

American College of Radiology ACR Appropriateness Criteria®

Clinical Condition: Palpable Breast Masses

Variant 1: Woman 30 years of age or older, initial evaluation.

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography diagnostic	9	Mammography should be done first for patients in this age group. It may demonstrate additional findings of concern. US should be used right after the mammogram. US is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging and clinical findings is essential.	☼ ☼
US breast	9	US should be done right after the mammogram. US is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging and clinical findings is essential. In addition, US may be used to guide intervention, if needed.	O
MRI breast with contrast	1		O
PET breast	1		☼ ☼ ☼ ☼
Fine needle aspiration breast	1		NS
Core biopsy breast	1		NS
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition:**Palpable Breast Masses****Variant 2:****Woman 30 years of age or older, mammography findings suspicious for malignancy.**

Radiologic Procedure	Rating	Comments	RRL*
US breast	9	Mammography should be done first for patients in this age group. It may demonstrate additional findings of concern. US should be used right after the mammogram. US is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging and clinical findings is essential. In addition, US may be used to guide intervention, if needed.	O
Core biopsy breast	9	Core biopsy should be performed after the diagnostic mammogram and US evaluation is complete.	NS
MRI breast with contrast	3		O
Fine needle aspiration breast	2		NS
PET breast	1		☼☼☼☼
Mammography short interval follow-up	1		☼☼
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 3:**Woman 30 years of age or older, mammography findings probably benign.**

Radiologic Procedure	Rating	Comments	RRL*
US breast	9	US is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging and clinical findings is essential.	O
Mammography short interval follow-up	7	Short-interval follow-up may be appropriate after workup with US.	☼☼
Core biopsy breast	5	US is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging findings and clinical findings is essential. The decision to biopsy may depend on the suspicion of clinical findings and US.	NS
Fine needle aspiration breast	3	US is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging findings and clinical findings is essential. The decision to biopsy may depend on how suspicious the clinical and US findings are.	NS
MRI breast with contrast	2		O
PET breast	1		☼☼☼☼
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition:**Palpable Breast Masses****Variant 4:****Woman 30 years of age or older, mammography findings benign (like lipoma).**

Radiologic Procedure	Rating	Comments	RRL*
US breast	7		O
Mammography short interval follow-up	2		☼☼
MRI breast with contrast	1		O
PET breast	1		☼☼☼☼
Fine needle aspiration breast	1		NS
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 5:**Woman 30 years of age or older, mammography findings negative.**

Radiologic Procedure	Rating	Comments	RRL*
US breast	9		O
MRI breast with contrast	2		O
Fine needle aspiration breast	2		NS
Core biopsy breast	2		NS
Mammography short interval follow-up	1		☼☼
PET breast	1		☼☼☼☼
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 6:**Woman younger than 30 years of age, initial evaluation.**

Radiologic Procedure	Rating	Comments	RRL*
US breast	9		O
Mammography diagnostic	3	In high-risk patients younger than age 30, mammography may be used first.	☼☼
MRI breast with contrast	2		O
PET breast	1		☼☼☼☼
Fine needle aspiration breast	1		NS
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition:**Palpable Breast Masses****Variant 7:****Woman younger than 30 years of age, US findings suspicious for malignancy.**

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography diagnostic	9	Bilateral diagnostic mammography should be performed immediately after the US to help characterize the mass and to evaluate for additional lesions that may be occult by US.	☼☼
Core biopsy breast	9	Core biopsy of the malignant palpable mass should only be done after bilateral diagnostic mammographic evaluation is complete.	NS
MRI breast with contrast	2		O
Fine needle aspiration breast	2		NS
US breast short interval follow-up	1		O
PET breast	1		☼☼☼☼
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 8:**Woman younger than 30 years of age, US findings probably benign.**

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
US breast short interval follow-up	8		O
Mammography diagnostic	5	Evidence is lacking. Variability in practice.	☼☼
Fine needle aspiration breast	3	Biopsy may be performed to alleviate patient anxiety.	NS
Core biopsy breast	3	Biopsy may be performed to alleviate patient anxiety.	NS
MRI breast with contrast	2		O
PET breast	1		☼☼☼☼
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition:**Palpable Breast Masses****Variant 9:****Woman younger than 30 years of age, US findings benign (like simple cyst).**

Radiologic Procedure	Rating	Comments	RRL*
Fine needle aspiration breast	2		NS
Mammography diagnostic	1		☼ ☼
US breast short interval follow-up	1		O
MRI breast with contrast	1		O
PET breast	1		☼ ☼ ☼ ☼
Core biopsy breast	1		NS
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 10:**Woman younger than 30 years of age, US findings negative.**

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	5	If clinically suspicious, mammography may be appropriate.	☼ ☼
Fine needle aspiration breast	2		NS
Core biopsy breast	2		NS
US breast short interval follow-up	1		O
MRI breast with contrast	1		O
PET breast	1		☼ ☼ ☼ ☼
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

PALPABLE BREAST MASSES

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Summary of Literature Review

Breast cancer is the most common female malignancy and the second leading cause of cancer deaths in the United States. The American Cancer Society estimates that 192,370 new cases of invasive breast cancer and 62,280 new cases of in situ breast cancer will be diagnosed in 2009. A breast mass will be one of the most frequent surgical indications [1]. A palpable breast mass may become evident during breast self-examination (BSE), clinical breast examination (CBE), or retrospectively following screening mammography.

Determining if a mass is present by physical examination can be difficult, as all breasts have variable combinations of glandular tissue, fibrosis, and fat. True masses are generally asymmetrical in relation to the other breast, distinct from the surrounding tissues, and three-dimensional [2]. A typical cancer may be firm, have indistinct borders, and have attachments to the skin or deep fascia with dimpling or nipple retraction. Benign lesions typically have discrete, well-defined margins and are mobile. Cysts cannot reliably be distinguished from solid breast masses by palpation. In one study, only 58% of 66 palpable cysts were correctly identified by physical examination [3]. Significant disagreement among experienced examiners may occur. In another study, four surgeons performed physical examinations independently and agreed on the need for biopsy of only 73% of 15 masses subsequently proven malignant [4].

Because many breast masses may not exhibit distinctive physical findings, an imaging evaluation is necessary in almost all cases to characterize the palpable lesion and screen the remainder of each breast for additional lesions.

Unfortunately not all palpable breast masses will be visualized with conventional imaging techniques. In the Breast Cancer Detection Demonstration Project (BCDDP) begun in the 1970s, 9% of the cancers were found by CBE alone [5]. With the improvement in imaging methods since the BCDDP, this percentage should be considerably less now. It is preferable for imaging to occur before biopsy, as changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. Nevertheless a negative imaging evaluation should never overrule a strongly suspicious finding on physical examination or vice versa. Any highly suspicious breast mass detected by imaging or palpation should be biopsied unless there are exceptional clinical circumstances such as patient comorbid factors.

Mammography

Several imaging techniques are commonly used in evaluating palpable breast masses. Screening mammography is most useful for early detection of nonpalpable breast lesions. The examination is performed on women thought to be asymptomatic and usually consists of craniocaudal and mediolateral oblique views of each breast. A mass found with screening mammography may become perceptible by palpation after its location has been identified radiographically. Following detection of a clinical or mammographic mass, diagnostic mammography may be performed. A small metal marker is placed on the skin over the mass to identify its location. Supplemental mammographic views may be needed to clarify the features, location, or reality of a mammographic lesion. These views have been discussed extensively [6]. They include spot compression, spot compression/magnification, magnification, exaggerated craniocaudal to the medial or lateral side, tangential, change of angle, cleavage, cleopatra, and 90-degree lateral views. Any creative nonstandard view may be used to image a lesion or move it closer to the film. These supplemental views improve visualization of palpable and nonpalpable masses and are predictive of whether they are benign or malignant.

Ultrasound

Ultrasound (US) was initially used only to differentiate cystic from solid lesions. Many palpable masses not visualized mammographically are cysts and can be diagnosed sonographically [7]. With the development of 7.5-10 MHz linear array transducers with excellent near-field resolution, the role of US has expanded to include characterization of the shape, margins, and internal matrix of masses and guidance for needle localization, aspiration, and biopsy. US is also highly accurate in identifying palpable malignant breast masses, although no one examination alone should be used to exclude malignancy [8].

Biopsy/Aspiration

Fine-needle aspiration/biopsy (FNAB) is used to remove fluid from a cyst and cellular material from a solid mass.

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Some physicians suggest FNAB as the first means of evaluation following physical examination [2], and patients with a palpable mass referred for imaging evaluation may have already undergone FNAB. Alternatively, stereotactic (x-ray) or US guidance may be used for FNAB or core biopsy, especially if the mass is vaguely palpable, small, deep, mobile, or multiple, or if attempts using palpation to biopsy the mass have been unsuccessful [9]. Core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [10-12].

Multiple Modalities

The use of multiple modalities in diagnosing palpable masses has been advocated as a measure to increase the true positive rate. In one study comparing physical examinations, mammography, and US, the authors concluded that for palpable masses, physical examination, and US formed the optimal preoperative test combination [8]. Mammography was also necessary to detect occult cancer in the contralateral or ipsilateral breast. Diagnostic breast US can improve the specificity of clinically detected abnormalities.

The most common uses of US are characterization of palpable and mammographically depicted masses and guidance for biopsy procedures. Using strict criteria for benign and malignant features for solid masses seen on US, a high negative predictive value (99.5%) is possible to achieve [13]. Early data suggest surveillance of solid palpable breast lesions with probably benign morphology as visualized on US [14-16], but more outcome studies are needed for confirmation. When both mammography and US are negative or benign in the evaluation of a palpable breast mass, the negative predictive value is also very high, over 97% [17-19]. Together, these imaging modalities can be reassuring when the physical examination is not highly suspicious and follow-up is planned. However, a highly suspicious physical examination should prompt biopsy regardless of the imaging findings.

Due to its lack of ionizing radiation, US is the modality of choice for evaluating a palpable mass in pregnant women [20,21]. However, mammography when performed preoperatively in pregnant patients has a sensitivity of around 90% [22]. US is also the modality of choice for evaluating palpable masses in lactating women [21,23] because tissue density limits mammographic evaluation. However, mammography is not contraindicated during lactation and should be performed if malignancy is suspected, because it is particularly effective in the detecting microcalcifications or subtle architectural distortion, features often not as well seen on US [21,24].

Magnetic Resonance Imaging

With respect to a palpable breast mass, other imaging techniques remain investigational. Magnetic resonance imaging (MRI) has emerged as a promising modality for detecting occult breast cancer in high-risk women and for evaluating disease extent in women diagnosed with breast cancer. The sensitivity of the examination is high, but

specificity continues to be problematic due to false positives [25]. Although palpable masses can be imaged with MRI, it is generally more cost effective to use mammography and US as the initial imaging examinations. In patients with palpable biopsy-proven breast malignancy in nonfatty tissue, MRI appears to be more sensitive than US or mammography for staging [26], and MRI appears to be superior to clinical examination, mammography, and US for monitoring response to neoadjuvant therapy [27].

Nuclear Medicine

New prospects for breast cancer detection using nuclear medicine are now being actively investigated. A study comparing positron emission tomography (PET) using an isotope of glucose and single-photon-emission computed tomography (SPECT) indicates that both techniques are comparable in diagnosing breast cancer, with a sensitivity of 79% for PET and 76% for SPECT using MIBI (Tc-99m methoxyisobutylisonitrile) tracer [28]. In another study [29] MIBI SPECT modified patient management in 49% of patients after a doubtful or discordant triple test with mammography, US, and FNAB. More work must be done to establish criteria for the use of nuclear medicine for breast cancer diagnosis.

Age-related Issues

Because of the theoretical increased radiation risk of mammography and the low incidence of breast cancer (less than 1%) in women younger than age 30 [30], the imaging evaluation for patients older than age 30 differs from that performed for younger patients, according to most investigators [31-35]. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

In determining the utility of mammography in women younger than age 30, most researchers have retrospectively either studied patients referred for mammography or reviewed the mammographic findings of patients in whom cancer was found. In the first group of studies, as one would expect, there was a predominance of benign masses and nonspecific benign findings [34-39], although a few carcinomas were found. Most of the benign lesions were not visualized mammographically, and US was suggested as the initial imaging modality [6,7,35]. If US demonstrates a suspicious finding, bilateral mammography is recommended to evaluate for additional ipsilateral and contralateral lesions. If US demonstrates a probably benign lesion such as a fibroadenoma in this age group, sonographic surveillance may be an acceptable alternative to traditional biopsy. In one study [16] only 0.3% of 357 patients with such features went on to be diagnosed with malignancy. Further studies are needed. If US demonstrates a classic benign lesion such a cyst correlating to the palpable abnormality, clinical follow-up without imaging follow-up is indicated. If US is negative, mammography is still recommended as a prebiopsy assessment in cases where cancer is strongly suspected clinically [32,35]. As with women age 30 and older, most

investigators agree that if physical examination is highly suspicious and mammography is negative, tissue sampling with FNAB, core biopsy, or surgical biopsy is warranted. In symptomatic young women subsequently proven to have breast cancer, mammography was abnormal preoperatively in 86%-90% of them, [40-42], suggesting that it is of substantial value in the diagnosis of malignancy.

Summary

- Because of inconsistencies in clinical examination, a thorough imaging workup of a palpable mass should be completed prior to biopsy.
- Diagnostic mammography is the initial imaging modality of choice for evaluating a clinically-detected palpable breast mass in a woman age 30 or older.
- Breast US is the initial imaging modality of choice for evaluating a clinically detected palpable breast mass in a woman younger than age 30.
- Correlation between imaging and the palpable area of concern is essential.
- Any highly suspicious breast mass detected by imaging should be biopsied, irrespective of palpable findings.
- Any highly suspicious breast mass detected by palpation should be biopsied, irrespective of imaging findings.

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, both because of 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 to 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.

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	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 NS (not specified).		

Supporting Document(s)

- [ACR Appropriateness Criteria® Overview](#)
- [Procedure Contrast Information](#)
- [Evidence Table](#)

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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.