National Imaging Associates, Inc.*	
Clinical guidelines **BREAST MRI**	**Original Date: September 1997**
CPT Codes: **Unilateral without contrast 77046** **Bilateral without contrast 77047** **Unilateral without and with contrast 77048** **Bilateral without and with contrast 77049** **+0698T**	**Last Revised Date: ~~July~~ April 2022~~1~~**
Guideline Number: NIA_CG_023	**Implementation Date: January 2023~~2~~**

INDICATIONS FOR BREAST MRI

See Legislative Requirements for specific mandates in: Commonwealth of Pennsylvania; State of Connecticut; State of Illinois; State of North Carolina
~~*(Please see boxed statements below for specific requirements for the following:* Commonwealth of Pennsylvania; State of Connecticut; State of North Carolina*)*~~

NO HISTORY OF KNOWN BREAST CANCER
For screening examination to detect breast cancer in any of the following situations

- 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 ~~(NCCN, 2021)~~ (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[1]
    - 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[2-6] ~~(ACR, 2018; ASBrS, 2017; Levitan, 2019; Marino, 2018; NCCN, 2021)~~
- 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] ~~(NCCN, 2021)~~

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- **Patients with intermediate lifetime risk (15%-20%) of developing breast cancer based on ALL a of the following:**
- **A history lobular neoplasia (LCIS/ALH (Lobular Carcinoma in Situ /Atypical Lobular Hyperplasia)) or ADH (atypical ductal hyperplasia)) AND have of lobular neoplasia (LCIS/ALH or ADH)**
- **dDense breast tissue on mammography**
    - **Approve annually beginning at age of diagnosis of LCIS/ALH or ADH but not prior to age 25**[2,7,8]
- 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[2] (NCCN, 2021)
- Patients with known *BRCA 1/2* mutation
    - Approve annually starting at age 25[2,3] (ASBrS, 2017; NCCN, 2021)
- Patients not yet tested for *BRCA* gene, but with known *BRCA* mutation in first-degree relative
    - Approve annually starting at age 25[2,3] (ASBrS, 2017; NCCN, 2021)
- Personal history of germline mutations known to predispose to a high risk of breast cancer[1] (NCCN, 2021):
    - 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** 30-35 or 5-10 years before earliest breast cancer diagnosis in family **(NCCN 2022)**
    - *ATM*
        - Begin age 40
    - *BARD1*
        - Begin age 40
    - *CDH1*
        - Begin age 30
    - *CHEK2*
        - Begin age 40
    - *NF1*
        - Begin age 30**, end age 50**[2] (NCCN 2022)
    - *PALB2*
        - Begin age 30
    - Peutz-Jeghers Syndrome (*STK11*)
        - Begin age 25

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[3,9,10] (ASBrS, 2017; Geiss, 2017; Yadav 2018)

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- Inconclusive or conflicting findings on a diagnostic mammogram or ultrasound when the finding is not a palpable or a discrete mass
- 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[11-13] ~~(Killelea, 2019)~~
- Patients diagnosed with biopsy-proven lobular neoplasia, i.e., LCIS/ALH (Lobular Carcinoma in Situ /Atypical Lobular Hyperplasia) or ADH (atypical ductal hyperplasia)[2,3,14,15] ~~(ASBrS, 2017; Monticciolo, 2017; NCCN, 2021)~~
- Spontaneous unilateral serous or bloody nipple discharge when conventional imaging is normal and there is no palpable mass[2,3,16] ~~(ASBrS, 2017; Bahl, 2015; NCCN, 2021)~~
- Paget's disease of the nipple: to detect underlying ductal carcinoma when conventional imaging is normal and there is no palpable mass[3] ~~(ASBrS, 2017)~~
- For a ~~phylloides~~**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[17-19] ~~(Grau, 2019)~~
- 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)[20-22] ~~(Lee, 2018; Panigrahi, 2019; Spick, 2018)~~

HISTORY OF KNOWN BREAST CANCER

- Yearly surveillance for history of breast cancer and dense breast tissue on mammography[4] ~~(ACR, 2018)~~
- Yearly surveillance for individuals with personal history of breast cancer diagnosed before age 50[4] ~~(ACR, 2018)~~
- Yearly surveillance in patients with genetic or other risk factors placing them at high risk for a new cancer or recurrence[3,23] ~~(ASBrS, 2017; Park, 2018)~~

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[2,3,14] ~~(ASBrS, 2017; NCCN, 2021)~~
- For invasive lobular carcinoma that is poorly or inadequately defined by mammography, ultrasound, or physical exam[2,14] ~~(NCCN, 2021)~~
- To identify primary cancer in a patient with axillary nodal adenocarcinoma and unidentified primary tumor[2] ~~(NCCN, 2021)~~
- Prior to treatment: To serve as a baseline for comparison prior to a patient starting planned neoadjuvant chemotherapy[24] ~~(ACR, 2017)~~
- During or after treatment: To identify candidates for breast conserving therapy or evaluate response to treatment, including preoperative neoadjuvant therapy [within three (3) months][3] ~~(ASBrS, 2017)~~

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Silicone Implants

MRI is not indicated for evaluation of saline implant complications or for asymptomatic silicone implants.[4,25]
~~(ACR, 2018; Lourenco, 2018)~~

- Confirmation of suspected silicone gel-filled breast implant ruptures in a*symptomatic* 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 ~~(ACR, 2018; ASbrS, 2017)~~.[3,4] 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[3,14,26,27] ~~(ASBrS, 2017; NCCN, 2019; Susnik, 2018; Wong, 2018)~~

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[4] ~~(ACR, 2018)~~

LEGISLATIVE REQUIREMENTS

- **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**[28]

- **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:**

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        - 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[29]; amended September 15, 2020

- 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)[30]

- Pennsylvania
  - 40 P.S. § 764c. Act of Jul. 1, 2020, P.L. 572, No. 52 (SB 595)
    - Plans that provide 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 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:

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- 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;
- 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.
- Source: Senate Bill 595[31]

*****FOR STATE OF CONNECTICUT ONLY*****

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
https://www.cga.ct.gov/current/pub/chap_700c.htm

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*****FOR STATE OF NORTH CAROLINA ONLY*****

Medicaid and NCHC cover magnetic resonance imaging (MRI) for the detection of:

1. Breast cancer in beneficiaries who are at a high genetic risk for breast cancer:
    A. known BRCA 1 or 2 mutation in beneficiary;
    B. known BRCA 1 or 2 mutation in relatives; or
    C. pattern of breast cancer history in multiple first-degree relatives, often at a young age and bilaterally.
2. Breast cancer in beneficiaries who have breast characteristics limiting the sensitivity of mammography (such as dense breasts, implants, scarring after treatment for breast cancer).
3. A suspected occult breast primary tumor in beneficiaries with axillary nodal adenocarcinoma with negative mammography and clinical breast exam.
4. 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.
5. To evaluate implant integrity in beneficiaries with breast implants.

Source: NC Medicaid, Amended March 15, 2019
https://files.nc.gov/ncdma/documents/files/1K-1_2.pdf

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*****FOR THE COMMONWEALTH OF PENNSYLVANIA ONLY*****
40 P.S. § 764c
Act of Jul. 1, 2020, P.L. 572, No. 52 (SB 595)

I. Plans that provide hospital or medical/surgical coverage shall also provide coverage for breast imaging.
II. The minimum coverage required shall include:
   1. Supplemental magnetic resonance imaging or, if such imaging is not possible, ultrasound
   2. If recommended by the treating physician because the woman is believed to be at an increased risk of breast cancer due to:
      a. personal history of atypical breast histologies;
      b. personal history or family history of breast cancer;
      c. genetic predisposition for breast cancer;
      d. prior therapeutic thoracic radiation therapy;
      e. 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:
         i. lifetime risk of breast cancer of greater than 20%, according to risk assessment tools based on family history;
         ii. personal history of BRCA1 or BRCA2 gene mutations;
         iii. first-degree relative with a BRCA1 or BRCA2 gene mutation but not having had genetic testing herself;
         iv. prior therapeutic thoracic radiation therapy between 10 and 30 years of age; or
         v. personal history of Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome or a first-degree relative with one of these syndromes;
         vi. 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.

Source: Senate Bill 595 @
https://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2020&sessInd=0&act=52

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 ~~(Panourgias, 2018)~~.[32] 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.

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OVERVIEW

Staging of newly diagnosed breast cancer[2] – The decision to use breast MRI as an adjunct to clinical exam, mammography, and ultrasound should be made by the physician on a case-by-case basis, taking into account frequent false positives, increased time to treatment, and increased mastectomy rates. "There is no convincing evidence that MRI reduces re-excision l~~L~~umpectomy rates, local recurrence, or overall survival in patients with invasive breast cancer or ductal carcinoma in situ~~" (ASBrS, 2017; NCCN, 2021)~~."[3]

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.

MRI and dense breasts – Women with extremely dense breasts are 4-6x more likely to develop breast cancer than women with fatty tissue. Between 40 - 50% of US women aged 40-74 years have dense breast tissue. Breast density decreases the sensitivity of mammography and is associated with aggressive tumors and worse outcomes. There are four categories for breast density- almost entirely fatty, scattered areas of fibroglandular tissue, heterogeneously dense, and extremely dense. The last two are considered dense. Women with dense breasts and a BCSC risk of ≥ 2.5% (about 21%) are at greatest risk for interval stage IIb or higher cancers. Thus, knowing a women's risk along with density identifies subgroups who will benefit most from supplemental testing, such as ultrasound or MRI. Without considering overall breast cancer risk, MRI could result in more harm than good in terms of anxiety, overdiagnosis, and increased benign breast biopsies.[33] ~~(Kerlikowski, 2019).~~ For women whose only risk is increased breast density, ultrasound can be considered for adjunctive screening ~~(Monticciolo, 2018)~~.[15]

A movement to notify women of their breast density is now expanded, as of April 2019, to 38 states and the District of Columbia. Although there has been an increase in notification and awareness of breast density, no clear guidelines have been established for supplemental screening in this subset of women. A recent study showed that the majority of practices are utilizing supplemental screening, but the modalities used and referral patterns vary depending on several factors including location, type of practice (i.e., private or academic), and whether the practice has breast specialists. Also, the exact notification requirements as well as insurance coverage vary from state to state. Screening ultrasound was most utilized (53%) and most available in the Northeast (80%). Connecticut, for example, requires insurance to cover supplemental ultrasound exams. In this study 19.5% had MRI for supplemental screening and 87% of these were private practice settings ~~(Choudhery, 2020)~~.[34] At the present time, except in states that require it, more research is needed before approval of MRI for supplemental screening based on breast density alone, without other risk factors ~~(Bakker, 2019; Destounis, 2020; Kerlikowski, 2019)~~.[33,35,36]

MRI and breast cancer risk associated with certain syndromes

- Lynch Syndrome- Women with Lynch syndrome and mismatch repair genes *MLH1* and *MSH2* may be at increased risk for breast cancer; however, breast screening is not recommended beyond what is recommended for an average risk patient ~~(NCCN, 2021)~~.[1]

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- NF-1- Mammography starting at age 30; breast MRI may be considered.

Management of patients with pathogenic variants of ~~There is currently limited evidence that~~ *RAD51C* and *RAD51D* genes **should be based on family history (NCCN 2022)**~~are associated with increased risk of breast cancer~~. **Currently, there is i**~~I~~nsufficient evidence for *FANCC*, *MRE11A*, ~~or~~ *MUTYH* heterozygotes,~~ or~~ *RECQL4, RAD50, RINT1, SLX4, SMARCA4*, or *XRCC2*. ~~For *STK11* (associated with Peutz-Jeghers syndrome) breast cancer risk is 8% at age 40, 13% age 50, 31% at age 60, and 45% age 70.~~

Surgical excision vs MRI – Select patients may be suitable for monitoring in lieu of excision (although MRI is not indicated); e.g., Flat epithelial hyperplasia, papillomas without atypia, fibroepithelial lesions favoring fibroadenoma, radial scars adequately sampled or incidental. Other pathologies that may require excision include mucin-producing lesions, potential ~~phylloides~~**phyllodes** tumor, papillary lesions, radial scar, or other histologies of concern to the pathologist~~ (NCCN, 2021)~~.[2]

MRI during or after neoadjuvant chemotherapy – Dynamic contrast-enhanced MRI may be used to monitor response of a tumor to neoadjuvant chemotherapy used to shrink the tumor before surgery. This is very important in clinical decision making as alternative therapies may be selected based upon the MRI results. It may also be used to depict residual disease after neoadjuvant chemotherapy. MRI-compatible localization tissue markers should be placed prior to neoadjuvant chemotherapy to evaluate the location of the tumor in the event of complete response~~ (ACR, 2018)~~.[4]

MRI and breast implants – For asymptomatic women with silicone implants, no imaging is recommended for evaluation. However, MRI may be used in asymptomatic patients with silicone breast implants to evaluate breast implant integrity when a mammogram and/or ultrasound is suspicious for implant rupture.

For evaluation of unexplained axillary adenopathy in a patient under age 30, ultrasound (US) of the axilla is the recommended initial test. For age over 30, a mammogram and/or US of the axilla are recommended.

MRI after mastectomy – Most breast tissue is removed after mastectomy; however, recurrence may occur in residual tissue. The majority occur in the skin, subcutaneous tissues or deep to the pectoralis muscle and are reported to be about 1-2% annually. Clinical evaluation is the mainstay of the post-mastectomy breast. For a palpable lump or pain on the side of mastectomy with or without reconstruction or a high-risk patient post-bilateral prophylactic mastectomy with reconstructions, MRI is not indicated. There is no relevant literature to support MRI to screen the post-mastectomy breast (although may be indicated for contralateral native breast based on breast cancer risk). MRI may be useful for a palpable lump to help characterize malignancy once identified by ultrasound. Note that tissue expanders may be a contraindication to MRI~~ (ACR, 2020)~~.[37]

Breast pain – Breast pain is a common complaint with the incidence of breast cancer with breast pain as the only symptom, 0-3%. Clinically insignificant breast pain is cyclical, non-focal, or diffuse. There is no relevant literature regarding the use of MRI for focal or non-cyclical breast pain at any **age**~~ age (ACR, 2018)~~.[4]

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MRI for a mass – "Any highly suspicious breast mass detected by imaging should be biopsied, irrespective of palpable findings; and any suspicious breast mass detected by palpation should be biopsied, irrespective of imaging findings" ~~(ACR, 2016)~~.[38]

MRI and known breast cancer – "The ASBrS does not recommend routine diagnostic MRI in newly diagnosed breast cancer patients except as part of a scientific study… Routine annual MRI is not indicated for screening of women with a prior history of breast cancer unless they have a known genetic or other significant risk factor placing them at high-risk for a new breast cancer …."[3] ~~(ASBrS, 2017).~~ Clinical indications and applications per NCCN state that Breast MRI may be used for staging evaluation to define extent of cancer or presence of multifocal or multicentric disease in the ipsilateral breast, or as screening of the contralateral breast at time of initial diagnosis (Category 2B); however, there are no high level data to demonstrate that the use of MRI to facilitate local therapy decision-making improves local recurrence or survival. False positive findings are common and surgical decisions should not be based solely on MRI, tissue sampling of areas of concern recommended ~~(NCCN, 2021)~~.[14]

MRI and breast cancer in men – Breast MRI is generally not indicated for palpable masses or axillary adenopathy prior to biopsy. Studies are limited as to the diagnostic accuracy or clinical usefulness of MRI in male patients ~~(ACR, 2018)~~.[4]

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 should be considered in cases in which other approaches have failed to identify an underlying cause of pathologic nipple discharge. The sensitivities of breast MRI for detection of underlying cause of pathologic nipple discharge are 86% to 100% for invasive cancer and 40% to 100% for noninvasive disease" ~~(ACR, 2016)~~.[39] Ductography (galactography) has the ability to demonstrate very 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 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 ~~(ACR, 2016)~~.[39]

BI-RADS 3 (Probably Benign) MRI and Follow-up – A follow-up MRI study may be indicated to confirm stability of a probably benign mass seen only on prior MRI. In a review of sixteen studies of high-risk patients, the frequency of MRI examinations reported as BI-RADS 3 was between 6 and 12% ~~(Lee, 2018)~~.[20] In an average risk screening population of 2120 women and 3,861 MRI exams, 4.9% of MRI exams were BI-RADS 3 ~~(Kuhl, 2017)~~.[40] Specific features of what constitutes a BI-RADS 3 lesion were not described in these studies, is at the discretion of the reporting radiologist, and still had an evolving definition during the study periods. At this writing the appropriate use of BI-RADS 3 for breast MRI has not been fully defined ~~(Panigrahi, 2019)~~.[21] "The most appropriate and common use of BI-RADS 3 assessment is for a round- or oval-shaped mass with circumscribed margins and hyperintense T2 signal,

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which has either homogeneous enhancement or dark internal septations on a baseline examination. A mass meeting these criteria is most likely an intramammary lymph node or fibroadenoma" ~~(Lee, 2018)~~.[20] The reported malignancy rate is ≤ 2% for lesions classified as BI-RADS 3 (~~Lee, 2018;~~ Spick, 2018).[20,22]

POLICY HISTORY

Date	Summary
September 2022	Added mandate language for State of Illinois
June 2022	• Added criteria for an intermediate lifetime risk of breast cancer • Reformatted mandates
April 2022	• Revised high-risk screening section for germline mutations • Updated background section on genetic syndromes • Updated citations
November 2021	• Added +0698T
July 2021	• Improved section on when to begin high risk screening for patients with lifetime risk of 20% or greater. • Added section on high risk screening in patients with lifetime risk of 20% or greater based on history of LCIS/ALH/ADH. • Changed high risk screening start date to 8 years after chest irradiation per NCCN • Added BARD1 germline mutation • Improved section on when MRI may be indicated for a new diagnosis of breast cancer • Added indication of baseline MRI prior to starting neoadjuvant chemotherapy • Improvement background section on MRI of the breast • Updated background section on genetic syndromes • Removed background section on abbreviated breast MRI
February 2021	• Added state specific language box for State of Pennsylvania • Added citations to state specific boxes
May 2020	• Added not indicated for saline implants, or asymptomatic silicone without prior imaging • Added gold standard for symptomatic silicone implant rupture • Removed section on increased breast density • Improved section on breast assessment tools • Improved section on germline mutations from NCCN 2019 • Added indication of new nipple inversion • Added phylloides

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	• Added ACR for known breast cancer surveillance with dense tissue or dx < age 50 • Added comment section on MR for dense breast, syndromes, implants, after mastectomy, breast pain, cancer in male
September 2019	• Added state specific language boxes for State of Connecticut and State of North Carolina
April 2019	• For silicone implants indication, added qualifying terms to assure patient is symptomatic and other imaging is inconclusive • For 'No history of breast cancer, screening examinations' added specifics about when the screening should be done • Removed indication "Two or more first degree relatives (parents, siblings, and children) have history of breast cancer" • Provided specifics on chest radiation including when to start screening: "Patients with histories of extensive chest irradiation (usually as treatment for Hodgkin's or other lymphoma between ages ten and thirty. Begin ten years after radiation, but not prior to age 25" • For indication: "Personal history of germline mutations", removed 'or first degree relative with' and added some of the different mutations and when screening should begin • For indication: "For evaluation of identified lesion, mass, or abnormality in breast in any of the following situations", removed "Two or more first degree relatives with history of breast cancer" • For "Evaluation of breast cancer when other imaging exams are inconclusive" added "includes skin changes of suspected inflammatory breast cancer" • Expanded the suspicious precursor lesions to include "atypical lobular hyperplasia and lobular carcinoma in situ" • Added indications: "Spontaneous unilateral serous or bloody nipple discharge when conventional imaging is normal and there is no palpable mass" AND "Paget's disease of the nipple: to detect underlying ductal carcinoma when conventional imaging is normal and there is no palpable mass" • Added indication: "Follow-up of a BI-RAD 3 lesion seen only on prior MRI when prior mammogram and US did not show the abnormality" • History of Known Breast Cancer: Changed subheading from "Screening exam to detect breast cancer" to "Staging, treatment, and surveillance of patients with a known history of breast cancer" AND added specific indications including:

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	○ Approve initial staging when conventional imaging is indeterminate in defining multifocal, multicentric, contralateral cancer or there is a discrepancy in estimated tumor size between physical exam and imaging ○ During or after treatment to identify candidates for breast conserving therapy or evaluate response to treatment, including preoperative neoadjuvant therapy [within three (3) months] ○ Yearly surveillance in patients with genetic or other risk factors placing them at high risk for a new cancer or recurrence” • For evaluation of suspicious mass, lesion, distortion, or abnormality of breast in patient with history of breast cancer: added - ‘when other imaging is inconclusive’ • Added Background information on Nipple Discharge and specifics on screening for newly diagnosed or patients with breast cancer history • Updated references

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~~**Reviewed / Approved by NIA Clinical Guideline Committee**~~

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~~**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.~~

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Reviewed / Approved by NIA Clinical Guideline Committee

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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.

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