American College of Radiology ACR Appropriateness Criteria[®]

<u>Clinical Condition:</u>

Palpable Breast Masses

Variant 1:

Woman 40 years of age or older, initial evaluation. (See <u>Appendices 1A-1B</u> for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography diagnostic	9		•
US breast	4	If she had recent mammogram (ie, past 6 months), US may be appropriate.	0
MRI breast without and with contrast	2		0
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 2:

Woman 40 years of age or older, mammography findings suspicious for malignancy. Next examination to perform. (See <u>Appendix 1A</u> for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
US breast	9		0
MRI breast without and with contrast	2		0
Image-guided core biopsy breast	2		Varies
Mammography short interval follow- up	1		* *
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Image-guided fine needle aspiration breast	1		Varies
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

1

Palpable Breast Masses

Variant 3:

Woman 40 years of age or older, mammography findings probably benign. Next examination to perform. (See <u>Appendix 1A</u> for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography short interval follow- up	8		\$ \$
US breast	8	US is frequently performed to confirm correlation of imaging and clinical findings, as well as lesion characterization.	0
MRI breast without and with contrast	2		0
Image-guided core biopsy breast	2		Varies
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Image-guided fine needle aspiration breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 4:

Woman 40 years of age or older, mammography findings benign (like lipoma) at site of palpable mass. Next examination to perform.

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography short interval follow- up	2		\$
US breast	2	US may be done if correlation between the clinical examination and mammography is not clear.	Ο
Image-guided fine needle aspiration breast	2		Varies
MRI breast without and with contrast	1		0
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Image-guided core biopsy breast	1		Varies
<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 5:

Palpable Breast Masses

Woman 40 years of age or older, mammography findings negative. Next examination to perform. (See <u>Appendix 1B</u> for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
US breast	9		О
Mammography short interval follow- up	1		⋧ ⋧
MRI breast without and with contrast	1		О
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		\$ \$ \$ \$
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
<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 6:

Woman younger than 30 years of age, initial evaluation. (See <u>Appendices 2A-2B</u> for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
US breast	9		0
Mammography diagnostic	3		*
MRI breast without and with contrast	1		0
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Palpable Breast Masses

Variant 7:

Woman younger than 30 years of age, US findings suspicious for malignancy. Next examination to perform. (See <u>Appendix 2A</u> for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Image-guided core biopsy breast	9	Either mammography or biopsy is appropriate. It depends on the history and findings.	Varies
Mammography diagnostic	8	Either mammography or biopsy is appropriate. It depends on the history and findings.	*
US breast short interval follow-up	1		0
MRI breast without and with contrast	1		0
MRI breast without contrast	1		0
FDG-PEM	1		\$ \$ \$ \$
Tc-99m sestamibi BSGI	1		* * * *
Image-guided fine needle aspiration breast	1		Varies
<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. Next examination to perform. (See <u>Appendix 2B</u> for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
US breast short interval follow-up	9		0
Mammography diagnostic	3		\$
Image-guided core biopsy breast	3		Varies
MRI breast without and with contrast	2		0
Image-guided fine needle aspiration breast	2		Varies
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Palpable Breast Masses

Variant 9:

Variant 10:

Woman younger than 30 years of age, US findings benign (like simple cyst). Next examination to perform.

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography diagnostic	2		* *
US breast short interval follow-up	2		0
Image-guided fine needle aspiration breast	2		Varies
MRI breast without and with contrast	1		0
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Woman younger than 30 years of age, US findings negative. Next examination to perform.

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography diagnostic	3		\$ \$
MRI breast without and with contrast	2		0
US breast short interval follow-up	1		0
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

<u>Clinical Condition:</u>

Palpable Breast Masses

Variant 11:

Woman age 30-39 years of age, initial evaluation. (See <u>Appendix 3</u> for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
US breast	8	If imaged initially with US, see variants 7- 10 for additional imaging.	0
Mammography diagnostic	8	If imaged initially with mammography, see variants 2-5.	**
MRI breast without and with contrast	2		0
MRI breast without contrast	1		0
FDG-PEM	1		* * * *
Tc-99m sestamibi BSGI	1		* * * *
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

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Summary of Literature Review

Introduction/Background

Breast cancer is the most common female malignancy and the second leading cause of female cancer deaths in the United States. The American Cancer Society estimates that 226,870 new cases of invasive breast cancer and 63,300 new cases of in-situ breast cancer will be diagnosed in 2012 [1]. A breast mass is one of the most frequent presenting features of breast carcinoma [1]. A palpable breast mass may become evident during breast self-examination (BSE) or clinical breast examination (CBE). Breast cancer may present as a palpable mass in women not undergoing regular screening mammography due to young or advanced age or personal choice, or within 1-2 years of a normal screening mammogram (interval cancer).

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 threedimensional. A typical cancer may be firm, have indistinct borders, and have attachments to the skin or deep fascia with dimpling or nipple retraction. Palpable breast thickening, defined as greater firmness of an area of the breast compared with the contralateral breast or other quadrants of the ipsilateral breast, may also be associated with breast cancer in about 5% of women [2]. Benign masses typically have discrete, well-defined

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margins, a soft or rubbery texture, 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, imaging evaluation is necessary in almost all cases to characterize the palpable lesion and screen the remainder of each breast for additional lesions if the patient is age 40 years or older. It is preferable for imaging to occur before biopsy, as changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. The negative predictive value of mammography with ultrasound (US) ranges from 97.4%-100% [5-8]. Nevertheless, 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 undergo biopsy unless there are exceptional clinical circumstances such as the patient having significant comorbid factors.

Mammography

Several imaging techniques are commonly used in evaluating palpable breast masses. Diagnostic mammography may be used to evaluate a palpable finding. It is typically performed under the direct supervision of a radiologist and usually consists of craniocaudal and mediolateral oblique views of each breast. The mammogram need only include the ipsilateral breast if the patient has had a recent bilateral mammogram (within the last 6 months). A small radioopaque marker is placed on the skin over the palpable finding to identify its location. Spot compression views obtained with or without magnification or tangential views are typically obtained to specifically evaluate the clinical finding. Supplemental mammographic views may also be needed to clarify the features, location, or reality of a mammographic lesion, including craniocaudal exaggerated to the lateral, cleavage, step-oblique [9], and 90-degree lateral views. Any creative nonstandard view may be used to image a palpable lesion or move it closer to the image receptor. These supplemental views improve visualization of palpable and nonpalpable masses and are predictive of whether they are benign or malignant.

Ultrasound

Breast US should be performed using a high-resolution, real-time, linear array scanner with an adjustable focal zone, and a transducer with a minimum center frequency of 10 MHz [10]. US is preferably targeted specifically to the palpable finding [11]. A major advantage of US is the ability to directly correlate the clinical and imaging findings. Many palpable masses that are not visualized on

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mammography can be characterized as benign using US. These may include simple cysts, clustered microcysts, or sebaceous cysts.

Due to its lack of ionizing radiation, US is the modality of choice for evaluating a palpable mass in pregnant women [10,12]. However, mammography when performed preoperatively in pregnant patients has a sensitivity of around 90% [13]. US is also the modality of choice for evaluating palpable masses in lactating women [12,14] because tissue density limits mammographic evaluation. However, mammography is not contraindicated during pregnancy or lactation and should be performed if malignancy is suspected, because it is particularly effective in detecting microcalcifications and subtle architectural distortion, features often not as well seen on US [12,15].

Multiple Modalities

The use of multiple modalities in diagnosing palpable masses has been advocated as a measure to increase the true positive rate. In two series evaluating palpable breast abnormalities [16,17], the sensitivity of mammography was 86-91%. The addition of US detects 93%-100% of cancers that are occult on mammography [6-8,16]. The addition of US to mammography may also improve detection of a benign etiology for a palpable finding. In one series, 40% of benign palpable masses were identified only on US [17].

When the mammogram shows a definite benign mass (eg, lymph node, hamartoma, oil cyst), US is not necessary as long the benign mass identified on mammography is a definite correlate of the clinical finding. When the mammogram shows a probably benign mass (eg, round or oval circumscribed mass), US is usually indicated to further characterize the finding. The addition of US in these cases will often yield a benign result (eg, simple cyst) and may identify features that are suspicious, appropriately prompting biopsy in other cases.

Solid palpable breast lesions with benign morphology as visualized on US have been studied in seven series [18-24]. These studies include 1,438 patients with solid masses that have benign features by US; nine cancers were diagnosed for an overall incidence of 0.6%. Cancer incidence for six of the seven series ranges from 0%-0.6%. One series [23] had a higher cancer incidence of 3.2%. Given the large number of women studied to date, short-interval follow-up is a reasonable alternative to biopsy for solid masses with benign features identified by US, if the mammogram and clinical examination also suggest a benign etiology. Benign US features of a solid mass include oval or round shape, abrupt well-defined margin, homogeneous echogenicity, and orientation parallel to the chest wall with no posterior acoustic shadowing [19,24]. The vast majority of these lesions represent benign fibroadenomas.

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% [6-8]. 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.

Magnetic Resonance Imaging

With respect to a palpable breast mass, other imaging techniques remain investigational. Magnetic resonance imaging (MRI) has emerged as a useful modality for detecting occult breast cancer in high-risk women and for evaluating disease extent in women diagnosed with breast cancer. Although palpable masses can be imaged with MRI, it is generally more cost-effective to use mammography and US as the initial imaging examinations. The use of MRI to evaluate women with a clinically suspicious clinical examination and negative imaging is not well documented. In one series [25], 112 women were referred for breast MRI with the indication of a clinical finding; MRI resulted in no true-positive findings and one false-negative finding. In patients with palpable biopsy-proven breast malignancy in nonfatty tissue, MRI appears to be more sensitive than mammography or US for evaluating the extent of disease [26].

Nuclear Medicine

The use of nuclear techniques using whole-body scanners has shown limited detection of small breast cancers [27,28]. The use of small, high-resolution cameras specifically designed for imaging of the breast have improved detection of small and noninvasive carcinomas [29-31]. However, research specific to evaluation of women with palpable findings is lacking. Initial imaging with mammography and US is preferable.

Age-Related Issues

The probability of a woman developing breast cancer over the next decade increases with age; the risk is one in 1,681 at age 20, one in 232 at age 30, and one in 69 at age 40 [1]. Diagnostic mammography is indicated as the initial examination in the evaluation of a palpable breast finding for women age 40 and older. Because of the theoretical increased radiation risk of mammography and the low incidence of breast cancer (less than 1%) in younger women, their imaging evaluation differs from that performed for older patients, according to most investigators [32-36]. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

Most benign lesions in young women are not visualized on mammography [33,35], and US is therefore used as the initial imaging modality in younger women. The criteria for "young" has historically been considered as younger than age 30. However, the risk of breast cancer remains relatively low for women in their fourth decade [1]. The sensitivity of US may be higher than mammography for women younger than age 40 [37]. A recent study of 1,208 women age 30-39 presenting with focal breast symptoms found higher sensitivity for US compared with mammography (95.7% vs 60.9%) with similar specificity (89.2% and 94.4% respectively) [38]. It is therefore reasonable to use US as the initial imaging modality for women younger than age 40, with a low threshold for using mammography if the clinical examination or other risk factors are concerning.

If US demonstrates a suspicious finding in a younger woman, 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 [39] only one of 357 patients (0.3%) younger than age 25 with such features were subsequently diagnosed with malignancy. If US demonstrates a classic benign lesion such a simple cyst correlating to the palpable abnormality, clinical follow-up without imaging surveillance is indicated. If the US finding is negative, mammography is still recommended as a prebiopsy assessment in cases where cancer is strongly suspected clinically [33]. As with women age 40 and older, if physical examination is highly suspicious and mammography and US are negative, tissue sampling with fine-needle aspiration/biopsy (FNAB), core biopsy, or surgical biopsy is warranted.

Biopsy/Aspiration

Imaging is preferably performed prior to intervention since biopsy changes may obscure or complicate a finding. FNAB is used to remove fluid from a cyst and cellular material from a solid mass. Some practices demonstrate very good results using FNAB as the first means of diagnostic evaluation of a palpable breast mass [40,41]. However, larger series demonstrate that core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [42-44]. 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 [45]. The decision to perform excisional versus percutaneous biopsy should involve the patient and her health care provider. About 20% of women prefer to have the palpable lesion removed surgically despite benign imaging features [19] or even benign core biopsy results [45].

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 40 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.
- For women age 30-39, either US or diagnostic mammography may be used for initial evaluation.
- 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			
0	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 Document(s)

- <u>ACR Appropriateness Criteria[®] Overview</u>
- Procedure 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.



Appendix 1A. Evaluation of palpable breast lesions in women age 40 years or older with probably benign or suspicious findings on mammography.

¹The algorithm assumes that the clinical examination shows a focal palpable are of concern. If the clinical examination reveals less concerning findings, such as mild nodularity or a ridge of tissue, then further evaluation after negative imaging is not required.



Appendix 1B. Evaluation of palpable breast lesions in women age 40 years or older with mammogram that is negative or shows benign findings.

¹The algorithm assumes that the clinical examination shows a focal palpable are of concern. If the clinical examination reveals less concerning findings, such as mild nodularity or a ridge of tissue, then further evaluation after negative imaging is not required.



Appendix 2A. Evaluation of palpable breast lesions in women less than 30 years old with probably benign or suspicious findings on US.

¹The algorithm assumes that the clinical examination shows a focal palpable are of concern. If the clinical examination reveals less concerning findings, such as mild nodularity or a ridge of tissue, then further evaluation after negative imaging is not required.



Appendix 2B. Evaluation of palpable breast lesions in women less than 30 years old with benign or negative findings on US.

¹The algorithm assumes that the clinical examination shows a focal palpable are of concern. If the clinical examination reveals less concerning findings, such as mild nodularity or a ridge of tissue, then further evaluation after negative imaging is not required.

Appendix 3. Management of palpable findings in women age 30-39 years of age.



¹The algorithm assumes that the clinical examination shows a focal palpable are of concern. If the clinical examination reveals less concerning findings, such as mild nodularity or a ridge of tissue, then further evaluation after negative imaging is not required.