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**American College of Radiology  
ACR Appropriateness Criteria®  
Palpable Breast Masses**

**Variant 1:** Palpable breast mass. Woman 40 years of age or older, initial evaluation. (See [Appendices 1A-1B](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	9	See references [13-15].	☼☼
Digital breast tomosynthesis diagnostic	9	See references [16-18,20,85].	☼☼
US breast	4	If she had recent mammogram (ie, past 6 months), US may be appropriate.	O
MRI breast without and with IV contrast	2	See references [4,49].	O
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided core biopsy breast	1		Varies
Image-guided fine-needle aspiration breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

**Variant 2:** Palpable breast mass. Woman 40 years of age or older, mammography findings suspicious for malignancy. Next examination to perform. (See [Appendix 1A](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
US breast	9	See reference [62].	O
MRI breast without and with IV contrast	2	See references [4,49].	O
Image-guided core biopsy breast	2		Varies
Mammography short-interval follow-up	1		☼☼
Digital breast tomosynthesis short-interval follow-up	1		☼☼
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided fine-needle aspiration breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

**Variant 3:**

**Palpable breast mass. Woman 40 years of age or older, mammography findings probably benign. Next examination to perform. (See [Appendix 1A](#) for additional steps in the workup of these patients.)**

Radiologic Procedure	Rating	Comments	RRL*
US breast	8	US is frequently performed to confirm correlation of imaging and clinical findings, as well as lesion characterization. See reference [62].	O
Mammography short-interval follow-up	8	See references [40,43,45].	☼☼
Digital breast tomosynthesis short-interval follow-up	8	See references [74,75].	☼☼
MRI breast without and with IV contrast	2	See references [4,49].	O
Image-guided core biopsy breast	2		Varies
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided fine-needle aspiration breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 4:**

**Palpable breast mass. 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	RRL*
Mammography short-interval follow-up	2		☼☼
Digital breast tomosynthesis short-interval follow-up	2		☼☼
US breast	2	US may be done if correlation between the clinical examination and mammography is not clear. See reference [62].	O
Image-guided fine-needle aspiration breast	2		Varies
Image-guided core biopsy breast	1		Varies
MRI breast without and with IV contrast	1	See references [4,49].	O
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 5:**

**Palpable breast mass. Woman 40 years of age or older, mammography findings negative. Next examination to perform. (See [Appendix 1B](#) for additional steps in the workup of these patients.)**

Radiologic Procedure	Rating	Comments	RRL*
US breast	9	See references [10-15].	O
Digital breast tomosynthesis diagnostic	3	If prior mammogram was 2-D only, consider doing DBT as part of the diagnostic workup.	☼☼
Mammography diagnostic	1		☼☼
MRI breast without and with IV contrast	1	See references [4,49].	O
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided core biopsy breast	1		Varies
Image-guided fine-needle aspiration breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 6:**

**Palpable breast mass. Woman younger than 30 years of age, initial evaluation. (See [Appendices 2A-2B](#) for additional steps in the workup of these patients.)**

Radiologic Procedure	Rating	Comments	RRL*
US breast	9	See references [25-29,62].	O
Mammography diagnostic	3		☼☼
Digital breast tomosynthesis diagnostic	3		☼☼
MRI breast without and with IV contrast	1	See references [4,49].	O
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided core biopsy breast	1		Varies
Image-guided fine-needle aspiration breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 7:**

**Palpable breast mass. Woman younger than 30 years of age, US findings suspicious for malignancy. Next examination to perform. (See [Appendix 2A](#) for additional steps in the workup of these patients.)**

Radiologic Procedure	Rating	Comments	RRL*
Image-guided core biopsy breast	9	Either mammography or biopsy is appropriate. It depends on the history and findings. See references [36-38].	Varies
Mammography diagnostic	8	Either mammography or biopsy is appropriate. It depends on the history and findings.	☼☼
Digital breast tomosynthesis diagnostic	8	Either DBT or biopsy is appropriate. It depends on the history and findings.	☼☼
US breast short-interval follow-up	1		O
MRI breast without and with IV contrast	1	See references [4,49].	O
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided fine-needle aspiration breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 8:**

**Palpable breast mass. Woman younger than 30 years of age, US findings probably benign. Next examination to perform. (See [Appendix 2B](#) for additional steps in the workup of these patients.)**

Radiologic Procedure	Rating	Comments	RRL*
US breast short-interval follow-up	9	See references [40,41,43-45].	O
Mammography diagnostic	3		☼☼
Digital breast tomosynthesis diagnostic	3	Evidence supports the use of US characterization of a mass in this population and setting.	☼☼
Image-guided core biopsy breast	3		Varies
MRI breast without and with IV contrast	2	See references [4,49].	O
Image-guided fine-needle aspiration breast	2		Varies
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 9: Palpable breast mass. Woman younger than 30 years of age, US findings benign (like simple cyst). Next examination to perform.**

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	2		☼☼
Digital breast tomosynthesis diagnostic	2		☼☼
US breast short-interval follow-up	2		O
Image-guided fine-needle aspiration breast	2		Varies
MRI breast without and with IV contrast	1	See references [4,49].	O
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided core biopsy breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 10: Palpable breast mass. Woman younger than 30 years of age, US findings negative. Next examination to perform.**

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	3		☼☼
Digital breast tomosynthesis diagnostic	3	If the clinical examination is highly suspicious and the breasts are dense, DBT may be helpful.	☼☼
MRI breast without and with IV contrast	2	See references [4,49].	O
US breast short-interval follow-up	1		O
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided core biopsy breast	1		Varies
Image-guided fine-needle aspiration breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 11:****Palpable breast mass. Woman 30 to 39 years of age, initial evaluation. (See [Appendix 3](#) for additional steps in the workup of these patients.)**

<b>Radiologic Procedure</b>	<b>Rating</b>	<b>Comments</b>	<b>RRL*</b>
US breast	8	If imaged initially with US, see Variants 7-10 for additional imaging.	O
Mammography diagnostic	8	If imaged initially with mammography, see Variants 2-5. See references [14,15].	☼☼
Digital breast tomosynthesis diagnostic	8	See references [16-20].	
MRI breast without and with IV contrast	2	See references [4,49].	O
MRI breast without IV contrast	1		O
FDG-PEM	1		☼☼☼☼
Tc-99m sestamibi MBI	1		☼☼☼
Image-guided core biopsy breast	1		Varies
Image-guided fine-needle aspiration breast	1		Varies
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

## PALPABLE BREAST MASSES

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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 death in the United States. It is estimated that 249,260 new cases of breast cancer will be diagnosed in 2016 [1]. Although the majority of palpable lumps are benign, a new palpable breast mass is a common presenting sign of breast cancer [2]. A palpable breast mass may become evident during breast self-examination or clinical breast examination. Breast cancer may present as a palpable mass in women not undergoing regular screening mammography because of young or advanced age or personal choice. Breast cancer may also present as a palpable mass in between mammographic screens (interval cancer). In general, cancers detected symptomatically tend to be more aggressive than screen-detected cancers and to have a poorer prognosis [2-5].

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. 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 [6]. Benign masses typically are mobile and have discrete, well-defined margins and a soft or rubbery texture. Cysts cannot reliably be distinguished from solid breast masses by palpation. In 1 study, only 58% of 66 palpable cysts were correctly identified by physical examination [7]. Significant disagreement among experienced examiners may occur. In another study, 4 surgeons performed physical examinations independently and agreed on the need for biopsy of only 73% of 15 masses subsequently proven malignant [8].

Because many breast masses may not exhibit distinctive physical findings, imaging evaluation is necessary in almost all cases to characterize the palpable lesion. Any woman presenting with a palpable lesion should have a thorough clinical breast examination, usually by the referring clinician or by a specialist breast clinician, but the radiologist must also be able to establish concordance between an imaging finding and a clinically detected mass [4]. When a suspicious finding is identified, image-guided biopsy is indicated. 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) in the context of a palpable mass ranges from 97.4% to 100% [9-12]. 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.

#### **Overview of Imaging Modalities**

Recommended imaging options in the context of a palpable mass include diagnostic mammography and targeted breast US and are dependent on patient age and degree of radiologic suspicion. There is little role for advanced technologies such as magnetic resonance imaging (MRI), positron emission mammography with fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG-PEM), or Tc-99m sestamibi molecular breast imaging (MBI) in the evaluation of a palpable mass.

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### *Mammography and digital breast tomosynthesis*

Diagnostic mammography is indicated for women greater than or equal to age 40 years presenting with a palpable lump (see Variant 1). In several series evaluating palpable breast abnormalities [13-15], the sensitivity of mammography alone was 86% to 91%. If a clearly benign correlate for a palpable finding (oil cyst, hamartoma, degenerating fibroadenoma, lipoma, benign lymph node) can be identified on mammography, this modality alone may be sufficient and clinical follow-up rather than imaging follow-up or tissue sampling is appropriate (see Variant 4). If the mammogram is negative or an imaging correlate is identified that is not clearly benign, multimodality imaging is usually indicated in this age group, with targeted US directed toward a palpable finding (see Variant 5).

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. DBT has been evaluated predominantly in the screening setting but has been shown to be useful in the diagnostic setting as well, improving lesion characterization in noncalcified lesions when compared to conventional mammographic workup [16-18]. Several studies have specifically included women presenting with clinical symptoms including palpable lumps, with promising results [17,19,20]. The diagnostic accuracy of 1-view breast tomosynthesis in diagnostic workup of women with clinical signs and symptoms and in women recalled from screening has also been demonstrated to be equivalent to or better than supplemental diagnostic mammographic views in several studies [16,18,20,21]. DBT can be used with or without spot compression views in the diagnostic context. Interpretation time for DBT images is greater than for standard mammography [22,23]. Additionally, dose is increased if standard 2-D images are obtained in addition to DBT images. However, synthesized reconstructed images (a virtual planar image created from the tomographic data set) may replace the need for a 2-D correlative view, and current data suggest that these synthetic images perform as well as standard full-field digital images [18,24].

Mammography or DBT may also be helpful in women ages 30 to 39 years with palpable lumps (see Variant 11) and in women younger than 30 years with palpable lumps and suspicious findings on US (see Variant 7).

### *Ultrasound*

Because of the theoretically increased radiation risk of mammography and the low incidence of breast cancer (<1%) in younger women, the recommended imaging evaluation algorithm for a younger woman <30 years with a palpable mass differs from that performed for older patients [25-29]. US is recommended as the first line of investigation for women under age 30 years. In addition, younger women also tend to have relatively denser breast tissue [30], which is associated with decreased mammographic sensitivity [31]. However, in the event of a suspicious finding, mammography or DBT is warranted even in younger women in order to better delineate disease and identify features of malignancy that may be seen on mammogram or DBT alone [26].

US is also an essential next step in evaluating women  $\geq 40$  years with a palpable mass and either a negative mammogram or a finding not unequivocally characterized as benign on diagnostic mammography or DBT. US may be able to characterize certain mammographic findings definitively and may also identify lesions that are mammographically occult [32]. If a palpable lump can be definitively characterized as benign on US (eg, simple cyst, benign lymph node, duct ectasia, lipoma), clinical follow-up is appropriate management, and imaging follow-up or tissue sampling is usually not indicated (see Variant 4).

US can be used as the initial means of image evaluation for women aged 30 to 39 years with a palpable breast mass, although diagnostic mammography or DBT may also be appropriate in this age group (see Variant 11).

### *Tissue sampling*

If a suspicious mass has been identified on mammogram or US, tissue sampling (US guided, stereotactic, or DBT guided) is warranted except in rare circumstances (for example, if the patient has comorbidities that would contraindicate biopsy). If a lesion is seen equally well on mammography and US, US guidance is preferred because of patient comfort, efficiency, economy, absence of ionizing radiation, and sampling accuracy due to real-time visualization of the needle within the lesion [33]. Although some practices demonstrate very good results using fine-needle aspiration biopsy (FNAB) as the first means of diagnostic evaluation of a palpable breast mass, especially if a cytopathologist is available to interpret results in real time [34,35], larger series demonstrate that core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [36-38]. Core biopsy is therefore recommended in most cases. Either stereotactic or DBT (x-ray)

or US guidance can be used for core biopsy, especially if the mass is vaguely palpable, small, deep, or mobile or if there are multiple lesions [39]. Even when a lesion is clinically palpable, image-guided biopsy of targets has advantages over tissue sampling by palpation, allowing confirmation of biopsy accuracy and the ability to place a biopsy marker clip. The decision to perform surgical excisional versus percutaneous biopsy should involve the patient and her health care provider. However, image-guided core-needle biopsy has become the procedure of choice for most image-detected breast lesions requiring tissue diagnosis. Its advantages over surgical biopsy are well recognized, including less scarring, fewer complications, faster recovery, less cost, and similar accuracy [33].

Historically, palpable masses with probably benign features on imaging also underwent biopsy. However, a growing body of literature suggests that short-interval follow-up may be appropriate in the context of probably benign palpable masses [40-45].

#### *Magnetic resonance imaging*

MRI with and without contrast is well known to have high sensitivity for detection of cancer, including palpable disease [46]; however, it is generally more cost effective to use mammography or DBT and US as initial imaging examinations. In addition, there are few studies that evaluate the efficacy of MRI specifically in the setting of palpable lesions. A recent study evaluating MRI workup of conventional imaging Breast Imaging Reporting and Data System (BI-RADS) 0 cases included 29 palpable masses and found a sensitivity of 100% and a specificity of 74% for this palpable lesion subset [47]. One small retrospective study has demonstrated high sensitivity and low specificity for MRI performed in the context of a palpable breast mass and negative conventional imaging [48]; the authors raise the possibility that negative MRI may falsely reassure patients into poor compliance with follow-up. The use of MRI to evaluate women with a *suspicious* clinical examination and negative imaging is not well documented. In 1 series [49], 112 women were referred for breast MRI with the indication of a clinical finding; MRI resulted in no additional true-positive findings and 1 false-negative finding.

MRI may have value in the very specific circumstance of distinguishing between scar and recurrent disease in the setting of a postlumpectomy patient with a palpable lump at the surgical site and nondefinitive conventional imaging findings; however, the evidence for this indication is not well established [4,50]. There is no role for MRI of the breast without contrast in evaluating a woman with a palpable breast mass.

#### *FDG-PEM*

Although PEM has been shown to be accurate in detecting malignant disease, with a reported sensitivity of 90%, specificity of 86%, and accuracy of 88% [51], the use of dedicated positron emission tomography scanners with high spatial resolution and breast compression to evaluate the breast is currently investigational. Most studies have focused on the use of PEM for screening or preoperative staging [52,53]. There are very few studies evaluating FDG-PEM in the context of a palpable mass, but a small study evaluating both women with abnormal mammograms and women with palpable breast masses found a high false-negative risk of 12.1% [54]. There is currently no role for FDG-PEM in evaluating symptomatic women [4].

#### *Tc-99m sestamibi MBI*

The use of nuclear techniques using whole-body scanners has shown limited detection of small breast cancers [55,56]. The use of small, high-resolution cameras specifically designed for imaging of the breast has improved detection of small and noninvasive carcinomas [51,57,58], and recent work has demonstrated increased detection of cancer in women with dense breasts when used in conjunction with mammography [59]. There has also been work evaluating alternative radionuclide tracers for detection of palpable and impalpable breast malignancy, but this is still experimental [60]. In general, scintigraphic research specific to evaluation of women with palpable findings is lacking. There is currently no role for nuclear medicine in the initial evaluation of a woman presenting with a palpable mass.

### **Discussion of Imaging Modalities by Variant**

**Variant 1: Palpable breast mass. Woman 40 years of age or older, initial evaluation. (See [Appendices 1A-1B](#) for additional steps in the workup of these patients.)**

#### *Mammography or digital breast tomosynthesis diagnostic*

Mammography is the main modality for initial imaging assessment of a palpable lump in women 40 years of age or older [13-15]. It is performed under the direct supervision of a radiologist and usually consists of craniocaudal and mediolateral oblique views of each breast, which enables screening the remainder of each breast for additional lesions. The mammogram need include only the ipsilateral breast if the patient has had a recent bilateral mammogram (within the last 3 to 6 months). A small radio-opaque 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 often obtained to specifically evaluate the clinical finding. Supplemental mammographic views may also be needed to clarify the features or location of a mammographic lesion, including craniocaudal exaggerated, cleavage, step-oblique [61], and 90° lateral views. Any creative nonstandard view can 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. DBT may also be employed for diagnostic evaluation of a palpable lesion [16,18-20]. Several recent studies show that the diagnostic accuracy of 1-view breast tomosynthesis in diagnostic workup of women with clinical signs and symptoms and in women recalled from screening is equivalent to or better than supplemental diagnostic mammographic views [16,18,20,21].

#### *US breast*

US may be considered as an initial means of imaging if the patient has had a recent mammogram within the past 6 months. US is more frequently used following mammography in this age group [4,32] (see Variants 2, 3, and 5).

#### *MRI breast without and with contrast*

There is no role for MRI without and with contrast in the initial evaluation of a woman presenting with a palpable mass [4,48,49].

#### *MRI breast without contrast*

There is no evidence to support MRI breast without contrast in the initial evaluation of a woman presenting with a palpable mass.

#### *FDG-PEM*

There is no role for FDG-PEM in the initial evaluation of a woman presenting with a palpable mass [4,54].

#### *Tc-99m sestamibi MBI*

There is insufficient evidence to support Tc-99m sestamibi MBI in the initial evaluation of a woman presenting with a palpable mass.

#### *Image-guided core biopsy breast*

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. Therefore, there is no role for image-guided core biopsy in the initial evaluation of a woman presenting with a palpable mass.

#### *Image-guided fine-needle aspiration breast*

Because many breast masses may not exhibit distinctive physical findings, imaging evaluation is necessary in almost all cases to characterize the palpable lesion. It is preferable for imaging to occur before biopsy, as changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. Therefore, there is no role for image-guided FNAB in the initial evaluation of a woman presenting with a palpable mass.

**Variant 2: Palpable breast mass. Woman 40 years of age or older, mammography findings suspicious for malignancy. Next examination to perform. (See [Appendix 1A](#) for additional steps in the workup of these patients.)**

#### *US breast*

US may be helpful in characterizing a suspicious mammographic finding [62] and may identify additional lesions not evident on mammography or DBT. 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 [63]. If a sonographic correlate is identified, biopsy can be performed under US guidance rather than via stereotactic guidance with the advantage of no radiation. US-guided core biopsy is also usually more easily tolerated because of lack of breast compression and may allow for biopsy of lesions that are difficult to access stereotactically (for example, far posterior lesions, axillary lesions) [64]. US also allows for evaluation of the axilla. If a suspicious lymph node is identified, US-guided biopsy can be performed at the time of biopsy of the index lesion. If there is no sonographic correlate for a suspicious mammographic finding, tissue sampling (stereotactic biopsy) should be guided by the suspicious mammographic finding. If there is no sonographic correlate for a suspicious DBT finding, tissue sampling (image-guided biopsy) should be guided by the suspicious DBT finding.

#### *MRI breast without and with contrast*

There is no evidence to support the use of MRI of the breast without and with contrast as the next step in evaluating a palpable mass in the context of a suspicious mammographic finding [4,48,49]. If malignancy is subsequently established by biopsy, MR may be useful in delineating extent of disease in certain circumstances [65].

#### *MRI breast without contrast*

There is no evidence to support the use of MRI of the breast without contrast as the next step in evaluating a palpable mass in the context of a suspicious mammographic finding.

#### *Image-guided core biopsy breast*

When a mammographically or DBT suspicious lesion is identified that correlates with a palpable mass, biopsy is warranted. If it is unlikely that the target will be seen with US (for example, calcifications without a mass), stereotactic-guided core biopsy may be performed. If a lesion is only identified on DBT, DBT-guided core biopsy may be pursued directly [66,67]. However, if the lesion can be seen with US, US is recommended as the next step in evaluation, as described above [64]. A postbiopsy marker clip with mammographic postbiopsy imaging is recommended to confirm tissue sampling of the lesion and to aid in correlation in cases where the finding was initially seen on mammogram but the biopsy was performed with US guidance. Similarly, a postbiopsy marker clip with DBT postbiopsy imaging is recommended to confirm tissue sampling of the lesion and to aid in correlation in cases where the finding was initially seen on DBT but the biopsy was performed with US guidance.

#### *Mammography or digital breast tomosynthesis short-interval follow-up*

In the context of a suspicious mammographic finding and a palpable mass, short-interval follow-up is not considered appropriate management. US imaging or, in certain cases, direct stereotactic-guided core biopsy should be performed (see “US breast” and “Image-guided core biopsy” sections above) and tissue sampling (image-guided core biopsy) is indicated. In the context of a suspicious DBT finding and a palpable mass, short-interval follow-up is not considered appropriate management. US imaging or, in certain cases, direct stereotactic or DBT-guided core biopsy should be performed (see “US breast” and “Image-guided core biopsy” sections above).

#### *FDG-PEM*

There is no role to support the use of FDG-PEM as the next step in evaluating a palpable mass in the context of a suspicious mammographic finding [4,54].

#### *Tc-99m sestamibi MBI*

There is no evidence to support the use of Tc-99m sestamibi MBI as the next step in evaluating a mammographically suspicious finding in women presenting with a palpable mass.

#### *Image-guided fine-needle aspiration breast*

It is preferable for imaging to occur before biopsy, as changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. If a mammographically suspicious lesion is identified that correlates with the palpable mass, first US is recommended as the next step in evaluation and then image-guided FNA may be pursued. However, larger series demonstrate that core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [36-38]. In addition, core biopsy allows for ready evaluation of tumor receptor status. It is preferred that US-guided core biopsy be used except in rare situations where patient comorbidities or technical considerations (lesion abuts an implant, for example) may render an FNA preferable to a core.

**Variant 3: Palpable breast mass. Woman 40 years of age or older, mammography findings probably benign. Next examination to perform. (See [Appendix 1A](#) for additional steps in the workup of these patients.)**

#### *US breast*

When the mammogram or DBT imaging shows a probably benign mass (eg, round or oval circumscribed mass), US is indicated to further characterize the finding and is preferably targeted specifically to the palpable finding [62]. The addition of US will often yield a definitively benign result (eg, simple cyst) or a solid mass with benign features including oval or round shape, abrupt well-defined margin, homogeneous echogenicity, and orientation parallel to the chest wall with no posterior acoustic shadowing [68,69]. The vast majority of these lesions

represent benign fibroadenomas. On the other hand, US may also identify features that are suspicious, appropriately prompting biopsy in other cases.

*Mammography or digital breast tomosynthesis short-interval follow-up*

Either short-interval mammographic follow-up or short-interval DBT follow-up is a reasonable alternative to biopsy for palpable solid masses with benign features confirmed by US if the mammogram and clinical examination also suggest a benign etiology and if there is definitive correlation between the mammographic and sonographic findings [70]. Historically, biopsy has been recommended for palpable solid masses with benign features. However, a growing body of evidence has demonstrated low cancer incidence in palpable masses described as probably benign on US when appropriately using BI-RADS lexicon (incidence of cancer in these studies ranges from 0% to 2.0%) [40,43,45]. Shin et al [71] found a cancer incidence of 3.2%, but as Lehman et al [4] point out, the patients in this study all underwent needle biopsy, likely explaining the higher cancer rate. However, biopsy is warranted if a mass is new on imaging or increasing in size by >20% in volume or >20% in each diameter in a 6-month period (see “Image-guided core biopsy breast” and “Image-guided fine-needle aspiration” sections below) [72,73].

*MRI breast without and with contrast*

There is no role for MRI of the breast without and with contrast as the next step in evaluating a palpable mass in the context of a probably benign mammographic finding for women  $\geq 40$  years [4,48,49].

*MRI breast without contrast*

There is no evidence to support the use of MRI of the breast without contrast as the next step in evaluating a palpable mass in the context of a probably benign mammographic finding in women  $\geq 40$  years.

*Image-guided core biopsy breast*

If a palpable mass has probably benign features as identified on mammogram and US, imaging follow-up is usually appropriate. However, if a mass is new or enlarging, image-guided biopsy is recommended. In addition, there are certain cases where biopsy may be performed even on probably benign lesions. For example, BI-RADS 3 lesions in high-risk patients, patients awaiting organ transplant, patients with known synchronous cancers, or patients trying to get pregnant may be appropriate candidates for tissue sampling. In addition, situations where biopsy may alleviate extreme patient anxiety may prompt tissue sampling [33,64].

*FDG-PEM*

There is no role for FDG-PEM as the next step in evaluating a palpable mass in the context of a probably benign mammographic finding in women  $\geq 40$  years [4,54].

*Tc-99m sestamibi MBI*

There is no evidence to support the use of Tc-99m sestamibi MBI in the evaluation of a woman with a probably benign palpable mass.

*Image-guided fine-needle aspiration*

If a palpable mass has probably benign features as identified on mammogram and US, imaging follow-up is usually appropriate. However, as discussed above, if a mass is new or enlarging, image-guided biopsy is the preferred method of tissue sampling. In addition, there are certain cases where biopsy may be performed even on probably benign lesions. For example, BI-RADS 3 lesions in high-risk patients, patients awaiting organ transplant, patients with known synchronous cancers, or patients trying to get pregnant may be appropriate candidates for tissue sampling. In addition, situations where biopsy may alleviate extreme patient anxiety may prompt tissue sampling [33,64].

**Variant 4: Palpable breast mass. Woman 40 years of age or older, mammography findings benign (like lipoma) at site of palpable mass. Next examination to perform.**

*Mammography or digital breast tomosynthesis short-interval follow-up*

When the mammogram or DBT shows a definite benign mass (for example, lymph node, hamartoma, lipoma, calcified fibroadenoma, oil cyst) that unequivocally correlates with the palpable finding, clinical follow-up is appropriate management, and there is no need for short-interval imaging follow-up. DBT has been shown to be helpful in characterizing lesion margin and to be accurate in characterizing masses according to BI-RADS classification [74,75].

### *US breast*

When the mammogram shows a definite benign mass (eg, lymph node, hamartoma, lipoma, calcified fibroadenoma, oil cyst), US is not necessary as long the benign mass identified on mammography is a definitive correlate of the clinical finding. In addition, if fatty tissue alone is identified in the palpable region of concern, US may not be necessary [4]. However, if correlation between the mammographic finding and the palpable lesion is uncertain, US is indicated. US is preferably targeted specifically to the palpable finding [62].

### *MRI breast without and with contrast*

There is no role for MRI of the breast without and with contrast as the next step in evaluating a palpable mass in the context of a benign mammographic finding.

### *MRI breast without contrast*

There is no evidence to support MRI of the breast without contrast as the next step in evaluating a palpable mass in the context of a benign mammographic finding.

### *FDG-PEM*

There is no role for FDG-PEM as the next step in evaluating a palpable mass in the context of a benign mammographic finding [4,54].

### *Tc-99m sestamibi MBI*

There is no evidence to support the use of Tc-99m sestamibi MBI in the evaluation of a woman presenting with a benign correlate for a palpable lump on mammogram.

### *Image-guided core biopsy breast*

This is not indicated if a palpable lump has a clearly benign etiology on mammogram.

### *Image-guided fine-needle aspiration breast*

This is not indicated if a palpable lump has a clearly benign etiology on mammogram.

**Variant 5: Palpable breast mass. Woman 40 years of age or older, mammography findings negative. Next examination to perform. (See [Appendix 1B](#) for additional steps in the workup of these patients.)**

### *US breast*

A major advantage of US is the ability to directly correlate the clinical and imaging findings. The use of multiple modalities in diagnosing palpable masses has been advocated as a measure to increase the true-positive rate. In 3 series evaluating palpable breast abnormalities [13-15], the sensitivity of mammography was 86% to 91%. The addition of US detects 93% to 100% of cancers that are occult on mammography [10-12,14]. The addition of US to mammography may also improve detection of a benign etiology for a palpable finding. In 1 series, 40% of benign palpable masses were identified only on US [15]. When both mammography and US are negative or benign in the evaluation of a palpable breast mass, the negative predictive value is very high, over 97% [10-12,76,77]. Together, these imaging modalities can be reassuring when the physical examination is not highly suspicious and clinical follow-up is planned. However, a suspicious physical examination should prompt biopsy regardless of the imaging findings [76].

### *Mammography or digital breast tomosynthesis short-term follow-up*

There is no role for either mammography or DBT short-term follow-up for women over 40 years with palpable masses and negative mammographic findings.

### *MRI breast without and with contrast*

MRI breast without and with contrast for women with a palpable mass and negative mammography is not recommended as the next step in a workup and remains investigational [4,48,49]. US should be performed next [10-12,14].

### *MRI breast without contrast*

There is no evidence to support MRI breast without contrast as the next step in the context of negative conventional imaging and a palpable mass.

### *FDG-PEM*

There is no role for FDG-PEM as the next step in evaluating a palpable mass in the context of a negative mammographic finding [4,54].

### *Tc-99m sestamibi MBI*

There is no evidence to support the use of Tc-99m sestamibi MBI as the next step in the evaluation of a woman presenting with a negative mammogram in the context of a palpable lump.

### *Image-guided core biopsy breast*

There is no role for image-guided core biopsy as the next step in the evaluation of a woman presenting with a negative mammogram and a palpable lump. US should be performed and if a correlate is found, then US-guided core biopsy is recommended. However, a suspicious physical examination should prompt biopsy guided by palpation, regardless of negative imaging findings [76].

### *Image-guided fine-needle aspiration breast*

There is no role for image-guided FNAB as the next step in the evaluation of a woman presenting with a negative mammogram and a palpable lump. US should be performed and if a correlate is found, then US-guided core biopsy is recommended. However, a suspicious physical examination should prompt biopsy guided by palpation, regardless of negative imaging findings [76].

## **Variant 6: Palpable breast mass. Woman younger than 30 years of age, initial evaluation. (See [Appendices 2A-2B](#) for additional steps in the workup of these patients.)**

### *US breast*

The probability of a woman developing breast cancer increases with age; a woman has a 1 in 53 chance of developing invasive breast cancer from birth to age 49 years compared to a 1 in 15 chance at  $\geq 70$  years of age [1]. Diagnostic mammography is indicated as the initial examination in the evaluation of a palpable breast finding for women aged 40 years and older. However, because of the theoretically increased radiation risk of mammography and the low incidence of breast cancer ( $<1\%$ ) in younger women, their imaging evaluation differs from that performed for older patients [25-29]. In addition, most benign lesions in young women are not visualized on mammography [26,28], and US is therefore used as the initial imaging modality in younger women. US is preferably targeted specifically to the palpable finding [62]. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

Of note, US is often recommended as the first modality for investigation of a lump in pregnant women [63,78]. US may also be the first modality chosen for evaluating palpable masses in lactating women [78,79] because tissue density limits mammographic evaluation. However, mammography, when performed preoperatively in pregnant patients and/or lactating patients with known cancer, has a high sensitivity for malignancy, reportedly from 90% to 100% [80,81]. Mammography is not contraindicated during pregnancy or lactation [82,83] 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 [78,80,84].

### *Mammography or digital breast tomosynthesis diagnostic*

Because of the theoretically increased radiation risk of mammography or DBT and the low incidence of breast cancer ( $<1\%$ ) in younger women, their recommended imaging evaluation differs from that performed for older patients [25-29]. In addition, most benign lesions in young women are not visualized on mammography [26,28]. Neither diagnostic mammography nor DBT is recommended as the initial imaging modality in younger women.

### *MRI breast without and with contrast*

There is no evidence to support the use of MRI of the breast with and without contrast as part of the initial workup in women under 30 years of age with a palpable lump [4,48,49].

### *MRI breast without contrast*

There is no evidence to support the use of MRI of the breast without contrast as part of the initial workup in women under 30 years of age with a palpable lump.

### *FDG-PEM*

There is no evidence to support the use of FDG-PEM of the breast as part of the initial workup in women under 30 years of age with a palpable lump [4,54].

### *Tc-99m sestamibi MBI*

There is no evidence to support the use of Tc-99m sestamibi MBI as part of the initial workup in women under 30 years of age with a palpable lump.

### *Image-guided core biopsy breast*

It is preferable for imaging to occur before biopsy, as changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. There is no evidence to support the use of image-guided core biopsy as part of the initial workup in women under 30 years of age with a palpable lump.

### *Image-guided fine-needle aspiration breast*

It is preferable for imaging to occur before biopsy, as changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. There is no evidence to support the use of image-guided FNAB as part of the initial workup in women under 30 years of age with a palpable lump.

**Variant 7: Palpable breast mass. Woman younger than 30 years of age, US findings suspicious for malignancy. Next examination to perform. (See [Appendix 2A](#) for additional steps in the workup of these patients.)**

### *Image-guided core biopsy breast*

If a suspicious mass has been identified on US, tissue sampling (US guided) is warranted except in rare circumstances (for example, if the patient has comorbidities that would contraindicate biopsy). It may be appropriate to proceed directly to image-guided biopsy if a palpable lesion has suspicious features on US. Some practices demonstrate very good results using FNAB as the first means of diagnostic evaluation of a palpable breast mass [34,35]. However, larger series demonstrate that core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [36-38]. It may also be appropriate to perform diagnostic mammography or DBT before tissue sampling (see “Mammography or digital breast tomosynthesis diagnostic” section below).

### *Mammography or digital breast tomosynthesis diagnostic*

It may be appropriate to obtain a mammogram or DBT in a woman younger than 30 years of age with a suspicious sonographic finding that correlates to a palpable mass. Mammography may also demonstrate findings such as calcifications or subtle architectural distortions that are not readily identified on US and that may indicate a more accurate extent of disease than appreciable on US. In addition, DBT may have relatively high diagnostic accuracy in women with dense breasts, as may be the case in a younger population [17,85].

Even in this age group, diagnostic mammography or DBT may be helpful in evaluating for additional ipsilateral and contralateral lesions.

### *US breast short-interval follow-up*

When a suspicious finding is identified as a correlate for a palpable mass on US, tissue sampling should be pursued. There is no role for short-interval US follow-up.

### *MRI breast without and with contrast*

After identifying a suspicious finding on US, the next step should be either tissue sampling or diagnostic mammography. There is no evidence to support MRI breast without and with contrast as the next step in evaluating a palpable mass with suspicious sonographic features in women younger than 30 years [4,48,49]. If malignancy is subsequently established by biopsy, MR may be useful in delineating extent of disease in certain circumstances [65].

### *MRI breast without contrast*

There is no evidence to support MRI breast without contrast as the next step in evaluating a palpable mass with suspicious sonographic features in women younger than 30 years.

### *FDG-PEM*

There is no role for FDG-PEM as the next step in evaluating a palpable mass with suspicious sonographic features in women younger than 30 years [4,54].

### *Tc-99m sestamibi MBI*

There is no evidence to support the use of Tc-99m sestamibi MBI as the next step in evaluating a palpable mass with suspicious sonographic features in women younger than 30 years.

### *Image-guided fine-needle aspiration breast*

It may be appropriate to proceed directly to image-guided biopsy if a palpable lesion has suspicious features on US. Although some practices demonstrate very good results using FNAB as the first means of diagnostic evaluation of a palpable breast mass [34,35], larger series demonstrate that core biopsy is superior to FNAB in



terms of sensitivity, specificity, and correct histological grading of palpable masses [36-38]. In addition, core biopsy allows for ready evaluation of tumor receptor status. It is preferred that US-guided core biopsy be used except in rare situations where patient comorbidities or technical considerations (lesion abuts an implant, for example) may render an FNA preferable to a core.

**Variante 8: Palpable breast mass. Woman younger than 30 years of age, US findings probably benign. Next examination to perform. (See [Appendix 2B](#) for additional steps in the workup of these patients.)**

*US breast short-interval follow-up*

Short-interval follow-up is a reasonable alternative to biopsy for palpable solid masses with benign features identified by US if the clinical examination also suggests a benign etiology [70]. 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 [68,69]. The vast majority of these lesions represent benign fibroadenomas. Although historically biopsy has been recommended for palpable solid masses with benign features, a growing body of evidence has demonstrated low cancer incidence in palpable masses described as probably benign on US when appropriately using BI-RADS lexicon [40,43-45]. The likelihood of a mass with probably benign features representing a cancer is low in all series and particularly low in young women [41]. In 1 study [45] only 1 of 357 patients (0.3%) younger than age 25 years with such features were subsequently diagnosed with malignancy.

*Mammography or digital breast tomosynthesis diagnostic*

If a correlate for a palpable mass has been identified on US and is probably benign, there is no indication for either diagnostic mammography or DBT in this age group.

*Image-guided core biopsy breast*

If a palpable mass has probably benign features as identified on US, US follow-up is recommended. However, image-guided core biopsy may be performed after complete imaging assessment if there are mitigating reasons to establish a definitive diagnosis more immediately. For example, BI-RADS 3 lesions in high-risk patients, patients awaiting organ transplant, patients with known synchronous cancers, or patients trying to get pregnant may be appropriate candidates for tissue sampling. In addition, situations where biopsy may alleviate extreme patient anxiety may prompt tissue sampling [64].

*MRI breast without and with contrast*

There is no evidence to support the use of MRI breast without and with contrast in women under 30 years with probably benign sonographic findings in the setting of a palpable lump [4,48,49].

*MRI breast without contrast*

There is no evidence to support the use of MRI breast without contrast in women under 30 years with probably benign sonographic findings in the setting of a palpable lump.

*Image-guided fine-needle aspiration breast*

If a palpable mass has probably benign features as identified on mammogram and US, imaging follow-up is recommended. Image-guided FNAB may be performed after complete imaging assessment if there are mitigating reasons to establish a definitive diagnosis more immediately. For example, BI-RADS 3 lesions in high-risk patients, patients awaiting organ transplant, patients with known synchronous cancers, or patients trying to get pregnant may be appropriate candidates for tissue sampling. In addition, situations where biopsy may alleviate extreme patient anxiety may prompt tissue sampling [64]. However, as discussed above, image-guided core biopsy is the preferred method of tissue sampling.

*FDG-PEM*

There is no role to support the use of FDG-PEM in women under 30 years with probably benign sonographic findings in the setting of a palpable lump [4,54].

*Tc-99m sestamibi MBI*

There is no evidence to support the use of Tc-99m sestamibi MBI in women under 30 years with probably benign sonographic findings in the setting of a palpable lump.

**Variant 9: Palpable breast mass. Woman younger than 30 years of age, US findings benign (like simple cyst). Next examination to perform.**

*Mammography or digital breast tomosynthesis diagnostic*

If a benign entity has been found on US and is a definitive correlate for a palpable lump, there is no role for further evaluation with either diagnostic mammography or DBT in women under 30 years. Clinical follow-up is warranted.

*US breast short-interval follow-up*

If a benign entity (eg, simple cyst, benign lymph node, and hamartoma) has been found on US and is a definitive correlate for a palpable lump, there is no role for further investigation or follow-up. Clinical follow-up is warranted.

*Image-guided core biopsy breast*

If a benign entity has been found on US and is a definitive correlate for a palpable lump, there is no role for tissue sampling. The likelihood of a palpable lump in a young woman that is benign on both clinical examination and US resulting in a cancer is extremely low; 1 study prospectively evaluating US-guided core biopsy in 248 young women under age 25 years with clinically benign lumps and predominantly benign findings found no cancers in this group [86].

*Image-guided fine-needle aspiration breast*

If a benign entity has been found on US and is a definitive correlate for a palpable lump, there is no role for tissue sampling.

*MRI breast without and with contrast*

If a benign entity has been found on US and is a definitive correlate for a palpable lump, there is no role for MRI breast without and with contrast in women under 30 years [4,48,49].

*MRI breast without contrast*

If a benign entity has been found on US and is a definitive correlate for a palpable lump, there is no role for MRI breast without contrast in women under 30 years.

*FDG-PEM*

If a benign entity has been found on US and is a definitive correlate for a palpable lump, there is no role for FDG-PEM in women under 30 years with a palpable lump [4,54].

*Tc-99m sestamibi MBI*

If a benign entity has been found on US and is a definitive correlate for a palpable lump, there is no evidence for Tc-99m sestamibi MBI.

**Variant 10: Palpable breast mass. Woman younger than 30 years of age, US findings negative. Next examination to perform.**

*Mammography or digital breast tomosynthesis diagnostic*

Mammography is not indicated unless the clinical findings are suspicious. As with women aged 40 years and older, if physical examination is highly suspicious and mammography or DBT and US are negative, tissue sampling with core biopsy or surgical biopsy is warranted. Either mammography or DBT is still recommended as a prebiopsy assessment in cases where cancer is strongly suspected clinically [26]. If a mammographic correlate to a suspicious finding is identified, then stereotactic biopsy is recommended. If a correlate to a suspicious finding is identified solely on DBT, then DBT-guided biopsy is recommended. In the absence of imaging correlate and a suspicious clinical examination, tissue sampling guided by palpation is warranted.

*MRI breast without and with contrast*

There is no role for MRI of the breast without and with contrast in women younger than 30 years with negative US findings [4,48,49].

*US breast short-interval follow-up*

There is no evidence to support US breast short-interval follow-up in young women younger than 30 years with negative US findings.

*MRI breast without contrast*

There is no evidence to support MRI breast without contrast in young women younger than 30 years with negative US findings.

*FDG-PEM*

There is no role for FDG-PEM in young women younger than 30 years with negative US findings [4,54].

*Tc-99m sestamibi MBI*

There is no evidence for Tc-99m sestamibi MBI in young women younger than 30 years with a palpable lump and negative US findings.

*Image-guided core biopsy breast*

There is no role for image-guided core biopsy in young women younger than 30 years with negative US findings.

*Image-guided fine-needle aspiration breast*

There is no role for image-guided FNAB in young women younger than 30 years with negative US findings.

**Variants 11: Palpable breast mass. Woman 30 to 39 years of age, initial evaluation. (See [Appendix 3](#) for additional steps in the workup of these patients.)**

*US breast*

Diagnostic mammography, DBT, or US can be used as the initial means of image evaluation for women aged 30 to 39 years with a palpable breast mass. (If imaged initially with US, see Variants 7-10 for additional imaging.) Most benign lesions in young women are not visualized on mammography [26,28], and US is therefore used as the initial imaging modality in younger women. The criterion for “young” has historically been considered younger than age 30 years. 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 years [87]. One study of 1208 women aged 30 to 39 years presenting with focal breast symptoms found higher sensitivity for US compared with mammography (95.7% versus 60.9%), with similar specificity (89.2% and 94.4%, respectively) [77]. It is therefore reasonable to use US as the initial imaging modality for women younger than age 40 years, with a low threshold for using mammography if the clinical examination or other risk factors are concerning. If a suspicious mass is identified on US in this group, bilateral mammography is recommended.

*Mammography or digital breast tomosynthesis diagnostic*

Diagnostic mammography, DBT, or US can be used as the initial means of image evaluation for women aged 30 to 39 years with a palpable breast mass. If imaged initially with mammography or DBT, see Variants 2-5.

*MRI breast without and with contrast*

There is no role for MRI breast without and with contrast in the initial evaluation of women aged 30 to 39 years with a palpable lump [4,48,49].

*MRI breast without contrast*

There is no evidence to support MRI breast without contrast in the initial evaluation of women aged 30 to 39 years with a palpable lump.

*FDG-PEM*

There is no role for FDG-PEM in the initial evaluation of women aged 30 to 39 years with a palpable lump [4,54].

*Tc-99m sestamibi MBI*

There is no evidence for Tc-99m sestamibi MBI in the initial evaluation of women aged 30 to 39 years with a palpable lump.

*Image-guided core biopsy breast*

There is no role for image-guided core biopsy in the initial evaluation of women aged 30 to 39 years with a palpable lump.

*Image-guided fine-needle aspiration breast*

There is no role for image-guided FNAB in the initial evaluation of women aged 30 to 39 years with a palpable lump.

## Summary of Recommendations

- Because of inconsistencies in clinical examination, a thorough imaging workup of a palpable mass should be completed prior to biopsy.
- Diagnostic mammography or DBT is the initial imaging modality of choice for evaluating a clinically detected palpable breast mass in a woman aged 40 years 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 years.
- For women aged 30 to 39 years, either US or diagnostic mammography or DBT can 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.

## Summary of Evidence

Of the 87 references cited in the *ACR Appropriateness Criteria® Palpable Breast Masses* document, all of them are categorized as diagnostic references including 4 well-designed studies, 12 good quality studies, and 38 quality studies that may have design limitations. There are 31 references that may not be useful as primary evidence. There are 2 references that are meta-analysis studies.

The 87 references cited in the *ACR Appropriateness Criteria® Palpable Breast Masses* document were published from 1981-2016.

While there are references that report on studies with design limitations, 16 well-designed or good quality studies provide good evidence.

## 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 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](http://www.acr.org/ac).

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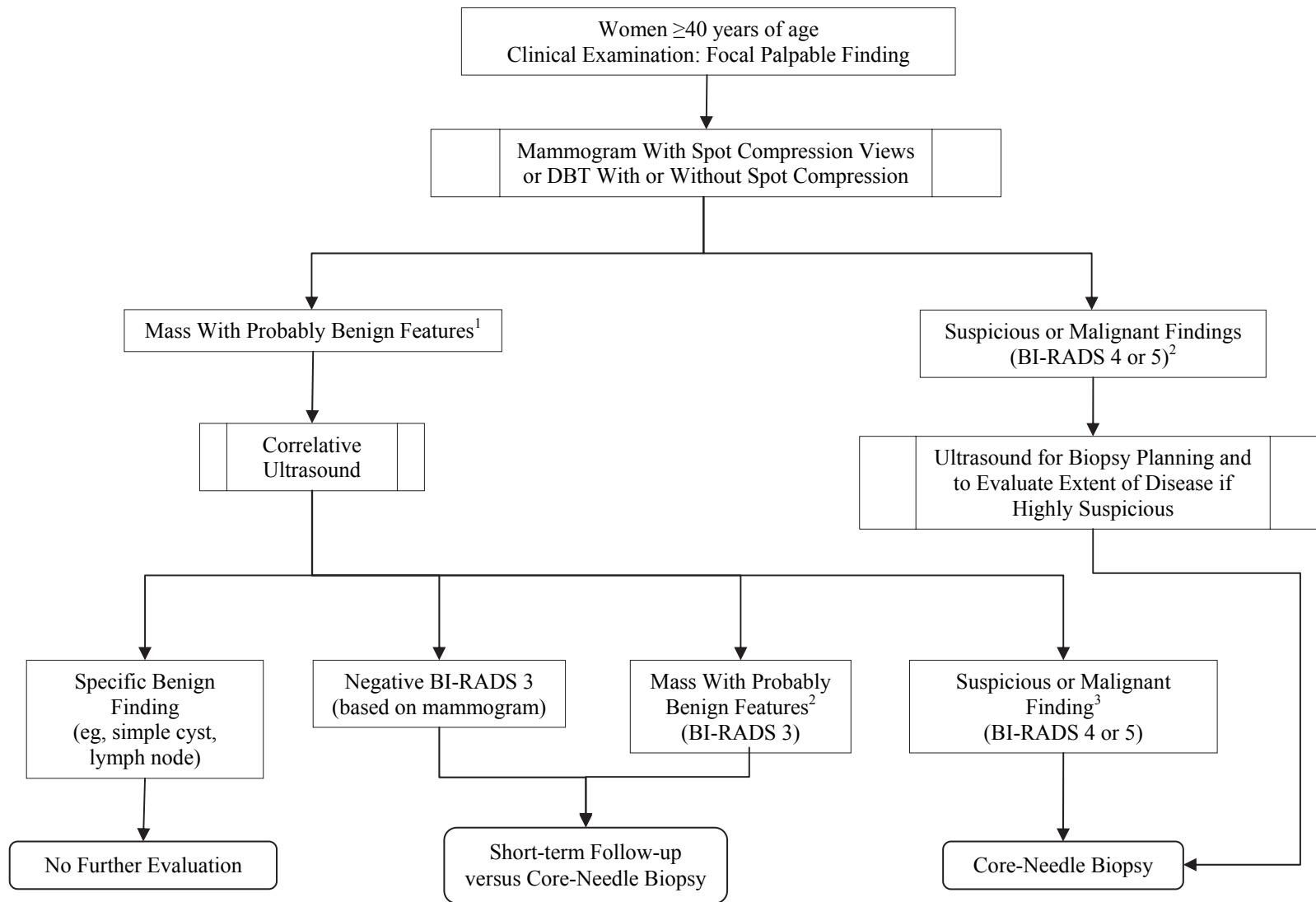
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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, 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.



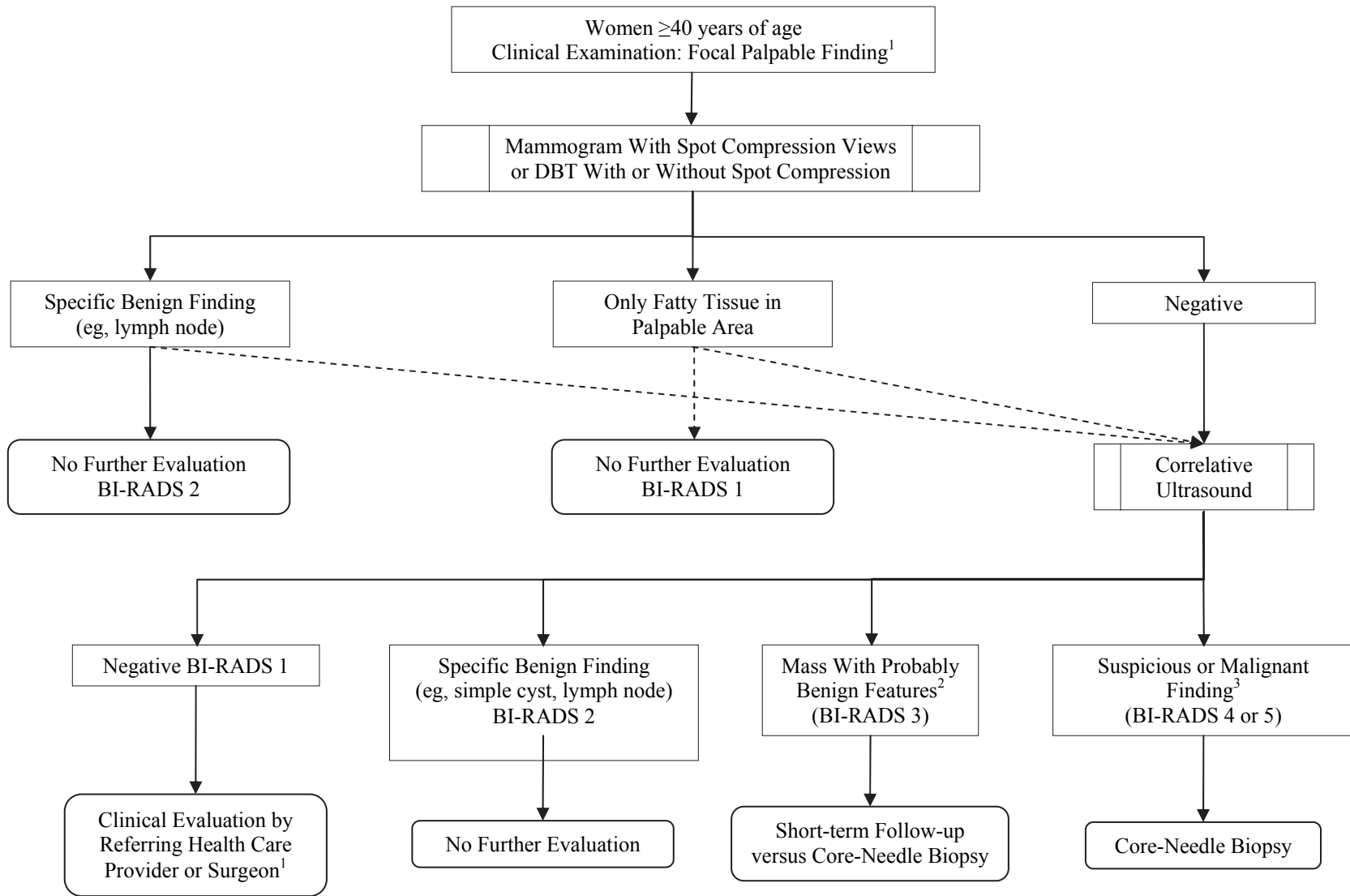
**Appendix 1A. Evaluation of palpable breast lesions in women aged 40 years or older with probably benign or suspicious findings on mammography.**



<sup>1</sup>Probably benign features include round, oval, or circumscribed margins; equal or low density on mammography; and homogeneously hypoechoic or isoechoic solid mass with circumscribed margins and lack of malignant features on US. If the mass is new on imaging, then biopsy is indicated.

<sup>2</sup>Suspicious features include irregular shape, ill-defined or spiculated margins, high density on mammography, nonparallel orientation, and posterior acoustic shadowing.

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

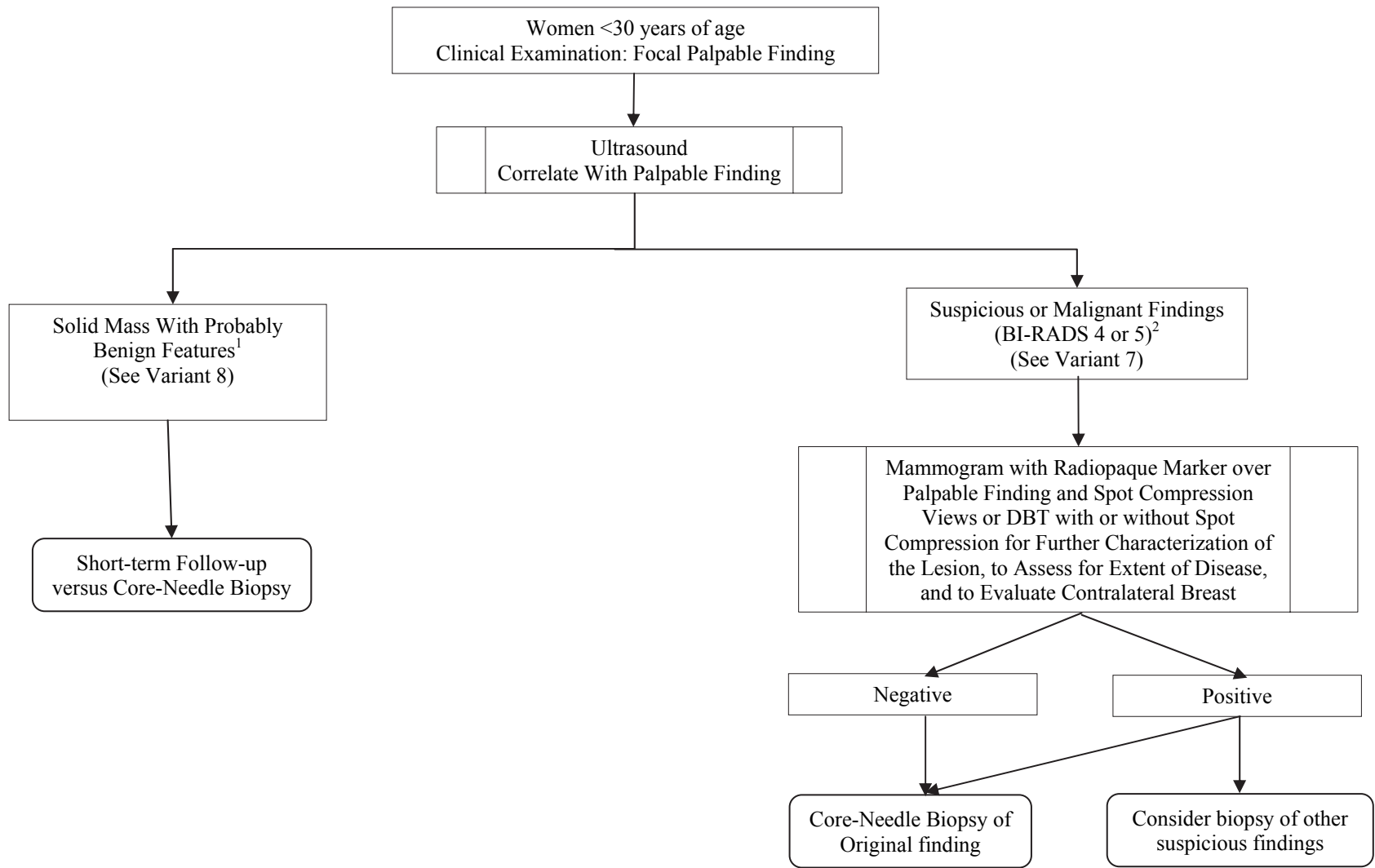


<sup>1</sup>The algorithm assumes that the clinical examination shows a focal palpable area of concern. If the clinical examination reveals less concerning findings, such as mild nodularity or a ridge of tissue, then further evaluation after negative imaging is not required.

<sup>2</sup>Probably benign features include round, oval, or circumscribed margins; equal or low density on mammography; and homogeneously hypoechoic or isoechoic solid mass with circumscribed margins and lack of malignant features on US. If the mass is new on imaging, then biopsy is indicated.

<sup>3</sup>Suspicious features include irregular shape, ill-defined or spiculated margins, high density on mammography, nonparallel orientation, or posterior acoustic shadowing.

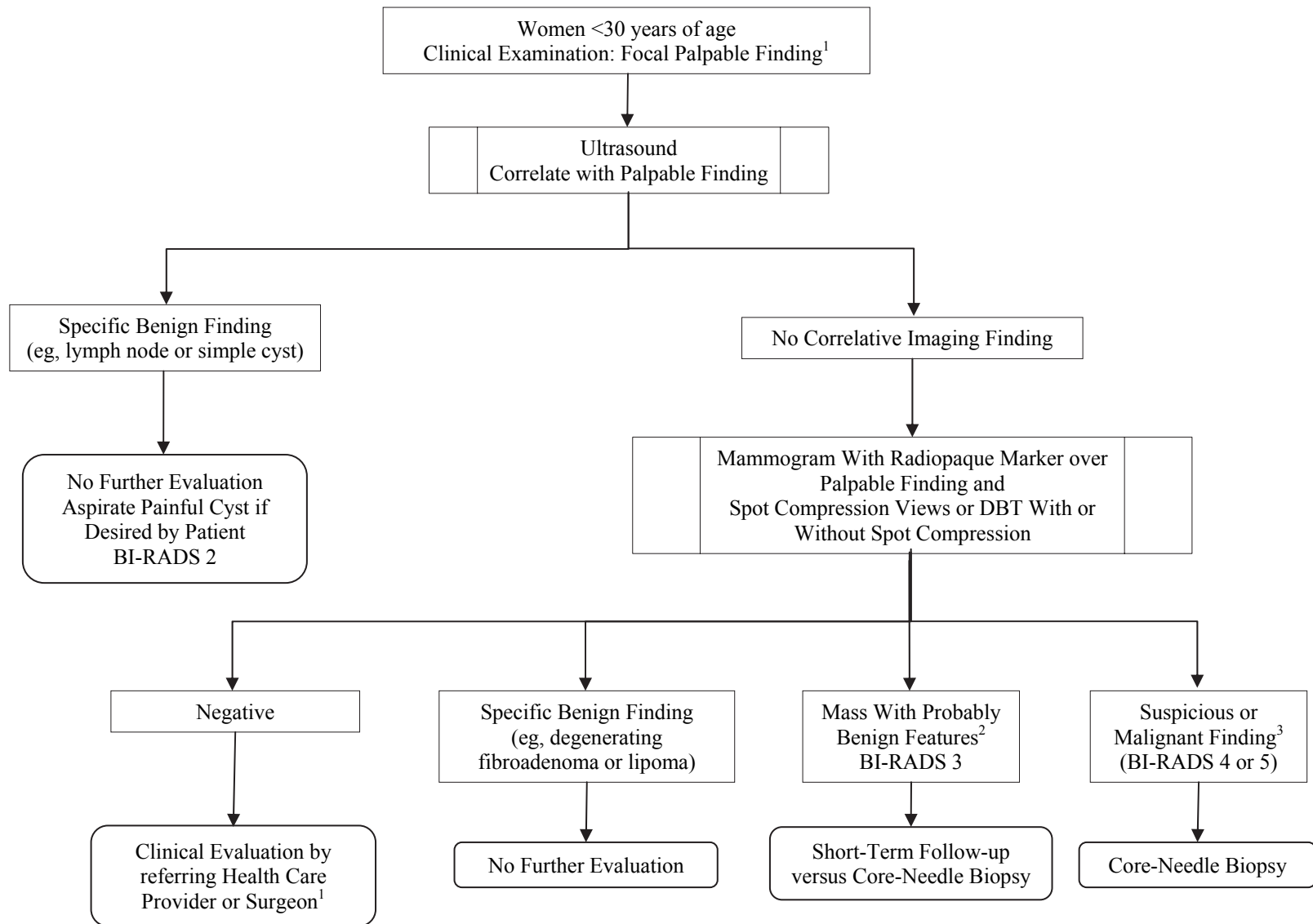
**Appendix 2A. Evaluation of palpable breast lesions in women <30 years old with probably benign or suspicious findings on US.**



<sup>1</sup>Probably benign features include round, oval, or circumscribed margins; equal or low density on mammography; and homogeneously hypoechoic or isoechoic solid mass with circumscribed margins and lack of malignant features on US. If the mass is new on imaging, then biopsy is indicated.

<sup>2</sup>Suspicious features include irregular shape, ill-defined or spiculated margins, high density on mammography, nonparallel orientation, or posterior acoustic shadowing.

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

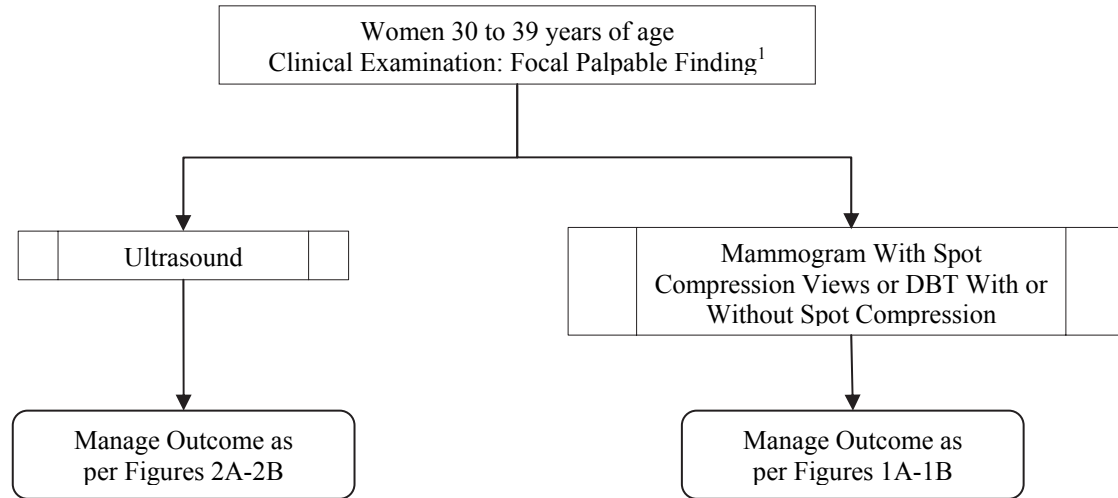


<sup>1</sup>The algorithm assumes that the clinical examination shows a focal palpable area of concern. If the clinical examination reveals less concerning findings, such as mild nodularity or a ridge of tissue, then further evaluation after negative imaging is not required.

<sup>2</sup>Probably benign features include round, oval, or circumscribed margins; equal or low density on mammography; and homogeneously hypoechoic or isoechoic solid mass with circumscribed margins and lack of malignant features on US. If the mass is new on imaging, then biopsy is indicated.

<sup>3</sup>Suspicious features include irregular shape, ill-defined or spiculated margins, high density on mammography, nonparallel orientation, or posterior acoustic shadowing.

**Appendix 3. Management of palpable findings in women aged 30 to 39 years of age.**



<sup>1</sup>The algorithm assumes that the clinical examination shows a focal palpable area 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.