



CLINICAL GUIDELINES

Breast Imaging Guidelines

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EviCore
By ~~EVERNORTH~~

EviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Imaging requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist, and/or individual's Primary Care Physician (PCP) may provide additional insight.

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Abbreviations for Breast Guidelines

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Abbreviations for Breast Guidelines	
BI-RADS™	Breast Imaging Reporting and Database System
BRCA	breast cancer gene
CAD	computer-aided detection
CT	computed tomography
CTA	computed tomography angiography
CTV	computed tomography venography
DCIS	ductal carcinoma in situ
FDA	Food and Drug Administration
FDG	fluorodeoxyglucose
FNA	fine needle aspiration
HRCT	high-resolution computed tomography
LCIS	lobular carcinoma in situ
MRA	magnetic resonance angiography
MRI	magnetic resonance imaging
NSM	nipple-sparing mastectomy
PEM	positron-emission mammography

Breast Imaging Guidelines

Abbreviations for Breast Guidelines	
PET	positron-emission tomography

General Guidelines (BR-Preface 1.0)

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- A current clinical evaluation since the onset or change in symptoms is usually required prior to considering advanced imaging.
 - A clinical evaluation should include the following:
 - A relevant history and physical examination since the onset or change in symptoms
 - Appropriate laboratory studies and non-advanced imaging modalities, such as mammogram and/or ultrasound
 - Other meaningful contact (telephone call, electronic mail or messaging) since the onset or change in symptoms by an established individual can substitute for a face-to-face clinical evaluation
- Current clinical evaluation is not required prior to screening studies.

Health Equity Considerations

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

BI-RADS™ Categories Chart (BR-Preface 1.1)

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BI-RADS™ Categories Chart	
Category	Description
Category 0: Incomplete	Need additional imaging evaluation or prior mammograms for comparison. Category 0 classification requires that additional imaging study be specified, e.g., ultrasound, additional mammogram view, MRI.
Category 1: Negative	There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances, or suspicious calcifications are present.
Category 2: Benign Finding	This is also a negative mammogram, but the interpreter may wish to describe a finding. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions (such as oil cysts, lipomas, galactoceles, and mixed density hamartomas) all have characteristic appearances, and may be labeled with confidence. The interpreter might wish to describe intramammary lymph nodes, implants, etc. while still concluding that there is no mammographic evidence of malignancy.

BI-RADS™ Categories Chart	
Category	Description
<i>Category 3: Probably Benign Finding – Short Interval Follow-up Suggested</i>	A finding placed in this category should have a very high probability of being benign. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability. Data is becoming available that sheds light on the efficacy of short interval follow-up. At the present time, most approaches are intuitive. These will likely undergo future modification as more data accrue as to the validity of an approach, the interval required, and the type of findings that should be followed.
<i>Category 4: Suspicious Abnormality – Biopsy Should Be Considered</i>	There are lesions that do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge a biopsy. If possible, the relevant possibilities should be cited so that the individual and their physician can make the decision on the ultimate course of action.
<i>Category 5: Highly Suggestive of Malignancy – Appropriate Action Should Be Taken</i>	These lesions have a high probability of being cancer and should be biopsied or treated surgically.
<i>Category 6: Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken</i>	These lesions have been biopsied and are known to be malignant.

BI-RADS™ Breast Density Categories (BR-Preface 1.2)

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BI-RADS™ Breast Density Categories
Category A: Almost entirely fatty
Category B: Scattered fibroglandular densities
Category C: Heterogeneously dense
Category D: Extremely dense

Breast Ultrasound (BR-1)

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Breast Ultrasound (BR-1.1)

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- Routine performance of breast ultrasound (US) as stand-alone screening or with screening mammography is not medically necessary.
 - Breast ultrasound is a supplemental screening alternative for high-risk females (as described in **MRI Breast Indications [BR-5]**) with dense breasts on mammography, when MRI Breast without and with contrast cannot be performed. The inability to perform MRI Breast may be because it cannot be tolerated (i.e., insurmountable claustrophobia or body habitus), or there exists a contraindication (i.e., non-MRI compatible implantable devices or an inability to receive MRI contrast).
 - Breast ultrasound (CPT[®] 76641 or CPT[®] 76642) is medically necessary when requested by the treating provider to complete the screening process, OR recommended by the radiologist report, OR to address a finding on the mammogram.
- Breast ultrasound (CPT[®] 76641: unilateral, complete; or, CPT[®] 76642: unilateral, limited) can be used to further evaluate abnormalities found on mammogram, especially in differentiating cysts from solid lesions.
 - A clinical office visit is not necessary prior to breast ultrasound when an abnormality has been identified on a mammogram.
- BI-RADS[™] Cat 3 ultrasound follow-up imaging for stable findings at 6 months:
 - if repeat imaging remains BI-RADS[™] 3, repeat at 12 months, 18 months, and 24 months from the date of the initial imaging.
 - After 2 years of stability, the finding should be assessed as benign (Cat 2).
 - if repeat imaging is BI-RADS[™] 1 or 2, then imaging reverts to routine per individual's risk profile.
- For breast implant imaging, please see **Breast Implant Evaluation (BR-5.2)**.
- Axilla ultrasound (CPT[®] 76882)
 - For individuals with clinically suspicious lymph nodes, pre-operative axillary ultrasound with a FNA or biopsy can help identify individuals who have positive nodes.
 - See **Axillary Lymphadenopathy (and Mass) (CH-2.2)** in the Chest Imaging Guidelines.
 - Bilateral should be coded CPT[®] 76882 x 2.
- US-guided breast biopsy (CPT[®] 19083) includes the imaging component.
 - Additional lesions should be billed using CPT[®] 19084.

- Breast ultrasound (CPT[®] 76641 or CPT[®] 76642) can be repeated at least 6 months after an US-directed breast biopsy to document successful lesion sampling if histology is benign and non-specific, equivocal or uncertain.
- 3D Reconstruction (CPT[®] 76376 or CPT[®] 76377) is **NOT** medically necessary for breast ultrasound. It is commonly requested in conjunction with automated breast ultrasound (ABUS); there is no evidence to support its clinical usefulness.

MRI Breast Coding (BR-2)

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MRI Breast Coding (BR-2.1)

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- The use of gadolinium contrast is required for the evaluation of breast parenchyma.
- The use of gadolinium contrast is **NOT** necessary for the evaluation of implant integrity in asymptomatic, average-risk individuals.
- Throughout this guideline, when MRI Breast is medically necessary, any **ONE** of the following codes is supported:
 - CPT[®] 77049 MRI Breast Bilateral, including CAD, without and with contrast
 - HCPCS C8908 MRI Breast Bilateral, without and with contrast
- If the individual meets medical necessity for advanced imaging to assess implant integrity, the appropriate code is CPT[®] 77047 MRI Breast Bilateral, without contrast.
- Computer-aided detection (CAD) is included with the MRI Breast CPT[®] 77049 and CPT[®] 77048 procedures.
 - The use of CAD has little influence on the sensitivity and specificity of MRI Breast interpretation.
 - Since the CAD software automatically performs 3D imaging, CPT[®] 76376 or CPT[®] 76377 should **NOT** be used in conjunction with MRI Breast.
- MRI-guided breast biopsy (CPT[®] 19085) includes the imaging component and the needle placement under MR guidance; CPT[®] 77021 MR guidance for needle placement is **NOT** an appropriate code to bill for a breast biopsy.
 - Additional lesions should be billed using CPT[®] 19086.
 - This program does not manage CPT[®] codes 19085 or 19086.

Background and Supporting Information

- Although MRI Breast has superior sensitivity in identifying new unknown malignancies, it carries a significant false positive risk when compared to mammogram and ultrasound. Incidental lesions are seen on 15% of MRI Breast and increase with younger age. The percentage of incidental lesions that turn out to be malignant varies from 3% to 20% depending on the individual population. Cancer is identified by MRI Breast in only 0.7% of those with “inconclusive mammographic lesions.”

Breast Reconstruction (BR-3)

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Breast Reconstruction (BR-3.1)

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- CTA or MRA of the body part **from which the free-tissue transfer flap is being taken**, can be performed for breast reconstruction pre-operative planning.
 - Examples include:
 - CTA Abdomen and/or Pelvis (CPT® 74175 or CPT® 72191 or CPT® 74174) or MRA Abdomen and/or Pelvis (CPT® 74185 and/or CPT® 72198) for Deep Inferior Epigastric Perforators (DIEP) flap
 - CTA Chest (CPT® 71275) for Thoracodorsal Artery Perforator (TDAP) flap
- Routine use of CTA Chest (CPT® 71275) to evaluate **recipient** vessels is **NOT** medically necessary.
 - **Criteria exception:** In circumstances where there has been previous cardiac/vascular surgery and/or known vascular anomalies in the chest, it may be warranted.
- There is currently insufficient evidence-based data to support the need for routine advanced imaging for TRAM flaps or other flaps performed on a vascular pedicle.

Evidence Discussion

The American College of Radiology (ACR) Appropriateness Criteria® stated that either MRA abdomen and pelvis with and without IV contrast or CTA abdomen and pelvis with IV contrast are usually appropriate for pre-operative planning in individuals undergoing DIEP flap breast reconstruction.² Studies have found CTA mapping results in a shorter operative time when compared with no mapping in cases of breast reconstruction with free-tissue flap transfer (e.g., with Deep Inferior Epigastric Perforator (DIEP) flaps).¹

In contrast, routine use of CTA chest to evaluate for recipient vessels (often the internal mammary vessels) is not medically necessary. This is because a number of studies have found that the anatomy and course of these vessels is largely consistent, and that there is good concordance between surgical and radiological findings – either with ultrasound or CTA.³ CTA, however, carries with it significant risks, including contrast nephrotoxicity and allergic reactions, and the significantly higher risk of radiation exposure in the chest than in the abdomen.⁴ As such, many surgeons will use hand-held Doppler ultrasound either pre- and/or intra-operatively to evaluate recipient vessels. In certain circumstances, such as with previous surgery and/or radiation that would be expected affect the candidacy of potential recipient vessels, pre-operative CTA of the chest may be considered.

As pedicled flaps, by definition, do not require a microvascular anastomosis and are not disconnected from their blood supply, there is no current evidence to support routine

pre-operative imaging in these individuals. A recent study evaluating the use of pre-operative CTA in individuals undergoing pedicled TRAM flap reconstruction found that there was no significant difference in terms of operative time nor flap loss in individuals who had a pre-operative CTA compared those who did not.⁵

Per the National Comprehensive Cancer Network (NCCN), "common donor sites for autologous tissue include the abdomen (ie, DIEP, MS TRAM [Muscle-Sparing Transverse Rectus Abdominis Myocutaneous], SIEA [Superficial Inferior Epigastric Artery], free TRAM, pedicled TRAM), gluteal region (ie, SGAP [Superior Gluteal Artery Perforator], IGAP [Inferior Gluteal Artery Perforator]), thigh (ie, TUG [Transverse Upper Gracilis], VUG [Vertical Upper Gracilis], DUG [Diagonal Upper Gracilis], PAP [Profunda Artery Perforator]), or the back (ie, LD [Latissimus Dorsi], TDAP, LAP [Lumbar Artery Perforator])".⁴⁶

MRI Breast Indications (BR-5)

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MRI Breast Indications (BR-5.1)

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MRI Breast Considerations

- When MRI Breast imaging is medically necessary (per the criteria listed in the sections below), an MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is medically necessary.
- MRI Breast Unilateral is **NOT** clinically supported.
- See **Breast Ultrasound (BR-1)** when there is a contraindication to MRI contrast.
- See **MRI Breast Coding (BR-2)** for MRI-guided breast biopsy.
- See **Breast Cancer (ONC-11)** in the Oncology Imaging Guidelines for imaging indications related to breast cancer as follows:
 - Breast Cancer - Initial work-up/Staging
 - Breast Cancer - Restaging/Recurrence
 - Breast Cancer - Surveillance/Follow-up
 - Annual screening with prior history of breast cancer

MRI Following a Screening Mammogram and/or US in Asymptomatic Individuals

- MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is medically necessary for **EITHER** of the following:
 - When requested by the treating provider to complete the screening process, OR recommended by the radiologist report, OR to address a finding on the mammogram.
 - Documented histopathologic discordance between core-needle biopsy findings and imaging findings. MRI Breast is medically necessary for further evaluation **after** the discordant biopsy (before consideration for surgical management vs. observation).
 - Discordance exists when the biopsy result does not adequately explain the abnormal (BI-RADS[™] 4 or 5) findings on mammogram and/or ultrasound.
- For symptomatic individuals, please refer to the following appropriate condition-based guideline:
 - **Nipple Discharge/Galactorrhea (BR-6.1)**
 - **Breast Pain (Mastodynia) (BR-7.1)**
 - **Breast Imaging in Males (BR-9.1)**
 - **Breast Mass (BR-14.1)**
 - **Skin Changes (BR-15.1)**
 - **Nipple Inversion/Retraction (BR-16.1)**
 - **Malignant Phyllodes Tumor/Cystosarcoma Phyllodes (BR-17.1)**

- See **MRI BI-RADS™ 3** section for lesions categorized as BI-RADS™ 3 on MRI.

MRI BI-RADS™ 3

- A probably benign lesion on **MRI** (MRI BI-RADS™ 3) should undergo repeat MRI in 6 months.
 - If repeat imaging remains MRI BI-RADS™ 3, then repeat at 12 months, 18 months, and 24 months from the date of the initial imaging.
 - After 2 years of stability, the finding should be assessed as benign (Cat 2)
 - If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individual's risk profile. See **Risk Factors** section.

Post-Biopsy or Attempted Biopsy Imaging

- For lesions initially seen on MRI Breast and that have benign and non-specific, equivocal or uncertain histology (based on a stereotactic, MRI-guided, or US-directed breast biopsy), an MRI Breast Bilateral without and with contrast (CPT® 77049 or HCPCS C8908) is medically necessary at least 6 months after the biopsy to document successful lesion sampling.
- MRI Breast Bilateral without and with contrast (CPT® 77049 or HCPCS C8908) is medically necessary 6 months after attempted MRI-guided breast biopsy, when recommended by a radiologist, due to targeted lesion not visualized at the time of the procedure.

Risk Factors

- Routine MRI Breast following bilateral mastectomy is **NOT** medically necessary (even if high-risk screening criteria may otherwise be met and/or nipple-sparing mastectomy was done).
- Annual MRI Breast screening with MRI Breast Bilateral without and with contrast (CPT® 77049 or HCPCS C8908) is medically necessary for individuals meeting the high-risk criteria in the table below (for male breast imaging, please see **Breast Imaging in Males (BR-9.1)**):

High-Risk Indications	Age at which screening can start**
Genetic Mutations:*	
Li Fraumeni (p53)	20
BRCA 1 or 2	25
STK11, Peutz-Jeghers syndrome (PJS), PTEN Mutation (Cowden Syndrome), CDH1, NF1, PALB2, ATM, CHEK2	30**

High-Risk Indications	Age at which screening can start**
BARD1, RAD51C, RAD51D	40**
Personal history of atypia/LCIS/breast cancer:	
ADH, ALH, LCIS	At diagnosis but not prior to age 25
Personal history of breast cancer at or before the age of 50	At diagnosis
Family history:	
If the individual has NOT been tested for BRCA mutation and there is a first-degree relative (parent, sibling, child; half siblings are considered second-degree relatives) with BRCA 1 or BRCA 2 mutation. Annual screening is NOT medically necessary if the individual has been tested and is negative for BRCA 1 or BRCA 2 mutation unless they meet other criteria.	40**
Two or more first-degree relatives with breast or ovarian cancer	40**
One first-degree relative with breast cancer or ovarian cancer that was diagnosed $\leq$ age 50	40**
One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer	40**
A first- or second-degree male relative (father, brother/half-brother, uncle, grandfather) diagnosed with breast cancer	40**
Elevated clinical lifetime-risk:	
Clinical lifetime-risk estimated at greater than or equal to 20% as calculated by one of the following models: • Gail (National Cancer Institute (NCI)) • Tyrer-Cuzick (International Breast Cancer Intervention Study (IBIS)) • The Breast Cancer Surveillance Consortium (BCSC) • Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA)/CanRisk • BRCAPRO Model	40**
Personal history of radiation therapy when younger than age 30:	

High-Risk Indications	Age at which screening can start**
Radiation to chest, whole lung, mediastinum, axilla, mantle (including mini mantle or extended mantle), total or subtotal lymphoid irradiation or total body irradiation (TBI)	25 or 8 years after completion of radiation therapy <i>whichever comes later</i>
Breast Density:	
Heterogeneously Dense Breasts (Category C) or Extremely Dense Breasts (Category D) with no additional risk factors	40

*The following have unknown or insufficient evidence of breast cancer risk and additional MRI screening is NOT medically necessary at this time: MSH2, MLH1, MSH6, PMS2, EPCAM, NBN, genetic variants of unknown significance, genetic variants favoring polymorphism, and genetic variants of intermediate penetrance. Any gene mutation not specified in the table above has not currently been found to have sufficient evidence to support surveillance with MRI.

**OR 10 years prior to the age of diagnosis of the earliest relative with breast cancer (first-, second-, and third-degree relatives) *whichever comes first, but not before age 25*

Background and Supporting Information

- myRisk[®] Hereditary Cancer (Myriad Genetics, Inc.) is not accepted as a risk calculator to determine high-risk for breast cancer.

Evidence Discussion

High-Risk Indications

Li-Fraumeni Syndrome is associated with an increased incidence of premenopausal breast cancer, with the median age of diagnosis being in the early 30s.¹⁰ Accordingly, the National Institute for Health and Care Excellence (NICE)⁹ recommended annual MRI screening beginning at age 20.⁹

While the American Cancer Society (ACS) found that there is not enough evidence to make a recommendation for or against screening MRI in these populations⁶, the NCCN has recommended annual breast MRI for those with ADH, ALH or LCIS who have at least a 20% residual lifetime risk of developing breast cancer. Screening could begin at the age of diagnosis of ADH or lobular neoplasia, but not before the age of 25. They further noted that the residual lifetime risk calculation depends on the age at diagnosis.⁷

BRCA1 and *2* are associated with a risk of developing breast cancer >60%.⁸ The NCCN guidelines recommended starting MRI screening at the age of 25.⁸

STK11 mutations are associated with a 32%-54% risk of developing primary breast cancer. *CDH1* and *PALB2* mutations each confer a risk of 41%-60% of developing breast cancer. NCCN guidelines recommended starting MRI screening in these individuals at age 30. For individuals with NF1, the risk of developing breast cancer is 20%-40%. NCCN guidelines recommended considering annual MRI screening from ages 30-50. *ATM* mutations are associated with a 20%-30% risk of developing breast cancer, and *CHEK2* mutations similarly are associated with a 20%-40% risk. NCCN guidelines suggested consideration of annual breast MRI starting at age 30-35 in both of these groups. *PTEN* mutations are associated with a 40%-60% risk of developing breast cancer. While NCCN guidelines are silent on breast cancer screening for this population, ESMO guidelines recommended starting annual MRI at the age of 30.^{8,11}

BARD1, *RAD51C* and *RAD51D* are each associated with a 17%-30% risk of developing breast cancer. The NCCN guidelines recommended considering an annual breast MRI starting at age 40.⁸

However, mutations and variants with a <15% absolute risk of developing breast cancer lack sufficient evidence to suggest that screening MRI would be beneficial. Therefore, the NCCN did not recommend screening MRI for these individuals unless other risks are present.⁸

The ACR Appropriateness Criteria[®] for "Female Breast Cancer Screening" had noted that "some females with a personal history of breast cancer may also fit into the high-risk category, particularly those diagnosed before 50 year of age...".⁴² They also went on to state that these women may have a greater than 20% estimated lifetime risk of another breast cancer diagnosis.⁴² The NCCN also noted that MRI Breast for screening is recommended annually for individuals diagnosed with breast cancer at or before age 50⁴⁶ who have not undergone bilateral mastectomy (see the Postmastectomy Imaging section below).

The ACS considered individuals who have a first-degree relative with a *BRCA 1* or *2* gene mutation and who have not been tested themselves to be at high risk. They recommended an annual MRI screening starting at age 30.⁶ On the other hand, NCCN guidelines suggested that untested individuals with a first-degree relative with a *BRCA 1* or *2* mutation should start screening either 10 years before the youngest family member was diagnosed with breast cancer, but not before age 25, or at age 40, whichever comes first.⁷

Per NCCN recommendations, BRCAPRO, Tyrer- Cuzick, Breast Cancer Surveillance Consortium (BCSC), and Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA)/CanRisk are appropriate models used to calculate clinical lifetime-risk.⁴⁶

The NCCN has issued guidance that recommended individuals with extremely dense breast tissue on mammogram begin screening with MRI Breast at age 50, but also notes that "consideration can be given to start at age 40 based on individual risk factors".⁷ The Updated Recommendations from ACR also addressed the use of MRI Breast in individuals with dense breast tissue for supplemental screening. They did not differentiate between heterogeneously and extremely dense breasts in their recommendation and instead, recommended screening for those with dense breasts starting at age forty.⁸⁴ ACR considers dense breasts to be heterogeneously dense (Category C) and extremely dense (Category D).⁸⁵

MRI utilizes a magnetic field and radio waves with computer processing to produce detailed images whereas CT uses ionizing radiation. Radiation dosages vary based on many factors and can be harmful to tissues. Thus, from a radiation safety perspective, MRI should be utilized when appropriate and supported by existing literature; however, the NCCN also acknowledged potential harms of MRI use, such as increased false positives, increased recall, and increased benign biopsies.⁷

Post-Biopsy or Attempted Biopsy Imaging

A study conducted by Pinnamaneni et al showed that of the 89 biopsies that were canceled secondary to nonvisualization, 74% of lesions resolved by 6 month follow-up, however 1.9% yielded carcinoma at the 6 month follow-up. Pinnamaneni et al. concluded that, "the majority of canceled MRI-guided biopsy lesions resolved on later follow-up; however, because of the small possibility of a missed malignancy, follow-up MRI imaging at 6 months is recommended".⁹⁰

The initial evaluation of individuals who present with a suspicious finding on breast imaging or a palpable mass upon examination involves a biopsy (percutaneous or surgical if percutaneous is not feasible). If the biopsy results are discordant with the imaging findings, an MRI for further evaluation is supported.¹⁶

Postmastectomy Imaging

According to the ACR Appropriateness Criteria[®] for "Imaging after Mastectomy and Breast Reconstruction", there is not enough evidence to support MRI imaging for breast cancer screening following a bilateral mastectomy.⁷³ In addition, in a study by Weed et al, it was found that "the use of surveillance MRI after NSM [nipple-sparing mastectomy] lead to increased rates of biopsy without improvement in overall survival in our study".⁸⁸

Breast Implant Evaluation (BR-5.2)

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Breast Implant Imaging

- Certain payors do **NOT** include breast implant imaging in their coverage policies if the breast implants were placed as part of purely cosmetic surgery. Thus, surveillance MRI in these individuals would also **NOT** be included in the coverage policy. Their coverage policies will take precedence over these clinical guidelines.
- Breast MRI is **NOT** medically necessary for evaluation of capsular contracture.
- Imaging for routine surveillance and/or suspected rupture of breast implants is dependent upon the type of implant. Please see below.

SALINE

Asymptomatic Screening in Females or Transfeminine Individuals

- For all ages, routine imaging is not medically necessary.

Exam Equivocal for Rupture in Females or Transfeminine Individuals

- If less than 30 years old, breast ultrasound (CPT[®] 76641 or CPT[®] 76642) is medically necessary.
- If 30 years old or older, breast ultrasound (CPT[®] 76641 or CPT[®] 76642) or diagnostic mammogram is medically necessary.
- If breast ultrasound or diagnostic mammogram results are indeterminate for saline implant rupture, additional imaging with MRI Breast Bilateral without contrast (CPT[®] 77047) is medically necessary for further evaluation.

SILICONE

Asymptomatic Screening in Females or Transfeminine Individuals

- For all ages, if it is less than 5 years since the implants were placed, routine advanced imaging is not medically necessary.
- For all ages, if it has been 5 years or more since the implants were placed, breast ultrasound (CPT[®] 76641 or CPT[®] 76642) is considered medically necessary.
 - Further evaluation with MRI Breast Bilateral without contrast (CPT[®] 774047) is medically necessary if the breast ultrasound is indeterminate.
 - Repeat breast ultrasounds (CPT[®] 76641 or CPT[®] 76642) can be done every 2 to 3 years after initial negative imaging.

Exam Equivocal for Rupture in Females or Transfeminine Individuals

- For all ages, breast ultrasound (CPT[®] 76641 or CPT[®] 76642) or diagnostic mammogram or MRI Breast Bilateral without contrast (CPT[®] 77047) is medically necessary.

- If breast ultrasound (CPT[®] 76641 or CPT[®] 76642) or diagnostic mammogram results are indeterminate for silicone implant rupture, additional imaging with MRI Breast Bilateral without contrast (CPT[®] 77047) is medically necessary for further evaluation.

Evidence Discussion

Breast Implant Evaluation

The two types of breast implants include saline and silicone. Saline implant rupture is more clinically apparent, since the body readily resorbs the leaking saline and the implant shell appears deflated on exam.¹³ Thus, there is no role for MRI Breast(s) in asymptomatic women with saline implants.¹⁴ However, if the exam is equivocal for rupture, initial imaging supported by the ACR includes diagnostic mammogram and/or ultrasound in individuals >30 years old. In those <30 years of age, diagnostic mammogram is not typically performed and ultrasound is the initial imaging of choice.¹⁴

An exam is not as reliable for detecting the rupture of silicone implants as it is for saline implants. Therefore, if an exam is equivocal for rupture, imaging with a combination of ultrasound, mammogram, and/or MRI of the breast (with the choice of mammogram depending upon age) is appropriate.¹⁵

Nipple Discharge/ Galactorrhea (BR-6)

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Nipple Discharge/Galactorrhea (BR-6.1)

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Physiologic nipple discharge (non-spontaneous or multi-duct, no suspicious findings on clinical exam)

- For individuals less than 40 years old, imaging is not medically necessary.
- For individuals 40 years old and older, a screening mammogram is medically necessary.
- If there is concern for a prolactinoma, please refer to **Pituitary, Sella, Hypothalamus (HD-19.1)**.

Pathologic nipple discharge (spontaneous, unilateral, single duct, clear or bloody, persistent and reproducible)

- For individuals less than 30 years old, breast ultrasound (CPT[®] 76641 or CPT[®] 76642) with or without a diagnostic mammogram is the medically necessary initial imaging.
 - If the breast ultrasound or diagnostic mammogram (if performed) is a BI-RADS[™] category 1-3, a MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is medically necessary.
 - If the breast ultrasound or diagnostic mammogram (if performed) are a BI-RADS[™] category 4 or 5, a MRI Breast is **NOT** medically necessary. Biopsy is recommended in these circumstances.
- For individuals 30 years old and older, breast ultrasound (CPT[®] 76641 or CPT[®] 76642) and diagnostic mammogram are the medically necessary initial imaging.
 - If the breast ultrasound or diagnostic mammogram is a BI-RADS[™] category 1-3, a MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is medically necessary.
 - If the breast ultrasound or diagnostic mammogram are a BI-RADS[™] category 4 or 5, a Breast MRI is **NOT** medically necessary. Biopsy is recommended in these circumstances.

Background and Supporting Information

- Physiologic nipple discharge is predominantly bilateral but may be unilateral. It is commonly multi-duct. It is predominantly milky but may be white or a variety of colors including serous, yellow, green, brown, or gray. Evaluation for hyperprolactinemia can be considered.
- For milky discharge, prolactin and TSH levels are recommended to diagnose prolactinoma; pituitary imaging is not needed if normal serum Prolactin.

- Pathologic nipple discharge is defined as unilateral, bloody or serous, arising from a single duct, persistent, and spontaneous.

Evidence Discussion

No specific breast imaging is used for evaluation of physiologic discharge, other than usual screening mammogram in the appropriate age group. Otherwise, the evaluation is medical, including lab studies to rule out endocrine etiology. In a study of 13,443 women with nipple discharge, 316 (2.3%) had nonspontaneous discharge, only 1 (0.3%) of whom had carcinoma.¹⁹ Similarly, a retrospective review of 273 women who underwent diagnostic and therapeutic surgery for nipple discharge found no malignancies in those presenting with physiologic nipple discharge.²⁰

The evaluation of pathologic nipple discharge is aimed at determining if there is an underlying intraductal papilloma, high-risk lesion, or a malignancy. Larger studies estimate the rate of malignancy or high-risk histopathologic lesions to be 11% to 16% of individuals with pathologic nipple discharge.²² Initial radiographic evaluation includes both diagnostic mammography and targeted breast ultrasound. If both are non-diagnostic, then MRI is the next imaging modality used for evaluation. Contrast-enhanced MRI has demonstrated sensitivities of 93 to 100 percent for invasive cancers as well as benign papillary lesions.²³

Breast Pain (Mastodynia) (BR-7)

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Breast Pain (Mastodynia) (BR-7.1)

BR.PA.0007.1.A

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- Evaluation of breast pain requires a history and physical exam.
 - When breast pain is present with another breast symptom such as nipple discharge, skin change(s), or palpable mass, the imaging should be done in accordance with the accompanying symptom's guideline rather than this guideline for breast pain.
- If pain is cyclical and/or generalized across more than one quadrant of the breast, an up-to-date screening mammogram is medically necessary.
- If pain is focal and the individual is 30 years old or older, diagnostic mammogram and breast ultrasound (CPT® 76641 or CPT® 76642) are medically necessary as the initial imaging.
- If pain is focal and the individual is less than 30 years old, breast ultrasound (CPT® 76641 or CPT® 76642) is medically necessary as the initial imaging.
- Advanced imaging is **NOT** medically necessary in individuals with breast pain or breast abscesses.

Background and Supporting Information

- The risk of malignancy following a negative clinical examination (clinical breast exam, mammogram, ultrasound) has been estimated to be only 0.5%.

Evidence Discussion

In a study of 2820 individuals presenting with breast pain, the cancer detection rate in those who underwent breast imaging was found to be 0.09%, 1% and 1.4% in individuals under the age of 40, 40-49 and 50 years of age or older, respectively.²⁴ Similarly, in a case control study comparing 987 women with painful breasts and 987 controls, the prevalence of breast cancer was similar between the two groups (0.8% vs. 0.7%, respectively).²⁵ Given these data, in the absence of other factors, the ACR recommends against the use of MRI in individuals with breast pain.²⁶

Breast abscesses can present with a variety of etiologies. In a review of various inflammatory diseases of the breast, Scott et al points to ultrasound as the appropriate initial imaging. It is also noted that while diagnostic mammogram can be done, it may not be very beneficial in all etiologies.⁹²

Alternative Breast Imaging Approaches (BR-8)

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Alternative Breast Imaging Approaches

(BR-8.1)

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Molecular Breast Imaging (MBI)

- Molecular Breast Imaging (CPT® 78800) is supported in individuals who meet criteria for breast cancer screening with MRI (per **BR-5**) but for whom MRI is contraindicated.
 - See **Risk Factors** below.

Risk Factors

- Routine MRI Breast following bilateral mastectomy is **NOT** medically necessary (even if high-risk screening criteria may otherwise be met and/or nipple-sparing mastectomy was done).
- Annual MRI Breast screening with MRI Breast Bilateral without and with contrast (CPT® 77049 or HCPCS C8908) is medically necessary for individuals meeting the high-risk criteria in the table below (for male breast imaging, please see **Breast Imaging in Males (BR-9.1)**):

High-Risk Indications	Age at which screening can start**
Genetic Mutations:*	
Li Fraumeni (p53)	20
BRCA 1 or 2	25
STK11, Peutz-Jeghers syndrome (PJS), PTEN Mutation (Cowden Syndrome), CDH1, NF1, PALB2, ATM, CHEK2	30**
BARD1, RAD51C, RAD51D	40**
Personal history of atypia/LCIS/breast cancer:	
ADH, ALH, LCIS	At diagnosis but not prior to age 25
Personal history of breast cancer at or before the age of 50	At diagnosis
Family history:	

High-Risk Indications	Age at which screening can start**
If the individual has NOT been tested for BRCA mutation and there is a first-degree relative (parent, sibling, child; half siblings are considered second-degree relatives) with BRCA 1 or BRCA 2 mutation. Annual screening is NOT medically necessary if the individual has been tested and is negative for BRCA 1 or BRCA 2 mutation unless they meet other criteria.	40**
Two or more first-degree relatives with breast or ovarian cancer	40**
One first-degree relative with breast cancer or ovarian cancer that was diagnosed $\leq$ age 50	40**
One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer	40**
A first- or second-degree male relative (father, brother/half-brother, uncle, grandfather) diagnosed with breast cancer	40**
Elevated clinical lifetime-risk:	
Clinical lifetime-risk estimated at greater than or equal to 20% as calculated by one of the following models: • Gail (National Cancer Institute (NCI)) • Tyrer-Cuzick (International Breast Cancer Intervention Study (IBIS)) • The Breast Cancer Surveillance Consortium (BCSC) • Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA)/CanRisk • BRCAPRO Model	40**
Personal history of radiation therapy when younger than age 30:	
Radiation to chest, whole lung, mediastinum, axilla, mantle (including mini mantle or extended mantle), total or subtotal lymphoid irradiation or total body irradiation (TBI)	25 or 8 years after completion of radiation therapy <i>whichever comes later</i>
Breast Density:	

High-Risk Indications	Age at which screening can start**
Heterogeneously Dense Breasts (Category C) or Extremely Dense Breasts (Category D) with no additional risk factors	40

*The following have unknown or insufficient evidence of breast cancer risk and additional MRI screening is NOT medically necessary at this time: MSH2, MLH1, MSH6, PMS2, EPCAM, NBN, genetic variants of unknown significance, genetic variants favoring polymorphism, and genetic variants of intermediate penetrance. Any gene mutation not specified in the table above has not currently been found to have sufficient evidence to support surveillance with MRI.

OR 10 years prior to the age of diagnosis of the earliest relative with breast cancer (first-, second-, and third-degree relatives) *whichever comes first*, **but not before age 25

Other Alternative Breast Imaging Techniques

Other alternative breast imaging techniques may have FDA approval, but they remain investigational with respect to **BOTH** screening and diagnosis of breast cancer. These include the following:

- Nuclear breast imaging, including:
 - Scintimammography
 - Breast specific gamma imaging (BSGI)
- PET Mammography (PEM)
- Thermography
- Impedance Mammography
- Other techniques to detect oxygen consumption, light absorption, microwave transmission, nitrous oxide production
- CT Breast (CPT[®] 0633T, CPT[®] 0634T, CPT[®] 0635T, CPT[®] 0636T, CPT[®] 0637T, or CPT[®] 0638T)
- Cone Beam CT Breast

Background and Supporting Information

- CT Breast
 - CT Breast is evolving and currently being studied as a mode of breast cancer detection. It remains under investigation, and is not to be used in lieu of conventional breast imaging modalities.
- Positron-Emission Mammography

- There is currently insufficient data available to generate appropriateness criteria for this modality, and this procedure should be considered investigational at this time.
 - High-resolution positron-emission mammography (PEM) by Naviscan™ PET Systems, also referred to as Naviscan™ or PET mammography, performs high-resolution metabolic imaging for breast cancer using an FDG tracer. The PEM detectors are integrated into a conventional mammography system, allowing acquisition of the emission images immediately after the mammogram.
 - Requesting providers often ask for PEM as CPT® 78811 or “PET scan of the breast.”
 - The spatial resolution of this technique is at the individual duct level (1.5 mm) and allows visualization of intraductal as well as invasive breast cancers. This technique is especially adept at detecting ductal carcinoma in situ.
 - Early clinical trials have shown high clinical accuracy in characterizing lesions identified as suspicious on conventional imaging or physical examination, as well as in detecting incidental breast cancers not seen on other imaging modalities.
 - A prospective multi-center clinical trial for females with newly diagnosed breast cancer anticipating breast-conservation surgery was performed. These females underwent both high-resolution PEM imaging and breast MRI. Results showed that PEM and MRI had comparable breast-level sensitivity, although MRI had greater lesion-level sensitivity and more accurately depicted the need for mastectomy. PEM had greater specificity at the breast and lesion levels. Of these, 3.6% of the females had tumors seen only with PEM.
 - The radiation exposure from a PEM study is 23 times higher than for digital mammography.

Evidence Discussion

There is limited data regarding the use of MBI in individuals of average breast cancer risk. However, in those classified as high risk (lifetime risk $\geq 20\%$), the NCCN guideline supported MBI for those who met criteria for supplemental breast MRI, but who could not undergo MRI.⁷

There is no data to support other alternative breast imaging techniques. They are not supported for screening by the ACR, NCCN, or other breast society guidelines. As more data becomes available, the guidelines will be updated accordingly.

The ACS considers individuals who have a first-degree relative with a BRCA 1 or 2 gene mutation and who have not been tested themselves to be at high risk. They recommended an annual MRI screening starting at age 30.⁶ On the other hand, NCCN guidelines suggested that untested individuals with a first-degree relative with a BRCA 1 or 2 mutation should start screening either 10 years before the youngest family member

was diagnosed with breast cancer, but not before age 25, or at age 40, whichever comes first.⁷

Breast Imaging in Males (BR-9)

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Breast Imaging in Males (BR-9.1)

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See **Breast Ultrasound (BR-1)**

Screening for Males at Increased Risk for Breast Cancer

- A clinical breast exam every 12 months is medically necessary.
- Annual mammogram, especially for those with *BRCA2* P/LP variants in whom the lifetime risk of breast cancer is up to 7%, starting at age 50 or 10 years before the earliest known male breast cancer in the family, is medically necessary.
 - MRI of the male breast is not medically necessary given the paucity of evidence supporting its efficacy in male breast disease.

Symptomatic Male Breast Imaging

- Diagnostic Mammogram and/or breast ultrasound (CPT® 76641 or CPT® 76642) is medically necessary for evaluation of the symptomatic male breast and preferred method depends on age and the suspected etiology of disease.
 - MRI of the male breast is not medically necessary given the paucity of evidence supporting its efficacy in male breast disease.

Background and Supporting Information

- Breast cancer in males presents as a mass, skin/nipple change, or pathologic nipple discharge.

Evidence Discussion

Breast cancer management in cis-gender males is similar to females. NCCN guidelines recommended that, for males presenting with bilateral breast enlargement consistent with gynecomastia or pseudogynecomastia, reassurance with clinical management of the presumed cause (e.g., drug induced, hypogonadism, hyperthyroidism, etc) is all that was needed. For males presenting with palpable symptoms not explained by gynecomastia, or for those presenting with bloody nipple discharge, work up should include mammography and ultrasound, followed by core needle biopsy if these studies should be found to be BIRADS™ category 4-5.⁷ Mammography has been found to be accurate in distinguishing benign from malignant lesions in men, and has a sensitivity and specificity of 92% and 90%, respectively, such that more advanced imaging is generally not required.²⁷

The NCCN noted support of annual mammogram for cis-gender males, noting it is especially recommended in those "with *BRCA2* P/LP variants in whom the lifetime risk of

breast cancer is up to 7%, starting at age 50 or 10 years before the earliest known male breast cancer in the family (whichever comes first)".⁸

Breast Evaluation in Pregnant or Lactating Females (BR-10)

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Breast Evaluation in Pregnant or Lactating Females (BR-10.1)

BR.PR.0010.1.A

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- Breast ultrasound (CPT[®] 76641 or CPT[®] 76642) is first-line imaging in pregnant and lactating females.
- If pregnant/lactating female has a palpable mass **OR** has persistent unilateral bloody nipple discharge and the ultrasound is negative or suspicious, follow with diagnostic mammogram (with lead abdominal shielding).
- IV Gadolinium is required with MRI to evaluate breast parenchyma but is contraindicated in pregnancy. Biopsy, rather than advanced imaging, is recommended after inconclusive mammogram and ultrasound.
- MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is supported for evaluation in lactating women if criteria are met otherwise (see **BR-5.1**).
- For imaging requests related to a breast abscess, please see **Breast Pain (Mastodynia) (BR-7.1)**.

Evidence Discussion

Pregnancy-associated breast cancer (PABC) is defined as breast cancer diagnosed during pregnancy, throughout the first postpartum year, or during lactation.

The most common presentation of PABC is a palpable mass, but >80% of palpable masses that are biopsied in pregnant and breastfeeding women are benign.⁸⁰

Given the difficulty examining the pregnant and lactating individual, diagnostic breast imaging is crucial in characterizing the features of a palpable mass. In up to 20% of lactating women, isolated bloody nipple discharge without an associated mass can occur, most commonly due to benign etiologies. However, if persistent, bloody nipple discharge can also be a sign of breast cancer. Diagnostic imaging is also recommended in these women.

Ultrasound has the highest sensitivity for the diagnosis of PABC.^{81,82} Additionally, both pregnant and lactating woman are predominantly young and have dense breast tissue. Therefore the sensitivity of mammography decreases in these women. For that reason, ultrasound is the first-line imaging in pregnant and lactating women.⁸²

Advanced imaging with breast MRI has a limited role in pregnant women. The IV administration of gadolinium is contraindicated. If there is clinical suspicion of malignancy, a biopsy is the next step in evaluation.^{61,83}

Transgender Breast Cancer Supplemental Screening (BR-12)

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Transgender Breast Cancer Supplemental Screening (BR-12.1)

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- Annual supplemental breast ultrasound (CPT[®] 76641 or CPT[®] 76642) **AND/OR** MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) screening is medically necessary for the following:
 - Transmasculine (female-to-male) with **ALL** of the following risk factors:
 - Reduction mammoplasty or no chest surgery
 - Age ≥ 25
 - High-risk ($\geq 20\%$ lifetime risk)
- Annual breast ultrasound and/or MRI Breast, in addition to mammogram, for breast cancer screening is **NOT** medically necessary in any other scenarios, including **ANY** of the following:
 - Transfeminine (male-to-female)
 - Transmasculine (female-to-male), who have had bilateral mastectomies
 - Transmasculine (female-to-male), who have **NOT** had mastectomies **AND** are at average risk or intermediate risk
- Acceptable models of calculating clinical lifetime-risk include the following: Gail (NCI), Tyrer-Cuzick (IBIS), The Breast Cancer Surveillance Consortium (BCSC), Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA)/CanRisk, or BRCAPRO.

Evidence Discussion

A number of studies have found that transgender individuals who have transitioned from female to male have the same risk of developing breast cancer as their cis-gendered female counterparts.²⁸⁻³⁰ As such, those who still have breast tissue (i.e., have only undergone reduction mammoplasty or no chest surgery), should be screened similarly to cis-gendered women.

The ACR Appropriateness Criteria[®] recommend the use of ultrasound and/or MRI for individuals who are at intermediate to high risk based on either having a lifetime risk $\geq 20\%$, a personal history of breast cancer, lobular neoplasia or atypia, chest wall irradiation, or have a genetic predisposition to developing breast cancer.³⁰ The ACR, does however, recommend transmasculine (female-to-male) individuals start screening earlier than their cis-gendered counterparts (starting at 25-30 years of age).³⁰

For transmasculine individuals who are at low to average risk, mammography alone is sufficient.²⁸⁻³⁰ Individuals who have had bilateral mastectomies have minimal

residual breast tissue, such that breast cancer screening using imaging is not medically necessary.²⁸⁻³⁰

The ACR found insufficient evidence to support the use of routine MRI screening in transfeminine (male-to-female) individuals, regardless of duration of hormone use and/or genetic factors. Transfeminine individuals who would otherwise be considered "high risk" based on personal or family history may consider annual mammography. Similarly, mammography may be appropriate in transfeminine individuals who have taken feminizing hormones for more than 5 years.³⁰

3D Rendering (BR-13)

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3D Rendering (BR-13.1)

BR.TD.0013.1.A

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- 3D rendering (CPT[®] 76376 or CPT[®] 76377) should **NOT** be used in conjunction with **ANY** 3D mammography code.
- 3D rendering (CPT[®] 76376 or CPT[®] 76377) is **NOT** indicated for breast ultrasound. It is commonly requested in conjunction with automated breast ultrasound (ABUS); there is no evidence to support its clinical usefulness.
- 3D rendering (CPT[®] 76376 or CPT[®] 76377) should **NOT** be used in conjunction with MRI Breast.

Breast Mass (BR-14)

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Breast Mass (BR-14.1)

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- MRI Breast is **NOT** medically necessary to determine biopsy recommendations for suspicious or indeterminate lesion(s) that can be readily biopsied on physical exam, such as palpable masses.
- For individuals 30 years old and older, diagnostic mammogram and breast ultrasound (CPT[®] 76641 or CPT[®] 76642) are medically necessary as the initial imaging.
 - If the breast ultrasound or diagnostic mammogram is a BI-RADS[™] category 4 or 5, a Breast MRI is NOT medically necessary. Biopsy is recommended in these circumstances.
- For individuals less than 30 years old, breast ultrasound (CPT[®] 76641 or CPT[®] 76642) is medically necessary as the initial imaging.
 - If the breast ultrasound or diagnostic mammogram is a BI-RADS[™] category 4 or 5, a Breast MRI is NOT medically necessary. Biopsy is recommended in these circumstances.

Evidence Discussion

According to the ACR Appropriateness Criteria[®] for "Palpable Breast Masses" there is a paucity of evidence to support the use of MRI Breast in the evaluation of a palpable mass regardless of what the BI-RADS[™] is on mammogram.⁹³

NCCN guidance for imaging of a palpable breast mass supports the use of diagnostic mammogram and/or ultrasound (preferred modality is dependent on age).⁷

Imaging with BI-RADS[™] assessment of category 4 require biopsy. MRI is not supported prior to biopsy.¹⁷

Imaging with BI-RADS[™] assessment of category 3 require short-term follow up imaging: at 6, 12, and 24 months.¹⁸

Skin Changes (BR-15)

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Skin Changes (BR-15.1)

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- Diagnostic mammogram with or without breast ultrasound (CPT[®] 76641 or CPT[®] 76642) is the medically necessary initial imaging.
 - If the diagnostic mammogram or breast ultrasound (if performed) is a BI-RADS[™] category 1-3, a MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is medically necessary.
 - If the diagnostic mammogram or breast ultrasound (if performed) is a BI-RADS[™] category 4 or 5, a MRI Breast is NOT medically necessary. Biopsy is recommended in these circumstances.
 - If a core needle biopsy is performed and is benign, a MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is medically necessary.
- Advanced imaging is **NOT** medically necessary in individuals with breast abscesses.

Evidence Discussion

NCCN guidance for imaging of skin changes of the breast supports the use of diagnostic mammogram with or without breast ultrasound as the initial imaging. Additional imaging with MRI Breast is appropriate for BI-RADS[™] 1, 2, or 3 on the initial imaging.⁷

Nipple Inversion/ Retraction (BR-16)

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Nipple Inversion/Retraction (BR-16.1)

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This guideline is only to be used when there is no palpable mass. If there is an associated palpable mass, please see **Palpable Mass (BR-14.1)**.

Congenital/Life-Long

- If there are no recent changes, only standard screening is recommended.
- If there are recent changes, see Acquired/New Onset below.

Acquired/New Onset

- If nipple discharge is present, please see **Nipple Discharge/Galactorrhea (BR-6.1)**.
- If skin changes are present, please see **Skin Changes (BR-15.1)**.
- For individuals 30 years old and older, diagnostic mammogram and breast ultrasound (CPT[®] 76641 or CPT[®] 76642) are medically necessary for the initial imaging.
 - If the breast ultrasound or diagnostic mammogram is a BI-RADS[™] category 1, 2, or 3, but is clinically suspicious, a MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is medically necessary.
 - If the breast ultrasound or diagnostic mammogram is a BI-RADS[™] category 4 or 5, a Breast MRI is NOT medically necessary. Biopsy is recommended in these circumstances.
- For individuals less than 30 years old, breast ultrasound (CPT[®] 76641 or CPT[®] 76642) with or without diagnostic mammogram is medically necessary for the initial imaging.
 - If the breast ultrasound or diagnostic mammogram is a BI-RADS[™] category 1, 2, or 3, but is clinically suspicious, a MRI Breast Bilateral without and with (CPT[®] 77049 or HCPCS C8908) is medically necessary.
 - If the breast ultrasound or diagnostic mammogram is a BI-RADS[™] category 4 or 5, a Breast MRI is NOT medically necessary. Biopsy is recommended in these circumstances.

Evidence Discussion

NCCN guidance for imaging of nipple inversion/retraction supports the use of diagnostic mammogram and/or breast ultrasound as the initial imaging (preferred modality is dependent on age). Additional imaging with MRI Breast is dependent on the BI-RADS[™] category of the initial imaging as well as level of clinical suspicion.⁷

Malignant Phyllodes Tumor/Cystosarcoma Phyllodes (BR-17)

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Malignant Phyllodes Tumor/ Cystosarcoma Phyllodes (BR-17.1)

BR.PT.0017.1.A

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- MRI Breast Bilateral without and with contrast (CPT[®] 77049 or HCPCS C8908) is medically necessary pre-operatively to establish extent of disease where a diagnosis of malignant phyllodes tumor has previously been established by tissue diagnosis.

Background and Supporting Information

- Phyllodes tumor is usually benign and has clinical characteristics of fibroadenoma, although they may exhibit rapid growth. MRI Breast has not been shown to be of value in distinguishing fibroadenoma from phyllodes tumor.
- Diagnosis is made by tissue diagnosis (percutaneous core biopsy or excisional biopsy). FNA biopsy is inaccurate in phyllodes tumor diagnosis and is not recommended.
- Treatment is wide local excision. Axillary lymph node dissection is not necessary. It has a predilection for local recurrence following local excision.
- If biopsy establishes a diagnosis of **malignant phyllodes** (cystosarcoma phyllodes), it should be treated as a soft tissue sarcoma. See **Sarcomas – Bone, Soft Tissue, and GIST (ONC-12)** in the Oncology Imaging Guidelines.

Evidence Discussion

Phyllodes tumors of the breast are usually benign, fibroepithelial lesions that have a range of biologic behaviors. Diagnosis is made by percutaneous core biopsy or excisional biopsy. MRI Breast has not been shown to be of value in distinguishing phyllodes tumor from fibroadenoma. However, malignant phyllodes have the propensity to metastasize. Thus, MRI is supported in malignant phyllodes to determine the extent of disease and resectability.¹²

References (BR)

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