irradiation (usually as treatment for Hodgkin's or other lymphoma between ages ~~ten~~ 10 and ~~thirty~~ 30) starting 8 years after radiation, but not prior to age 25
-

Being eight years after radiation, but not prior to age 25 ⁽²⁾ Increased breast density characterized as "extremely dense" (American College of Radiology (ACR) Category D) starting

at age 50 ⁽²⁾

- **NOTE:** Screening starting at age 40 may be considered on a case-by-case basis
- Increased breast density characterized as “heterogeneously dense” (ACR Category C) **AND** intermediate lifetime risk of 15-20% based on a validated risk assessment model starting at age 50
 - **NOTE:** Screening starting at age 40 may be considered on a case-by-case basis
- 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)
- Known personal genetic mutation:
 - ATM (Ataxia-Telangiectasia): annually starting at age 25 yrs in females ^(3,4)
 - BARD1: annually starting at age 40 yrs ⁽³⁾
 - BRCA1: annually beginning at age 25 yrs **OR** ^(3,5)
 - Earlier Annually (beginning at any age) ~~(any age)~~ with positive family history for breast cancer diagnosed at age < 30 yrs
 - BRCA2: beginning at age 25 yrs **OR** ^(3,5)
 - Earlier Annually (beginning at any age) ~~(any age)~~ with positive family history for breast cancer diagnosed at age < 30 yrs
 - CDH1: annually starting at age 30 yrs ⁽³⁾
 - CHEK2: annually starting at age 30 yrs ⁽³⁾
 - Li-Fraumeni (TP53): annually starting at age 20 yrs ^(3,6)
 - Neurofibromatosis 1 (NF1): annually starting at age 30 yrs ^(3,7)
 - PALB2: annually starting at age 30 yrs ⁽³⁾
 - PTEN: annually starting at age 30 yrs **OR** ⁽⁸⁾
 - 10 yrs younger than the earliest breast cancer diagnosis in the family, whichever is earlier
 - RAD51C: annually starting at age 40 yrs **OR** ⁽³⁾
 - 10 yrs younger than the earliest breast cancer diagnosis in the family, whichever is earlier
 - RAD51D: annually starting at age 40 yrs **OR** ⁽³⁾
 - 10 yrs younger than the earliest breast cancer diagnosis in the family, whichever is earlier
 - STK11 (Peutz-Jeghers Syndrome): annually starting at age 30 yrs ⁽⁹⁾
- Known family history of a positive BRCA1 or BRCA2 mutation in a first degree relative and genetic testing is not yet completed: starting at age 25 yrs

~~Patients with known *BRCA 1/2* mutation~~

~~Approve annually starting at age 25^(2,4)~~

~~Patients not yet tested for *BRCA* gene, but with known *BRCA* mutation in first-degree relative~~

~~Approve annually starting at age 25^(2,4)~~

~~Personal history of germline mutations known to predispose to a high risk of breast cancer:⁽⁴⁾~~

~~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⁽²⁾~~

~~*PALB2*~~

~~Begin age 30~~

~~Peutz-Jeghers Syndrome (*STK11*)~~

~~Begin age 30~~

~~*RAD51C*~~

~~Begin age 40~~

~~*RAD51D*~~

~~Begin age 40~~

For Evaluation of Identified Lesion, Mass or Abnormality

- For any **ONE** of the following:
 - Biopsy proven atypical hyperplasia (AH) (ductal or lobular)
 - Biopsy proven lobular carcinoma in situ (LCIS)
 - Skin biopsy positive for Paget Disease⁽¹⁰⁾

- Follow-up of a BI-RADS 3 lesion on prior MRI **AND** not present on ultrasound or mammogram. Short-term follow-up intervals are typically at 6, 12, and 24 months following the post the initial assessment. ⁽¹¹⁾m
- Phyllodes tumor that is malignant, suspicious or borderline for malignancy following biopsy or for evaluation of extent of disease in the pre-operative setting ⁽¹⁰⁾ -
- For any **ONE** of the following **after** inconclusive mammogram **AND** ultrasound:
 - New nipple inversion or retraction
 - Suspected breast cancer and biopsy cannot be performed (e.g. seen only in single view mammogram without ultrasound correlation)
 - Skin changes suspicious for breast cancer and **with** negative skin biopsy
 - Unilateral serous or bloody nipple discharge and no palpable mass ⁽¹²⁾
- 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 ⁽⁴⁾
- 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 ⁽⁷⁾
- Patients diagnosed with biopsy-proven lobular neoplasia, i.e., LCIS/ALH (Lobular Carcinoma in Situ/Atypical Lobular Hyperplasia) or ADH (atypical ductal hyperplasia) ^(2,4,8)
- 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 ^(2,4)
- 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 ⁽⁴⁾
- 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 ^(9,10)
- 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) ⁽¹¹⁾

History of Known Breast Cancer ⁽¹⁰⁾

Staging, Treatment, and SurveillanceInitial Staging:

- Stage 1 or higher breast cancerNew breast cancer diagnosis
- Axillary nodal carcinoma and unidentified primary tumor

Restaging:

- Prior to neoadjuvant chemotherapy
- Following neoadjuvant chemotherapy
- Prior to breast surgery

Surveillance:

- When breast cancer was diagnosed at age < 50: Annually
- With history of breast conservation surgery **AND** radiation **AND** dense breasts: Annually
- Yearly Surveillance surveillance for^(3,4,12,13):
 - History of breast cancer and heterogeneously dense or extremely dense breast tissue on mammography
 - Individuals with personal history of breast cancer diagnosed before age 50
 - Patients with genetic or other risk factors placing them at high risk for a new cancer or recurrence
 - Individuals with a mammographically occult primary breast cancer
- 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^(2,4,8,14)
- For invasive lobular carcinoma that is poorly or inadequately defined by mammography, ultrasound, or physical exam^(2,8,14)
- To identify primary cancer in a patient with axillary nodal adenocarcinoma and unidentified primary tumor⁽²⁾
- Prior to treatment: To serve as a baseline for comparison prior to a patient starting planned neoadjuvant chemotherapy⁽¹⁵⁾
- During or after treatment: To identify candidates for breast conserving therapy or evaluate response to treatment, including preoperative neoadjuvant therapy [within three (3) months]⁽⁴⁾

Silicone Implants⁽¹³⁾

Surveillance of asymptomatic **silicone** implants at the following intervals: MRI is **not indicated** for evaluation of saline implant complications⁽¹⁶⁾

- ~~ONCE~~ Initial MRI 5 years after placement (no prior imaging required)
 - If initial MRI is negative: Every 2-3 years
 - If initial MRI is indeterminate or abnormal: As clinically indicated
- Following abnormal or indeterminant mammography or ultrasound

For ~~S~~ suspected symptomatic silicone breast implant complication

NOTE: MRI is **not indicated** for evaluation of saline implant complications⁽¹⁶⁾. 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. Prior imaging is not required in patients with silicone implants and symptoms of possible rupture (3,4,16).~~

~~For postoperative evaluation of silicone breast implant complications when other imaging is inconclusive~~

~~For evaluation of asymptomatic silicone implants, initial imaging 5-6 years after placement, with follow-up every 2-3 years after initial negative imaging⁽¹⁶⁾~~

~~As initial imaging to evaluate suspected silicone implant complications⁽¹⁶⁾~~

PREOPERATIVE OR-AND POSTOPERATIVE ASSESSMENT PROCEDURAL EVALUATIONS

Pre-Operative/~~Procedural~~ Evaluation⁽¹⁰⁾

- ~~For preoperative evaluation for known~~ Known breast cancer when surgery planned within thirty (30) days ~~may be considered to be determined~~ on a case-by-case basis^(4,8)

Post-Operative/~~Procedural~~ Evaluation^(14,15)

- Known or suspected complications
- A clinical reasoning rationale is provided on how imaging may change management 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^(3,13)

NOTE: This section applies ~~to~~ only to within the first few months following surgery

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 a change was found on the last follow-up exam)

COMBINATION STUDIES FOR KNOWN GENETIC CONDITIONS

NOTE: When medical necessity is met for an individual study **AND** conscious sedation is required (such as for young pediatric patients or patients with significant developmental delay), the entire combination is indicated)

Breast/Brain/Whole Body MRI

- Li-Fraumeni (TP53): Annually ⁽³⁾

NOTE: Can include Abdomen MRI if meets family history requirement. Additional imaging may be needed based on patient-specific factors.

Breast/Whole Body MRI

- Neurofibromatosis 1 (NF1): Annually starting at age 30 ⁽⁷⁾

LEGISLATIVE LANGUAGE

State of Connecticut

General Assembly 38a-530 ⁽¹⁷⁾

~~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.~~

State of Illinois

SB 0162 ⁽¹⁶⁾

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

State of North Carolina

CCP 1K-1; 3.2.1(c) ⁽¹⁷⁾

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.

Note: This is not an all-inclusive list.

State of Ohio

HB 371 ⁽¹⁸⁾

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.

Commonwealth of Pennsylvania

SB 8 ⁽¹⁹⁾

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 employee 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.

State of Washington

Health Technology Assessment 20100820A ⁽²⁰⁾

Number and Coverage Topic

20100820A – Breast MRI

HTCC Coverage Determination

Breast MRI is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination

- **Limitations of Coverage**

Breast MRI is a covered benefit for screening for breast cancer, with a minimum of 11 months between screenings in women at high risk of breast cancer. Women at high risk are defined as:

- A personal history or strong family history of breast cancer;
- A genetic mutation of BRCA 1, BRCA2, TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes);
- GAIL model lifetime cancer risk of 20% or higher; or
- History of radiation treatment to the chest between ages 10 and 30, such as for Hodgkin's disease.

- **Non-Covered Indicators**

- N/A


CODING AND STANDARDS

Codesing

CPT Codes

77046, 77047, 77048, 77049, +0698T

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/> 	Medicare Advantage

BACKGROUND

Contraindications and Preferred Studies

- Contraindications and reasons why a CT/CTA cannot be performed may include: impaired renal function, significant allergy to IV contrast, pregnancy (depending on trimester).
- Contraindications and reasons why an MRI/MRA cannot be performed may include: impaired renal function, claustrophobia, non-MRI compatible devices (such as non-compatible defibrillator or pacemaker), metallic fragments in a high-risk location, patient exceeds weight limit/dimensions of MRI machine.

SUMMARY OF EVIDENCE

These guidelines are developed using evidence-based and peer-reviewed resources from medical publications and societal organization guidelines, ensuring that the indications for Breast MRI are grounded in the best available evidence and standard of care.

- **High-Risk Breast Cancer Screening** ^(1,2): Annual screening with Breast MRI is recommended for individuals with a lifetime risk of developing breast cancer of 20% or higher, based on validated risk assessment models. This includes individuals with a personal history of atypical hyperplasia or lobular carcinoma in situ, those with a history of extensive chest irradiation, and those with increased breast density.

- **Evaluation of Identified Lesion, Mass, or Abnormality** ^(10–12): Breast MRI is indicated for the evaluation of biopsy-proven atypical hyperplasia, lobular carcinoma in situ, Paget Disease, and other specific conditions. It is also used for follow-up of BI-RADS 3 lesions and for further evaluation after inconclusive mammogram and ultrasound.
- **Known Breast Cancer** ⁽¹⁰⁾: Breast MRI is used for initial staging, restaging prior to and following neoadjuvant chemotherapy, and surveillance in specific cases such as when breast cancer was diagnosed at a young age or in individuals with dense breasts.
- **Silicone Implants** ⁽¹³⁾: MRI is used for the surveillance of asymptomatic silicone implants and for suspected silicone breast implant complications.

Analysis of Evidence:

When choosing Breast MRI, several factors should be considered to ensure it is the appropriate imaging modality for the patient. These considerations ensure that Breast MRI is used effectively for screening, diagnosis, and management of breast conditions.

- **High-Risk Breast Cancer Screening** ^(1,2): Annual screening with Breast MRI is recommended for individuals with a lifetime risk of developing breast cancer of 20% or higher, based on validated risk assessment models. This includes those with a personal history of atypical hyperplasia or lobular carcinoma in situ, a history of extensive chest irradiation, or increased breast density.
- **Evaluation of Identified Lesion, Mass, or Abnormality** ^(10–12): Breast MRI is used for evaluating biopsy-proven atypical hyperplasia, lobular carcinoma in situ, skin biopsy positive for Paget Disease, and follow-up of BI-RADS 3 lesions on prior MRI.
- **Known Breast Cancer** ⁽¹⁰⁾: MRI is used for initial staging, restaging prior to neoadjuvant chemotherapy, following neoadjuvant chemotherapy, and prior to breast surgery. It is also used for surveillance in patients diagnosed with breast cancer at a young age or those with dense breasts.
- **Silicone Implants** ⁽¹³⁾: MRI is used for surveillance of asymptomatic silicone implants and for suspected silicone breast implant complications.

POLICY HISTORY

Date	Summary
<u>July 2025</u>	<ul style="list-style-type: none"> ● <u>Added a Summary of Evidence and Analysis of Evidence</u>
<u>June 2025</u>	<ul style="list-style-type: none"> ● <u>This guideline number changed from 023 to 2014</u> ● <u>Adjusted high-risk breast cancer screening section for:</u> <ul style="list-style-type: none"> ○ <u>Timing and age of screening throughout sections including within sections for dense breast and genetic mutations</u>

Date	Summary
	<ul style="list-style-type: none"> ○ Updated societal guidance regarding dense breasts ● Simplified and restructured the section for evaluation of identified lesion, mass, or abnormality ● Simplified and restructured the section for known breast cancer into initial staging, restating, and surveillance ● Simplified and restricted the section for silicone implants ● Updated language in the preoperative/postoperative section ● Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices ● Medicare line of business checked ● The State of Connecticut was removed from regulatory language
July 2024	<ul style="list-style-type: none"> ● Updated references ● Added new guidance on silicone implant monitoring ● Legislative language updated/adjusted ● Moved background section to purpose ● Added in Contraindications and Preferred Studies section to Background ● Added Legislative Language for Washington
May 2023	<ul style="list-style-type: none"> ● Updated background ● Updated references ● Added dense breast to indications for breast MRI ● Change screening ages based on society recommendations for high-risk conditions ● Added language regarding lactating and pregnant patients ● General Information moved to beginning of guideline with added statement on clinical indications not addressed in this guideline ● Added statement regarding further evaluation of indeterminate findings on prior imaging

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

REFERENCES

1. Referenced with permission from the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer Risk Reduction Version 2.2025 © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org.
2. Referenced with permission from the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer Screening and Diagnosis Version 2.2025 © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org.
3. Referenced with permission from the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate Version 3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org.
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