



CLINICAL GUIDELINES

Breast Imaging Guidelines

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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

AAA	abdominal aortic aneurysm		
ACE	angiotensin-converting enzyme		
AVM	arteriovenous malformation		
BI-RADS	Breast Imaging Reporting and Database System		
BP	blood pressure	BRCA	tumor suppressor gene
CAD	computer-aided detection	CBC	Complete blood count
COPD	chronic obstructive pulmonary disease		
CT	computed tomography		
CTA	computed tomography angiography		
CTV	computed tomography venography		
DCIS	ductal carcinoma in situ	DVT	deep venous thrombosis
ECG	electrocardiogram	EM	electromagnetic
EMG	electromyogram	FDA	Food and Drug Administration
FDG	fluorodeoxyglucose	FNA	fine needle aspiration
GERD	gastroesophageal reflux disease		
GI	gastrointestinal		
HRCT	high resolution computed tomography		
IPF	idiopathic pulmonary fibrosis		
LCIS	lobular carcinoma in situ		
LFTP	localized fibrous tumor of the pleura		
MRA	magnetic resonance angiography		
MRI	magnetic resonance imaging		
MRV	magnetic resonance venography		
NCV	nerve conduction velocity		
PE	pulmonary embolus		
PEM	positron-emission mammography		
PET	positron emission tomography		
PFT	pulmonary function tests		

PPD	purified protein derivative of tuberculin
RODEO	Rotating Delivery of Excitation Off-resonance MRI
SPN	solitary pulmonary nodule
SVC	superior vena cava

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General Guidelines (BR-Preface1.0)

- 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.
- Throughout this guideline when MRI Breast is indicated any ONE of the following codes is supported:
 - ◆ CPT® 77049 MRI Breast Bilateral, including CAD, with and without contrast
 - ◆ HCPCS C8908 MRI Breast Bilateral, with and without contrast
- If the individual has breast implants the following code is supported when MRI Breast is indicated in the guidelines:
 - ◆ CPT® 77047 MRI Breast Bilateral, without contrast

BI-RADS™ Categories Chart (BR-Preface1.1)

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
Category 3: Probably Benign Finding – Short Interval Follow-up Suggested	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.
Category 4: Suspicious Abnormality – Biopsy Should Be Considered	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 her physician can make the decision on the ultimate course of action.
Category 5: Highly Suggestive of Malignancy – Appropriate Action Should Be Taken	These lesions have a high probability of being cancer and should be biopsied or treated surgically.
Category 6: Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken	These lesions have been biopsied and are known to be malignant.

BI-RADS™ Breast Density Categories (BR-Preface1.2)

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

Breast Ultrasound (BR-1)

Breast Ultrasound (BR-1.1)

- Routine performance of breast ultrasound as stand-alone screening or with screening mammography is inappropriate.^{1,2,3}
 - ◆ Breast ultrasound is a supplemental screening alternative for high-risk females (as described in **MRI Breast Indications (BR-5.1)**) 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). When a MRI Breast has not been performed in the past year for high-risk screening, then a bilateral breast ultrasound requested for supplemental screening in high-risk females with dense breasts on mammography is supported.⁶²
 - ◆ Equivocal or Occult Findings:
 - Breast ultrasound (CPT® 76641 or CPT® 76642): Radiologist Report recommendation and inconclusive or conflicting findings on mammography or MRI Breast
- 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.¹
 - ◆ A clinical office visit is not necessary prior to breast ultrasound when an abnormality has been identified on recent (within the last 60 days) 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).¹⁶
 - ◆ If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individuals risk profile.
- Mammography and breast ultrasound, in any order, regardless of age for palpable breast masses or other clinical abnormalities (such as skin change, pain, nipple inversion). Ultrasound can enhance biopsy.³
- If recent clinical examination is equivocal for rupture of breast implants (saline or silicone), initial imaging is indicated as below:

Evaluation of Suspected Rupture of Breast Implants		
Age	Saline Breast Implant	Silicone Breast Implant
<30	Breast Ultrasound	Breast Ultrasound or MRI Breast without contrast (CPT® 77047)
30-39	Breast Ultrasound or mammography/Digital breast tomosynthesis (DBT)	Breast Ultrasound, mammography/Digital breast tomosynthesis (DBT) or MRI Breast without contrast (CPT® 77047)
≥40	Mammography/Digital breast tomosynthesis (DBT)	Mammography/Digital breast tomosynthesis (DBT) or MRI Breast without contrast (CPT® 77047)

- Axilla ultrasound (CPT® 76882)
 - ◆ For females with clinically suspicious lymph nodes, preoperative axillary ultrasound with a FNA or biopsy can help identify individuals who have positive nodes.³
 - 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.
- Ultrasound Breast can be repeated at least 6 months after an US directed breast biopsy to document successful lesion sampling if histology is benign and nonspecific, equivocal or uncertain.
- 3D Reconstruction (CPT® 76376 or CPT® 76377) is not considered 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.
- State Specific Density Reporting and Imaging Mandate Laws
 - ◆ Breast density notification laws have been put into effect by many states. Breast density notification laws vary, but some also contain mandates for additional imaging, which may include MRI and/or ultrasound. For applicable requests involving members in these states, their legislative mandates should be followed.

MRI Breast (BR-2)

MRI Breast (BR-2.1)

- 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.
- Computer-aided detection (CAD) is included with the MRI Breast CPT® 77049 and CPT® 77048 procedures. The use of HCPCS code C8937 (CAD including computer algorithm analysis of MRI Breast data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation) is unnecessary with these procedures.
 - ◆ The use of CAD has little influence on the sensitivity and specificity of MRI Breast interpretation.⁹
 - ◆ The use of HCPCS code C8937 (CAD including computer algorithm analysis of MRI Breast data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation) is currently considered investigational, experimental, and/or unproven.
 - ◆ 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.
 - ◆ eviCore does not manage codes CPT® 19085 or CPT® 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”.^{6,7}

Breast Reconstruction (BR-3)

Breast Reconstruction (BR-3.1)

- CTA or MRA of the body part from which the free tissue transfer flap is being taken, can be performed for breast reconstruction preoperative planning.^{2,3}
 - ◆ For example, 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.⁸
- 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.⁸

MRI Breast is NOT Indicated (BR-4)

MRI Breast is NOT Indicated (BR-4.1)

- MRI Breast should not be used to determine biopsy recommendations for suspicious or indeterminate lesion(s) that can be readily biopsied, either using imaging guidance or physical exam, such as palpable masses and microcalcifications.^{3,6}
- Individuals with dense breasts as determined by mammogram
 - ◆ To date, evidence does not suggest improved outcomes for females whose only risk factor is breast density [See “Equivocal or Occult Findings” (Radiologist Report) in **MRI Breast Indications (BR-5.1)**].^{13,14,15}
- Low risk, probably benign (BI-RADS™ 3) lesions
 - ◆ Repeat the original type study (mammogram, US, or MRI) in 6 months
 - If repeat imaging remains BI-RADS™ 3, repeat original study 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).¹⁶
 - If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individuals risk profile.
- Suspicious (BI-RADS™ 4 or 5) lesion on mammogram and/or ultrasound
 - ◆ A lesion categorized as BI-RADS™ 4 or 5 should be biopsied.¹⁶
- Routine surveillance imaging for asymptomatic females to assess the integrity of breast implants (silicone or saline) is not supported. However, certain payors may cover this surveillance and those coverage policies take precedence over eviCore guidelines.^{17,18}
 - ◆ Certain payors do not include breast implants 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 eviCore guidelines.
- Routine surveillance MRI Breast following bilateral mastectomy is not indicated.^{45,63}
- MRI Breast Unilateral is not clinically indicated. When MRI Breast imaging is clinically indicated an MRI Breast Bilateral with and without contrast is supported.

MRI Breast Indications (BR-5)

MRI Breast Indications (BR-5.1)

- See **Breast Cancer (ONC-11)** in the Oncology Imaging Guidelines for indication for imaging related to breast cancer including:
 - ◆ Breast Cancer - Suspected/Diagnosis
 - ◆ Breast Cancer - Initial work-up/Staging
 - ◆ Breast Cancer - Restaging/Recurrence
 - ◆ Breast Cancer - Surveillance/Follow-up
 - ◆ Annual screening with prior history of breast cancer
- When MRI Breast imaging is clinically indicated an MRI Breast Bilateral with and without contrast is supported. MRI Breast Unilateral is not clinically supported. See **Breast Ultrasound (BR-1.1)** when there is a contraindication to MRI contrast.
- If recent clinical examination is equivocal for rupture of breast implants (saline or silicone), initial imaging is indicated as below:

Evaluation of Suspected Rupture of Breast Implants		
Age	Saline Breast Implant	Silicone Breast Implant
<30	Breast Ultrasound	Breast Ultrasound or MRI Breast without contrast (CPT® 77047)
30-39	Breast Ultrasound or mammography/Digital breast tomosynthesis (DBT)	Breast Ultrasound, mammography/Digital breast tomosynthesis (DBT) or MRI Breast without contrast (CPT® 77047)
≥40	Mammography/Digital breast tomosynthesis (DBT)	Mammography/Digital breast tomosynthesis (DBT) or MRI Breast without contrast (CPT® 77047)

- If initial imaging, per above table, is inconclusive additional imaging maybe indicated
- Phyllodes Tumor (Cystosarcoma Phyllodes)
 - ◆ MRI Breast is indicated preoperatively to establish extent of disease where a diagnosis of malignant phyllodes tumor has previously been established by tissue diagnosis.^{18,19,20} (See **Background and Supporting Information**)

- Equivocal or Occult Findings
 - ◆ Radiologist Report Recommendation for MRI Breast to assess inconclusive or conflicting findings on mammography or ultrasound that are not associated with a discrete palpable mass. This would include possible fat necrosis which is most commonly due to trauma or surgery.
 - ◆ Discordance between imaging findings and core needle biopsy findings. Biopsy result does not adequately explain the abnormal findings on mammogram and/or ultrasound (BI-RADS™ 4 or 5). MRI Breast can be used for further evaluation after the discordant biopsy, before consideration for surgical management vs. observation, when there is documentation provided of histopathologic discordance.
 - ◆ Fat Necrosis (most commonly due to trauma or surgery)
 - Evaluate with MRI if Ultrasound or mammogram reports inconclusive findings of fat necrosis in a female with a history of breast cancer treated with surgery (lumpectomy or mastectomy with or without reconstruction)
 - ◆ A probably benign lesion on MRI (MRI BI-RADS™ 3) should undergo repeat MRI in 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).¹⁶
 - If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individuals risk profile.
- MRI Breast can be repeated at least 6 months after a stereotactic, MRI guided or US directed breast biopsy of lesion initially seen on MRI Breast to document successful lesion sampling if histology is benign and nonspecific, equivocal or uncertain.⁵

➤ Indications for annual MRI Breast screening See table below:

High Risk Indications	
<i>MRI screening to begin at age 20:</i>	
1.	Li-Fraumeni Syndrome (TP53 mutation) should start annual breast screening MRI starting at age 20 or at the age of the earliest diagnosed breast cancer in the family, whichever comes first.
<i>MRI screening to begin at diagnosis but not prior to age 25:</i>	
2.	<i>Individuals with a history of :</i> ◆ Atypical ductal hyperplasia (ADH) ◆ Atypical lobular hyperplasia (ALH) ◆ Lobular carcinoma in situ (LCIS) ²¹
<i>MRI screening to begin at age determined by gene mutation:</i>	
3.	BRCA 1 or BRCA 2, Peutz-Jehgers Syndrome (STK11/LKB1 gene variations) begin age 25
4.	PTEN Mutation (Cowden Syndrome), CDH1, NF1, PALB2 begin age 30
5.	ATM, CHEK2, NBN begin age 40
6.	The following have unknown or insufficient evidence of breast cancer risk and additional MRI screening is not indicated at this time: ◆ BARD1, MSH2, MLH1, MSH6, PMS2, EPCAM, RAD51C, Genetic variants of unknown significance, genetic variants favoring polymorphism, genetic variants of intermediate penetrance.⁴¹
<i>MRI screening begins at age 40:</i>	
7.	First-degree relative (parent, sibling, child. Half siblings are considered second degree relatives) with BRCA 1 or BRCA 2, if individual has not been tested for BRCA mutation. (If individual has been tested and negative for mutation then annual screening is not indicated.)
<i>MRI screening begins at age 40, or 10 years before the age of relative (lineage as described below) when first diagnosed with breast cancer, but not prior to the age of 25: ^{4,12,22,30,42,43}</i>	
8.	Two or more first-degree relatives with breast or ovarian cancer.
9.	One first-degree relative with breast cancer or ovarian cancer that was diagnosed ≤age 50.
10.	One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer.
11.	A first or second-degree male relative (father, brother, uncle, grandfather) diagnosed with breast cancer.
<i>MRI screening begins at age 40:</i>	

12.	Clinical lifetime risk estimated at greater than or equal to 20% using genetic risk or clinical risk estimator, acceptable models are Gail (NCI), Claus, Tyrer-Cuzick (IBIS) or BRCAPRO.
<i>MRI screening to begin at age 25 or 8 years after completion of radiotherapy (whichever occurs later - screening MRI Breast is not supported prior to age 25)</i>	
13.	Annual MRI Breast and annual mammogram is recommended for individuals who received therapeutic radiation exposure in the following fields while they were under 30 years of age: ◆ Chest (thorax) ◆ Whole lung ◆ Mediastinal ◆ Axilla ◆ Mini-mantle, mantle, or extended mantle ◆ Total (TLI) or subtotal (SLTI) lymphoid irradiation ◆ Total body irradiation (TBI)

Background and Supporting Information

- myRisk® Hereditary Cancer (Myriad Genetics, Inc.) is not accepted as a risk calculator to determine high risk for breast cancer
- MRI should not be used in lieu of biopsy of mammographically, clinically, and/or sonographically suspicious findings (ACR Practice Guidelines).
- State Specific Density Reporting and Imaging Mandate Laws
 - ◆ Breast density notification laws have been put into effect by many states. Breast density notification laws vary, but some also contain mandates for additional imaging, which may include MRI and/or ultrasound. For applicable requests involving members in these states, their legislative mandates should be followed.
- Phyllodes Tumor (Cystosarcoma Phyllodes)
 - ◆ 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).^{18,19,20}

Nipple Discharge/Galactorrhea (BR-6)

Nipple Discharge/Galactorrhea (BR-6.1)

- Pathologic nipple discharge
 - ◆ Initial imaging should include diagnostic mammogram and ultrasound (CPT® 76641: unilateral, complete or CPT® 76642: unilateral, limited). If these are negative or inconclusive, MRI Breast is the next appropriate imaging study.^{31,32,33,34}
- Physiologic nipple discharge
 - ◆ If nipple discharge is physiologic, there are no suspicious findings on clinical exam, and mammogram and ultrasound are negative, no additional imaging is necessary, and the individual can be reassured.^{31,32,33,34}

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.^{31,32 33,34}
- 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.

Breast Pain (Mastodynia) (BR-7)

Breast Pain (Mastodynia) (BR-7.1)

- Mammogram and ultrasound are the initial imaging for breast pain.³⁹
- Advanced imaging is NOT routinely indicated in individuals with breast pain and negative evaluation (evaluation includes individual history and physical exam, pregnancy test, mammogram and ultrasound (CPT® 76641: unilateral, complete or CPT® 76642: unilateral, limited)).³⁹
 - ◆ If evaluation is not negative, See **MRI Breast Indications (BR-5.1)**.

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%.³⁹

Alternative Breast Imaging Approaches (BR-8)

Alternative Breast Imaging Approaches (BR-8.1)

- New and/or alternative breast imaging techniques include:
 - ◆ Nuclear breast imaging, including:
 - Scintimammography
 - Molecular breast imaging (MBI)
 - 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
- While alternative breast imaging techniques may have FDA approval, they remain investigational with respect to both screening and diagnosis of breast cancer.

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.

Suspected Breast Cancer in Males (BR-9)

Suspected Breast Cancer in Males (BR-9.1)

See **Breast Ultrasound (BR-1.1)**

- There is limited evidence on the use of MRI in the evaluation of male breast disease.
- Further diagnostic pathway for suspicious clinical or imaging findings usually requires tissue diagnosis.

Background and Supporting Information

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

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

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

- Breast US (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 US 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 US.

Transgender Breast Cancer Supplemental Screening (BR-12)

Transgender Breast Cancer Supplemental Screening (BR-12.1)

- Annual supplemental Ultrasound and/or MRI Breast screening is indicated for the following:
 - ◆ Transmasculine (female-to-male) with ALL the following risk factors⁶⁴:
 - Reduction mammoplasty or no chest surgery
 - Age ≥ 25
 - High-risk ($\geq 20\%$ lifetime risk)
- Annual Ultrasound and/or MRI Breast, in addition to mammogram, for breast cancer screening is **not indicated** in any other scenarios, including⁶⁴:
 - ◆ 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 are: Gail (NCI), Claus, Tyrer-Cuzick (IBIS) or BRCAPRO.)

3D Rendering (BR-13)

3D Rendering (BR-13.1)

- 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 considered 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.
- 3D rendering, CPT® 76376 or CPT® 76377 should not be used in conjunction with MRI Breast

References

1. Sprague BL, Stout NK, Schechter C, et al. Benefits, harms, and cost-effectiveness of supplemental ultrasonography screening for women with dense breasts. *Ann Intern Med.* 2015; 162(3):157-166.
2. Mendelson EB, Böhm-Vélez M, Berg WA, et al. ACR BI-RADS® Ultrasound. In: ACR BI-RADS® Atlas, Breast imaging reporting and data system. Reston, VA, *American College of Radiology.* 2013.
3. Peters NHG, Borel Rinkes IHM, Zuithoff NPA, et al. Meta-analysis of MR imaging in the diagnosis of breast lesions. *Radiology* 2008; 246(1).
4. Moy L, Elias K, Patel V, et al. Is Breast MRI helpful in the evaluation of inconclusive mammographic findings? *American Journal of Roentgenology.* 2009; 193(4):986-993.
5. Pinel-Giroux FM, El Khoury MM, Trop I, et al. Continuing medical education: breast reconstruction: review of surgical methods and spectrum of imaging findings. *Radiographics.* 2013; 33(2):435-453.
6. Dorrius MD, Van der Weide MCJ, van Ooijen PMA, et al. Computer-Aided Detection in Breast MRI: A systematic review and meta-analysis. *Eur Radiol.* August 2011; 21(8):1600–1608.
7. Lehman CD, Blume JD, DeMartini WB, et al. Accuracy and interpretation time of computer-aided detection among novice and experienced breast MRI readers. *American Journal of Roentgenology* 2013; 200(6):W683–W689.
8. NCCN Guidelines Version 2.2022. Invasive Breast Cancer: Principles of Dedicated Breast MRI Testing. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2022: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2022 ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
9. Saslow D, Boetes C, Burke W, et al. American Cancer Society Guidelines for breast screening with MRI as an adjunct to mammography. *CA Cancer J Clin* 2007; 57(2):75-89.
10. Emaus MJ, Bakker MF, Peeters PHM, et al. MR Imaging as an additional screening modality for the detection of breast cancer in women aged 50-75 years with extremely dense breasts: The DENSE trial study design. *Radiology.* 2015; 277(2).
11. American College of Obstetricians and Gynecologists. Management of women with dense breasts diagnosed by mammography. Committee Opinion No. 625 *American College of Obstetricians and Gynecologists. Obstet Gynecol.* 2015; 125. <https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Management-of-Women-With-Dense-Breasts-Diagnosed-by-Mammography#here>.
12. Siu AL. Screening for breast cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2016; 164(4):279-296.
13. Sickles EA and D'Orsi CJ. ACR BI-RADS® Follow-up and Outcome Monitoring. In: ACR BI-RADS® atlas, breast imaging reporting and data system. *American College of Radiology.* 2013.
14. McCarthy CM, Pusic A, and Kerrigan CL. Silicone breast implants and magnetic resonance imaging screening for rupture: do U.S. food and drug administration recommendations reflect an evidence-based practice approach to patient care? *Plastic & Reconstructive Surgery:* April 2008; 121(4):1127-1134.
15. Holmich LR, Vejborg I, Conrad C, et al. Untreated Silicone Breast Implant Rupture, *Plastic & Reconstructive Surgery:* July 2004; 114(1):204-214.
16. Grau AM, Bapsi C, Chugh R, et al. Phyllodes tumors of the breast. *UpToDate,* 6/2017.
17. Tan H, Zhang S, Liu H, et al, Imaging findings in phyllodes tumors of the breast. *Eur J Radiol.* Jan 2012; 81(1):e62-69.
18. NCCN Guidelines Version 2.2022: Phyllodes Tumor National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2022: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2022 ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
19. NCCN Guidelines Version 1.2022: Breast Cancer Risk Reduction National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2022: Breast Cancer Risk Reduction. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer Risk Reduction 1.2022 ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
20. Morris EA, Comstock CE, Lee CH, et al. ACR BI-RADS® Magnetic Resonance Imaging. In: ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, *American College of Radiology.* 2013.
21. Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): *Institute for Clinical Systems Improvement (ICSI);* 2012 Jan. 45 p.

22. NCCN Guidelines Version 2.2022: Ductal Carcinoma in Situ. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2022: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2022 ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
23. NCCN Guidelines Version 2.2022: Invasive Breast Cancer National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2022: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2022 ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
24. Lehman CD, Gatsonis C, Kuhl CK, et al. MRI evaluation of the contralateral breast in women with recently diagnosed breast cancer. *N Engl J Med*. 2007 March; 356(13):1295-1303.
25. NCCN Guidelines Version 2.2022: Paget's Disease. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2022: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2022 ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
26. Lim HS et al. Paget Disease of the breast: mammographic, US, and MR imaging findings with pathologic correlation. *Radiographics*. 2011; 31(7); 1973-1987.
27. NCCN Guidelines Version 2.2022. Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2022: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic 2.2022 ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
28. Lee SJ, Trikha S, Moy L, et al. ACR Appropriateness Criteria® Evaluation of Nipple Discharge. *Journal of the American College of Radiology*. 2017; 14(5):138-153.
29. Berger N, Luparia A, Di G, et al. Diagnostic Performance of MRI versus galactography in women with pathologic nipple discharge: a systematic review and meta-analysis. *AJR. American Journal of Roentgenology*. August 2017; 209(2):465-471.
30. Bahl M, Gadd MA, Lehman CD. Diagnostic utility of MRI after negative or inconclusive mammography for the evaluation of pathologic nipple discharge. *American Journal of Roentgenology*. 2017; 209(6):1404-1410.
31. Morrogh M, Morris EA, Liberman L, et al. The predictive value of ductography and magnetic resonance imaging in the management of nipple discharge. *Ann Surg Oncol*. 2007; 14; 3369.
32. Berg WA. Current status of dedicated nuclear breast imaging. Society of breast imaging white paper. *Journal of Nuclear Medicine*. 2016 Feb; 57(Supplement 1):46S-52S.
33. Lee CH, Dershaw DD, Kopans D, et al. Breast cancer screening with imaging: recommendations from the Society of Breast Imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. *J Am Coll Radiol*. 2010; 7(1):18-27.
34. Monticciolo DL, Newell MS, Moy L, Niell B, Monsees B, Sickles EA. Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR. *Journal of the American College of Radiology*. 2018;15(3):408-414.
35. Centers for Disease Control and Prevention (CDC). <https://www.cdc.gov/genomics/gtesting/file/print/fbr/BCAnaVal.pdf>.
36. NCCN Guidelines Version 1.2021, May 6, 2021 Breast Cancer Screening and Diagnosis. National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2021: Breast Cancer Screening and Diagnosis. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer Screening and Diagnosis 1.2021 ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
37. Koning Breast CT. Koning Corporation. <http://koninghealth.com/en/kbct/>.
38. Golan O, Amitai Y, Barnea Y, Menes TS. Yield of surveillance magnetic resonance imaging after bilateral mastectomy and reconstruction: a retrospective cohort study. *Breast Cancer Research and Treatment*. 2018;174(2):463-468. doi:10.1007/s10549-018-05077-9.
39. Sanders LM, El-Madany M, Persing A, Mehta A. Use of Contrast-Enhanced MRI in Management of Discordant Core Biopsy Results. *American Journal of Roentgenology*. 2019;212(5):1157-1165. doi:10.2214/ajr.18.20157.

40. Sanders LM. Breast MRI in the management of the discordant-benign core biopsy. *Diagnostic Imaging Europe*. 2019;35(5). 13-16.
41. ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast. Revised 2018. (Resolution 34). <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/mr-contrast-breast.pdf>.
42. Diflorio-Alexander RM, Slanetz PJ, Moy L, et al. ACR Appropriateness Criteria® Breast Imaging of Pregnant and Lactating Women. *Journal of the American College of Radiology*. 2018;15(11). doi:10.1016/j.jacr.2018.09.013.
43. Children's Oncology Group. Long-term follow up guidelines for survivors of childhood, adolescent and young adult cancers, version 5.0. Monrovia, CA: Children's Oncology Group; pg 90. October 2018. http://www.survivorshipguidelines.org/pdf/2018/COG_LTFU_Guidelines_v5.pdf.
44. Boone JM, Kwan ALC, Yang K, Burkett GW, Lindfors KK, Nelson TR. Computed Tomography for Imaging the Breast. *Journal of Mammary Gland Biology and Neoplasia*. 2006;11(2):103-111. doi:10.1007/s10911-006-9017-1.
45. Boone JM, Nelson TR, Lindfors KK, Seibert JA. Dedicated Breast CT: Radiation Dose and Image Quality Evaluation. *Radiology*. 2001;221(3):657-667. doi:10.1148/radiol.2213010334.
46. Diekmann F. Contrast-enhanced Dedicated Breast CT. *Radiology*. 2011;258(2):650-650. doi:10.1148/radiol.101761.
47. Glick SJ. Breast CT. *Annual Review of Biomedical Engineering*. 2007;9(1):501-526. doi:10.1146/annurev.bioeng.9.060906.151924.
48. Hendrick RE. Radiation Doses and Cancer Risks from Breast Imaging Studies. *Radiology*. 2010;257(1):246-253. doi:10.1148/radiol.10100570.
49. The Future of Breast Imaging is Here. Koning Corporation. <http://koninghealth.com/en/>.
50. Lindfors KK, Boone JM, Nelson TR, Yang K, Kwan ALC, Miller DF. Dedicated Breast CT: Initial Clinical Experience. *Radiology* 2008; 246: 725- 733.
51. Prionas ND, Lindfors KK, Ray S, et al. Contrast-enhanced Dedicated Breast CT: Initial Clinical Experience. *Radiology*. 2010;256(3):714-723. doi:10.1148/radiol.10092311.
52. Aminololama-Shakeri S, Abbey CK, Gazi P, et al. Differentiation of ductal carcinoma in-situ from benign micro-calcifications by dedicated breast computed tomography. *European Journal of Radiology*. 2016;85(1):297-303. doi:10.1016/j.ejrad.2015.09.020.
53. Aminololama-Shakeri S, Abbey CK, López JE, et al. Conspicuity of suspicious breast lesions on contrast enhanced breast CT compared to digital breast tomosynthesis and mammography. *The British Journal of Radiology*. 2019;92(1097):20181034. doi:10.1259/bjr.20181034.
54. Aminololama-Shakeri S, Hargreaves JB, Boone JM, Lindfors KK. Dedicated Breast CT: Screening Technique of the Future. *Current Breast Cancer Reports*. 2016;8(4):242-247. doi:10.1007/s12609-016-0227-2.
55. SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED). https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf.
56. Expert Panel on Breast Imaging, Heller SL, Lourenco AP, et al. ACR Appropriateness Criteria® Imaging After Mastectomy and Breast Reconstruction. *J Am Coll Radiol*. 2020;17(11S):S403-S414. doi:10.1016/j.jacr.2020.09.009
57. Expert Panel on Breast Imaging; Mainiero MB, Moy L, et al. ACR Appropriateness Criteria® Breast Cancer Screening. *J Am Coll Radiol*. 2017;14(11S):S383-S390. doi:10.1016/j.jacr.2017.08.044
58. Expert Panel on Breast Imaging, Lewin AA, Moy L, et al. ACR Appropriateness Criteria® Stage I Breast Cancer: Initial Workup and Surveillance for Local Recurrence and Distant Metastases in Asymptomatic Women. *J Am Coll Radiol*. 2019;16(11S):S428-S439. doi:10.1016/j.jacr.2019.05.024
59. Expert Panel on Breast Imaging; Holbrook AI, Moy L, et al. ACR Appropriateness Criteria® Breast Pain. *J Am Coll Radiol*. 2018;15(11S):S276-S282. doi:10.1016/j.jacr.2018.09.014
60. Expert Panel on Breast Imaging; Lourenco AP, Moy L, et al. ACR Appropriateness Criteria® Breast Implant Evaluation. *J Am Coll Radiol*. 2018;15(5S):S13-S25. doi:10.1016/j.jacr.2018.03.009
61. Children's Oncology Group. Long-term follow up guidelines for survivors of childhood, adolescent and young adult cancers, version 5.0. Monrovia, CA: Children's Oncology Group; October 2018; Available on-line: www.survivorshipguidelines.org
62. Expert Panel on Breast Imaging, Weinstein SP, Slanetz PJ, et al. ACR Appropriateness Criteria® Supplemental Breast Cancer Screening Based on Breast Density. *J Am Coll Radiol*. 2021;18(11S):S456-S473. doi:10.1016/j.jacr.2021.09.002
63. Gradishar WJ, Moran MS, Abraham J, et al. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2022 – December 20, 2021. Breast cancer, available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer V2.2022 – December 20, 2021. ©2021 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines™, go online to NCCN.org

64. Expert Panel on Breast Imaging, Brown A, Lourenco AP, et al. ACR Appropriateness Criteria® Transgender Breast Cancer Screening. J Am Coll Radiol. 2021;18(11S):S502-S515. doi:10.1016/j.jacr.2021.09.005