CLINICAL GUIDELINES

Breast Imaging Policy

Version 1.0.2018

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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		

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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

BI-RADS™ Categories Chart

Category 0: Incomplete
Need additional imaging evaluation or prior mammograms for comparison.

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.

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-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 Breast MRI
- 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 is appropriate at 6, 12, 18 and 24 months from the original study.[4]
- Palpable breast masses 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**
  - Bilateral should be coded CPT® 76882 x 2
- 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. The pertinent language in these mandates is provided via the link below.
  - Link: **State Specific Mandates**

BR-2: Breast MRI

- Breast MRI is usually bilateral (CPT® 77059) or can be unilateral (CPT® 77058) in some after mastectomy, per physician request.
- 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]

Breast MRI – Practice Notes

- Although breast MRI 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 breast MRI's 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 breast MRI 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 pelvis (CPT® 74175 or CPT® 72191 or CPT® 74174) or MRA (CPT® 74185 and CPT® 72198) of the abdomen and pelvis 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: CAD for Breast MRI

- The use of CAD with breast MRI is currently considered investigational, experimental, and/or unproven.[9,10]
  - CAD has little influence on the sensitivity and specificity of the performance of radiologists experienced in breast MRI diagnosis.[9]
  - 3D rendering codes (CPT® 76376 or CPT® 76377) should not be used in conjunction with code CPT® 0159T.
    - See: **Preface-4.1: 3D Rendering**

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BR-5: Breast MRI is NOT Indicated

- Breast MRI 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]
- MRI should not be used for routine surveillance in patients with history of breast cancer, unless there are physical exam, imaging findings, evidence of recurrent disease or residual disease at the mastectomy site. Routine annual surveillance is indicated for those whose lifetime risk of a second primary cancer is greater than 20% based on models largely dependent on family/genetic history.[11,12]
  - Annual screening breast MRI study is indicated for high risk patients as outlined in **BR-6: Breast MRI Indications**.[11,12]
- 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-6: Breast MRI Indications**].[13,14,15]
- Low risk, probably benign (BI-RADS™3) lesions
  - Repeat the original type study (mammogram, US, or MRI) in 6 months, with repeat at 12, 18 months, and 24 months from the original study. After 2 years of stability, the finding should be assessed as benign (Cat 2).[16]
- 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.

BR-6: Breast MRI Indications

- Breast MRI 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
  - Breast MRI 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]

Practice Note

- 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 (**ONC-12: Sarcomas – Bone, Soft Tissue and GIST**).[18,19,20]

- Annual breast MRI is indicated for high risk histologies or characteristics:
  - Atypical ductal hyperplasia (ADH)
  - Atypical lobular hyperplasia (ALH)
  - Lobular carcinoma in situ (LCIS) [21]
- Equivocal or Occult Findings
  - Radiologist Report Recommendation for Breast MRI and inconclusive or conflicting findings on mammography or ultrasound of a finding that is not a palpable mass.
  - A probably benign lesion on MRI (MRI **BI-RADS™ 3**) should undergo repeat MRI in 6 months, with repeat at 12, 18 months and 24 months from the original study. After 2 years of stability, the finding should be assessed as benign (Cat 2).
- 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]
  - 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]

High Risk Indications	
For 1 and 2 below, begin MRI screening at age 25. [2,12,22,30]	
1.	BRCA 1 or BRCA 2 mutation
2.	Presence of Cowden (PTEN), Bannayan-Riley-Ruvalcaba. Genetic factors also associated with > 20% risk of breast cancer, include ATM, CDH1, CHEK2, PALB2, PTEN, STK11.
For 3 through 8 below, MRI screening begins at age 40, or 10 years before the age of relative when first diagnosed with breast cancer, whichever is earlier. The screening MRI not to begin prior to the age of 25. [4, 12, 22, 30]	
3.	First-degree relative (parent, sibling, child) with BRCA 1 or BRCA 2, even if patient has not been tested for BRCA mutation.
4.	Two or more first-degree relatives with breast or ovarian cancer.
5.	One first-degree relative with breast cancer or ovarian cancer that was diagnosed <=age 50.
6.	One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer.
7.	A first or second-degree male relative (father, brother, uncle) diagnosed with breast cancer.
8	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.
Additional Risks:	
9.	Women with history of radiation to the chest between ages 10 and 30; breast screening should start 8 to 10 years post-therapy, or at age 25, whichever comes first.[4,12,30]
10.	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, if below age 20 years of age.[22]

Breast MRI Indications - 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. The pertinent language in these mandates is provided via the link below.
  - Link to **State Specific Mandates**

BR-7: 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, breast MRI 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 - Nipple Discharge/Galactorrhea

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

BR-8: 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-6: Breast MRI Indications**

Breast Pain – Practice Notes

- The risk of malignancy following a negative examination has been estimated to be only 0.5%.[39]

BR-9: 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
- While alternative breast imaging techniques may have FDA approval, they remain investigational with respect to both screening and diagnosis of breast cancer.

BR-10: 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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