CLINICAL GUIDELINES

Breast Imaging Guidelines

Version 1.0

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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.

Breast Imaging Guidelines

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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

BR-Preface1: General Considerations

BR-Preface1.0: General Guidelines

- A current clinical evaluation (within 60 days) is usually required prior to considering advanced imaging.
  - A clinical evaluation should include the following:
    - A relevant history and physical examination
    - Appropriate laboratory studies and non-advanced imaging modalities, such as mammogram and/or ultrasound
    - Other meaningful contact (telephone call, electronic mail or messaging) by an established patient can substitute for a face-to-face clinical evaluation
- Current clinical evaluation is not required prior to screening studies.

BR-Preface1.1: BI-RADS™ Categories Chart

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.
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.

BI-RADS™ Categories Chart	
Category	**Description**
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 patient 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.

BR-Preface1.2: BI-RADS™ Breast Density Categories

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

BR-1: Breast Ultrasound

- Routine performance of breast ultrasound as stand-alone screening or with screening mammography is inappropriate.[1,2,3]
  - Ultrasound screening for women whose only indication is dense breast tissue is not indicated.[1,2,3]
  - Equivocal or Occult Findings:
    - Radiologist Report recommendation for Breast ultrasound (CPT® 76641 or CPT® 76642) 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.
- Palpable breast masses or other clinical abnormalities (such as skin change, pain, nipple inversion) should be evaluated with mammography and breast ultrasound, in any order, regardless of age. Ultrasound can enhance biopsy.[3]
- Axilla ultrasound (CPT® 76882)
  - For women with clinically suspicious lymph nodes, preoperative axillary ultrasound with a FNA or biopsy can help identify patients who have positive nodes.[3]
    - See **CH-2.2: Axillary Lymphadenopathy** 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.

BR-2: MRI Breast

- 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 patients.
- 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 CPT® 77049, CPT® 77048 or HCPCS code C8937.
- Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral (CPT® 77049) is preferred in most individuals for the evaluation of breast parenchyma.
- Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral (CPT® 77048) may be preferred in some individuals after mastectomy, per physician request.
- Magnetic resonance imaging, breast, without contrast material; bilateral (CPT® 77047) or Magnetic resonance imaging, breast, without contrast material; unilateral (CPT® 77046) may be performed if there are clinical reasons or concerns regarding the use of gadolinium contrast.
- MRI guided breast biopsy (CPT® 19085) includes the imaging component.
  - Additional lesions should be billed using CPT® 19086.
- MRI Breast can be repeated at least 6 months after an MRI directed breast biopsy to document successful lesion sampling if histology is benign and nonspecific, equivocal or uncertain.[5]

Practice Notes

- 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 patient population. Cancer is identified by MRI Breast in only 0.7% of those with "inconclusive mammographic lesions".[6,7]

BR-3: Breast Reconstruction

- 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]

BR-4: MRI Breast is NOT Indicated

- 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]
- Patients with dense breasts as determined by mammogram
  - To date, evidence does not suggest improved outcomes for women whose only risk factor is breast density [See heading "Equivocal or Occult Findings" (Radiologist Report) in **BR-5: MRI Breast Indications**].[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 have BI-RADS™ 4 or 5 should be biopsied.[16]
- Surveillance MRI for silent/asymptomatic rupture of silicone implants is considered investigational, as there is no evidence basis that surveillance reduces morbidity and/or mortality. However, certain payers may cover this surveillance and those coverage policies take precedence over eviCore guidelines.[17,18]
  - Certain payers 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 patients 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]

BR-5: MRI Breast Indications

- MRI Breast is indicated for breast augmentation, breast implants (saline or silicone), breast reconstruction, free injection, and capsular contracture to:
  - Evaluate or confirm breast implant rupture when mammography or ultrasound is uninterpretable.[1]
- 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 **Practice Note**)
- Equivocal or Occult Findings
  - Radiologist Report Recommendation for MRI Breast and inconclusive or conflicting findings on mammography or ultrasound of a finding that is not a discrete palpable mass.
  - 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.
  - Fat Necrosis (most commonly due to trauma or surgery)
    - May evaluate with MRI if Ultrasound or mammogram reports inconclusive findings of fat necrosis in a woman 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 an MRI directed breast biopsy to document successful lesion sampling if histology is benign and nonspecific, equivocal or uncertain.[5]
- Newly Diagnosed Breast Cancer[4] (including DCIS).[1,6,24,25,26]
- Newly Diagnosed Paget's Disease[5] (thereafter treat as DCIS according to these guidelines).[26,28]
- Residual or Recurrent Malignancy
  - Assessment of residual tumor in patients who have undergone lumpectomy and have close or positive margins, when the findings may indicate a significant change in surgical management.[29]
  - Evaluate clinical suspicion of recurrence, following evaluations with mammography and/or ultrasound, if those evaluations are inconclusive or conflict with physical examination or other clinical indicators. This applies to intact breasts, reconstructed breasts, and possible chest wall recurrences following mastectomy.[29]

- Indications for annual MRI Breast screening See table below:

High Risk Indications	
MRI screening to begin at age 20:	
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.
MRI screening to begin at diagnosis but not prior to age 25:	
2.	*Patients with a history of :* ◆ Atypical ductal hyperplasia (ADH) ◆ Atypical lobular hyperplasia (ALH) ◆ Lobular carcinoma in situ (LCIS) [21]
MRI screening to begin at age determined by gene mutation:	
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]
MRI screening begins at age 40, or 10 years before the age of relative when first diagnosed with breast cancer, but not prior to the age of 25: [4,12,22,30,42,43]	
7.	First-degree relative (parent, sibling, child. Half siblings are considered second degree relatives) with BRCA 1 or BRCA 2, if patient has not been tested for BRCA mutation. (If patient has been tested and negative for mutation then annual screening is not indicated.)
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.
12.	Clinical lifetime risk estimated at greater than or equal to 20% using genetic risk or clinical risk estimator such as Gail, Claus, Tyrer-Cuzick (also known as IBIS) or BRCAPRO models.

Additional Risks:	
13.	Annual MRI Breast is recommended beginning at age 25 or 8 years after completion of radiotherapy (whichever occurs later) for patients receiving therapeutic radiation exposure in the following fields for any pediatric cancer: ◆ Chest (thorax) ◆ Whole lung ◆ Mediastinal ◆ Axilla ◆ Mini-mantle, mantle, or extended mantle ◆ Total (TLI) or subtotal (SLTI) lymphoid irradiation ◆ Total body irradiation (TBI)
Personal History of Breast Cancer	
14.	MRI Breast surveillance (annual) is indicated for patients with a personal history of breast cancer (not treated with bilateral mastectomy) who had a clinical lifetime risk estimated at greater than or equal to 20% using genetic risk or clinical risk estimator such as the Gail, Claus, Tyrer-Cuzick or BRCAPRO models prior to initial diagnosis of breast cancer.[11,12]
15.	MRI Breast surveillance (annual) is indicated for patients with a personal history of breast cancer (not treated with bilateral mastectomy) and extremely dense breast tissue (Breast Density Category D) on mammography.[39]
16.	MRI Breast surveillance (annual) is indicated for patients with a personal history of breast cancer (not treated with bilateral mastectomy) diagnosed before age 50.[39]

Practice Notes

- MRI should not be used in lieu 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. Breast MRI 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 **ONC-12:**

Sarcomas – Bone, Soft Tissue and GIST in the Oncology Imaging Guidelines).[18,19,20]

BR-6: Nipple Discharge/Galactorrhea

- Pathologic nipple discharge is defined as unilateral, bloody or serous, arising from a single duct, persistent, and spontaneous.
  - If the nipple discharge is pathologic, ductography should be attempted.
  - If mammogram and ultrasound are negative, and ductography is unavailable or technically limited, MRI Breast can be performed.[31,32,33,34]
- 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 (See **Practice Note**).[31,32 33,34]
- Mammogram and ultrasound (CPT® 76641: unilateral, complete or CPT® 76642: unilateral, limited) should be obtained as initial imaging, with clinical pathway determined by results.[31,32,33,34]
- 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 patient can be reassured.[31,32,33,34]

Practice Notes

- For milky discharge, prolactin and TSH levels are recommended to diagnose prolactinoma; pituitary imaging is not needed if normal serum Prolactin.

BR-7: Breast Pain (Mastodynia)

- Mammogram and ultrasound are the initial imaging for breast pain.[39]
- Advanced imaging is NOT routinely indicated in patients with breast pain and negative evaluation (evaluation includes patient 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 **BR-5: MRI Breast Indications**.

Practice Notes

- The risk of malignancy following a negative clinical examination (clinical breast exam, mammogram, ultrasound) has been estimated to be only 0.5%.[39]

BR-8: Alternative Breast Imaging Approaches

- 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.

Practice Notes

- 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 women with newly diagnosed breast cancer anticipating breast-conservation surgery was performed. These women 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 women had tumors seen only with PEM.
    - The radiation exposure from a PEM study is 23 times higher than for digital mammography.

BR-9: Suspected Breast Cancer in Males

- Breast cancer in men presents as a mass, skin/nipple change, or pathologic nipple discharge.
- For men <25 years of age with an indeterminate palpable mass, ultrasound is recommended as initial imaging followed by mammography if ultrasound is inconclusive or suspicious.
- For men ≥25 years of age with an indeterminate palpable mass or with a concerning physical examination, mammography is recommended initially followed by ultrasound if mammography is inconclusive or suspicious.
- 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.

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BR-10: Evaluation in Pregnant or Lactating Women

- Breast US is first-line imaging in pregnant and lactating women.
- If pregnant/lactating woman 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 mammogram and US.

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