

**American College of Radiology
ACR Appropriateness Criteria®
Breast Pain**

Variant 1: Female with clinically insignificant breast pain (nonfocal [greater than one quadrant], diffuse, or cyclical) without other suspicious clinical finding. Any age. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| Digital breast tomosynthesis diagnostic | Usually Not Appropriate | ☼☼ |
| Mammography diagnostic | Usually Not Appropriate | ☼☼ |
| MRI breast without and with IV contrast | Usually Not Appropriate | ○ |
| MRI breast without IV contrast | Usually Not Appropriate | ○ |
| Sestamibi MBI | Usually Not Appropriate | ☼☼☼ |
| US breast | Usually Not Appropriate | ○ |

Variant 2: Female with clinically significant breast pain (focal and noncyclical). Age less than 30. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| US breast | Usually Appropriate | ○ |
| Digital breast tomosynthesis diagnostic | Usually Not Appropriate | ☼☼ |
| Mammography diagnostic | Usually Not Appropriate | ☼☼ |
| MRI breast without and with IV contrast | Usually Not Appropriate | ○ |
| MRI breast without IV contrast | Usually Not Appropriate | ○ |
| Sestamibi MBI | Usually Not Appropriate | ☼☼☼ |

Variant 3: Female with clinically significant breast pain (focal and noncyclical). Age 30 to 39. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| Digital breast tomosynthesis diagnostic | Usually Appropriate | ☼☼ |
| Mammography diagnostic | Usually Appropriate | ☼☼ |
| US breast | Usually Appropriate | ○ |
| MRI breast without and with IV contrast | Usually Not Appropriate | ○ |
| MRI breast without IV contrast | Usually Not Appropriate | ○ |
| Sestamibi MBI | Usually Not Appropriate | ☼☼☼ |

Variant 4:**Female with clinically significant breast pain (focal and noncyclical). Age greater than or equal to 40. Initial imaging.**

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| Digital breast tomosynthesis diagnostic | Usually Appropriate | ☼☼ |
| Mammography diagnostic | Usually Appropriate | ☼☼ |
| US breast | Usually Appropriate | ○ |
| MRI breast without and with IV contrast | Usually Not Appropriate | ○ |
| MRI breast without IV contrast | Usually Not Appropriate | ○ |
| Sestamibi MBI | Usually Not Appropriate | ☼☼☼ |

BREAST PAIN

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Summary of Literature Review

Introduction/Background

Breast pain is a common complaint for which patients seek medical attention, with a prevalence of up to 70% to 80% [1-5]. However, breast pain or tenderness is rarely found to result from cancer when not associated with a palpable mass or other suspicious clinical finding. Studies show that the incidence of breast cancer in patients with breast pain as their only symptom is 0% to 3.0% [6-13]. Some authors have found no increased risk of malignancy in patients with breast pain, while others have even found a decreased risk when compared to those without pain [14,15].

Breast pain should be triaged into one of two categories: pain that is not suspicious for associated malignancy versus pain that may be clinically significant. Clinically insignificant pain is cyclical (temporally associated with the menstrual cycle) or nonfocal/diffuse, either unilateral or bilateral. This type of pain is not associated with malignancy [8]. Benign causes of breast pain are numerous and include hormonal variations, larger cup size, ill-fitting or unsupportive bra, lower levels of fitness or activity, fibromyalgia, cysts, periductal mastitis, stretching of Cooper ligaments, fat necrosis, surgery, Mondor disease, diabetic mastopathy, duct ectasia, musculoskeletal disease, referred nerve root pain from degenerative spinal changes, herpes zoster, heart disease, biliary pain, and peptic ulcer [3,5,16-26].

Clinically significant pain, while still overwhelmingly due to a benign etiology, has occasionally been found to be associated with malignancy [8,9,11,12]. When malignancy related, pain tends to be well localized and persistent [27]. Therefore, breast pain is considered potentially clinically significant when it persists and is focal, defined as involving <25% of the breast and axillary tissue.

Special Imaging Considerations

Digital breast tomosynthesis (DBT) can address some of the limitations encountered with standard mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that may decrease the lesion-masking effect of overlapping normal tissue, and reveal the true nature of potential false positive findings without the need for recall. While there is no specific literature assessing its use in evaluation of breast pain, DBT can be useful in the diagnostic setting, improving lesion characterization [28-31] in noncalcified lesions, when compared to conventional mammographic workup.

The following discussion is for cases of isolated breast pain without other symptoms. In cases where the pain is associated with other symptoms, for example, lump or nipple discharge, pain should be considered a secondary symptom and the workup should follow the ACR Appropriateness Criteria recommendations for that additional symptom.

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The American College of Radiology seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply individual or society endorsement of the final document.

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Discussion of Procedures by Variant

Variant 1: Female with clinically insignificant breast pain (nonfocal [greater than one quadrant], diffuse, or cyclical) without other suspicious clinical finding. Any age. Initial imaging.

Mammography

There is very limited literature specifically evaluating the use of imaging in patients with nonfocal or cyclical breast pain. In a retrospective review of 236 patients with breast pain, authors found no mammographic or sonographic correlate in the 10 patients who had cyclical breast pain [8].

Given that this type of breast pain is not associated with malignancy, the use of mammography beyond the usual screening recommendations is not expected to result in increased cancer detection. Some argue that imaging may be helpful in order to reassure the patient of the absence of malignancy [14,32]. One study found patients with breast pain reported a decreased level of pain and anxiety after sonography [33]. However, the assumption that negative imaging reassures the patient or clinician is challenged by a retrospective cohort study that found that imaging women with breast pain at the time of the initial clinical visit increased the odds of subsequent clinical visits [34].

DBT

There is no relevant literature regarding the specific use of DBT in the evaluation of nonfocal or cyclical breast pain.

US Breast

There is scant literature specifically evaluating the use of ultrasound (US) imaging in patients with nonfocal or cyclical breast pain. In a retrospective review of 236 patients with breast pain, authors found no mammographic or sonographic correlate in the 10 patients who had cyclical breast pain [8]. A prospective study of 76 patients younger than age 30 who presented with cyclical breast pain as their only complaint and underwent US found no malignancy [35]. A limitation of this study was the lack of follow-up.

MRI Breast

There is no relevant literature regarding the use of MRI in the evaluation of nonfocal or cyclical breast pain.

Sestamibi MBI

There is no relevant literature regarding the use of molecular breast imaging (MBI) in the evaluation of nonfocal or cyclical breast pain.

Variant 2: Female with clinically significant breast pain (focal and noncyclical). Age less than 30. Initial imaging.

Mammography

There is little in the literature specifically evaluating the use of mammography in patients less than 30 years of age who have focal and noncyclical breast pain. Because of greater breast density, mammography is known to be less accurate than US in evaluating symptomatic women less than 30 years of age [36].

DBT

There is no relevant literature regarding the use of DBT in the evaluation of focal and noncyclical breast pain in patients less than 30 years of age.

US Breast

The literature regarding the efficacy of US in evaluation of breast pain is somewhat limited by lack of age-group-specific results. Most authors have found that cancer is a rare cause of focal, clinically significant breast pain [12,35], and that US has a high negative predictive value (NPV), sensitivity, and specificity for evaluation of breast pain. Leddy et al [11] performed a retrospective review of 257 patients who underwent US after presenting with focal breast pain and found cancer in 1.2% of patients, with a sensitivity of 100%, specificity of 92.5%, positive predictive value of 13.6%, and NPV of 100%. Loving et al [37] found a 100% NPV and sensitivity in their retrospective study of 830 patients less than 30 years of age with focal breast signs or symptoms (not limited to but including breast pain).

Some authors suggest that, despite the low incidence of malignancy, US may be useful in that it could potentially find treatable causes of breast pain, such as cysts [9]. On the other hand, a prospective, observational follow-up study of 987 patients with breast pain alone found benign findings in 8.6% of cases, which consisted mostly of

small cysts [14]. The authors argued that in the absence of a palpable abnormality, any cyst that may be found by US would be unlikely to be large enough to cause pain or benefit from aspiration.

MRI Breast

There is no relevant literature regarding the use of MRI in the evaluation of focal and noncyclical breast pain.

Sestamibi MBI

There is no relevant literature regarding the use of MBI in the evaluation of focal and noncyclical breast pain.

Variant 3: Female with clinically significant breast pain (focal and noncyclical). Age 30 to 39. Initial imaging.

Mammography

Though the incidence is low, mammography may be used to exclude malignancy in cases of focal and noncyclical breast pain. Mammography was found to have a high sensitivity (100%) and NPV (100%) in a retrospective review of 206 patients with focal breast pain [11]. While this study found specificity to be slightly lower at 87.6%, another retrospective study of focal, noncyclical pain calculated a specificity of mammography of 97% for nondense breasts and 96% for dense breasts [9]. Additionally, Tumyan et al [38] in a retrospective study of mammography in combination with US found a NPV of 100%, though the study was limited by a significant number of patients being lost to follow-up.

DBT

While there is no literature specifically evaluating the use of DBT in the workup of focal and noncyclical breast pain, DBT can be useful in the diagnostic setting. It is known to improve lesion characterization in noncalcified lesions and cancer detection when compared to conventional mammographic workup [28-30,39-41].

US Breast

While there are few studies evaluating US independently of mammography in the setting of focal and noncyclical breast pain, the existing literature suggests that US may be useful to exclude malignancy in these cases. A retrospective review of 110 cases of focal breast pain evaluated by US found no imaging abnormality in 85 cases (77.3%) [12] and there were no malignancies. In 15 cases (13.6%), cysts were identified, and 3 patients (2.7%) had solid masses, all of which were benign. Fluid collections and edema were seen in the remaining cases.

Several studies have evaluated the usefulness of US in addition to mammography in cases of focal, noncyclical breast pain and concluded that in the setting of a negative mammogram, US may not be indicated, especially in patients with nondense breasts. A retrospective study of 206 patients with focal breast pain as their only symptom evaluated with US after a mammogram found that US resulted in 8 additional biopsies and 14 additional 6-month follow-up examinations without detecting any additional cancers [11]. Another retrospective study found 76 imaging abnormalities in 413 cases of focal pain, with 46 (61%) seen on US alone, for a specificity of 82%. While there were no malignancies, US found a benign lesion in 40 of 56 cases in which mammography was negative in patients with dense breasts and found a benign lesion in 6 of 20 cases with a negative mammogram and nondense breasts. The specificity of US was 95% for nondense breasts and 87% for dense breasts [9].

Some authors suggest that, despite the low incidence of malignancy, US may be useful in that it could potentially find treatable causes of breast pain, such as cysts [9]. On the other hand, a prospective, observational follow-up study of 987 patients with breast pain alone found benign findings in 8.6% of cases, which consisted mostly of small cysts [14]. The authors argued that in the absence of a palpable abnormality, any cyst that may be found by US would be unlikely to be large enough to cause pain or benefit from aspiration.

MRI Breast

There is no relevant literature regarding the use of MRI in the evaluation of focal and noncyclical breast pain.

Sestamibi MBI

There is no relevant literature regarding the use of MBI in the evaluation of focal and noncyclical breast pain.

Variant 4: Female with clinically significant breast pain (focal and noncyclical). Age greater than or equal to 40. Initial imaging.

Mammography

Though the incidence is low, mammography may be used to exclude malignancy in cases of focal and noncyclical breast pain. Mammography was found to have a high sensitivity (100%) and NPV (100%) in a retrospective review of 206 patients with focal breast pain [11]. While this study found specificity to be slightly lower at

87.6%, another retrospective study of focal, noncyclical pain calculated a specificity of mammography of 97% for nondense breasts and 96% for dense breasts [9]. Additionally, Tumyan et al [38] in a retrospective study of mammography in combination with US found a NPV of 100%, though the study was limited by a significant number of patients being lost to follow-up. A mammogram should be obtained if the patient has not undergone mammography within the last 3 to 6 months.

DBT

While there is no literature specifically evaluating the use of DBT in the workup of focal and noncyclical breast pain, DBT can be useful in the diagnostic setting and is known to improve lesion characterization in noncalcified lesions when compared to conventional mammographic workup [28-30].

US Breast

While there are few studies evaluating US independently of mammography in the setting of focal and noncyclical breast pain, the existing literature suggests that US may be useful to exclude malignancy in these cases. A retrospective review of 110 cases of focal breast pain evaluated by US found no imaging abnormality in 85 cases (77.3%) [12], and there were no malignancies. In 15 cases (13.6%), cysts were identified, and of those, 3 patients (2.7%) had solid masses, all of which were benign. Fluid collections and edema were seen in the remaining cases.

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If a mammogram has been obtained within the last 3 to 6 months, the patient may proceed directly to US.

MRI Breast

There is no relevant literature regarding the use of MRI in the evaluation of focal and noncyclical breast pain.

Sestamibi MBI

There is no relevant literature regarding the use of MBI in the evaluation of focal and noncyclical breast pain.

Summary of Recommendations

- **Variation 1:** For females with clinically insignificant breast pain (nonfocal [greater than one quadrant], diffuse, or cyclical) without other suspicious clinical finding, no imaging beyond usual screening recommendations is indicated.
- **Variation 2:** In females less than 30 years of age with clinically significant breast pain (focal and noncyclical), US is appropriate.
- **Variation 3:** In females 30 to 39 years of age with clinically significant breast pain (focal and noncyclical), mammography, including DBT, and US are appropriate and are equivalent alternatives.
- **Variation 4:** In females 40 years of age and older with clinically significant breast pain (focal and noncyclical), mammography and DBT are appropriate equivalent alternatives, and are complementary to US.

Summary of Evidence

Of the 42 references cited in the *ACR Appropriateness Criteria® Breast Pain* document, all of them are categorized as diagnostic references, including 6 good-quality studies, and 16 quality studies that may have design limitations. There are 20 references that may not be useful as primary evidence.

The 42 references cited in the *ACR Appropriateness Criteria® Breast Pain* document were published from 1976 to 2018.

Although there are references that report on studies with design limitations, 6 good-quality studies provide good evidence.

Appropriateness Category Names and Definitions

| Appropriateness Category Name | Appropriateness Rating | Appropriateness Category Definition |
|-----------------------------------|------------------------|--|
| Usually Appropriate | 7, 8, or 9 | The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients. |
| May Be Appropriate | 4, 5, or 6 | The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal. |
| May Be Appropriate (Disagreement) | 5 | The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel’s recommendation. “May be appropriate” is the rating category and a rating of 5 is assigned. |
| Usually Not Appropriate | 1, 2, or 3 | The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable. |

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the *ACR Appropriateness Criteria® Radiation Dose Assessment Introduction* document [42].

| Relative Radiation Level Designations | | |
|---------------------------------------|-------------------------------------|---|
| Relative Radiation Level* | Adult Effective Dose Estimate Range | Pediatric Effective Dose Estimate Range |
| ○ | 0 mSv | 0 mSv |
| ☼ | <0.1 mSv | <0.03 mSv |
| ☼☼ | 0.1-1 mSv | 0.03-0.3 mSv |
| ☼☼☼ | 1-10 mSv | 0.3-3 mSv |
| ☼☼☼☼ | 10-30 mSv | 3-10 mSv |
| ☼☼☼☼☼ | 30-100 mSv | 10-30 mSv |

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as “Varies”.

Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.