

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

**Variant 1:**                      **Adult female, 40 years of age or older. Palpable breast mass. Initial imaging.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| Digital breast tomosynthesis diagnostic    | Usually Appropriate      | ☼☼                       |
| Mammography diagnostic                     | Usually Appropriate      | ☼☼                       |
| US breast                                  | May Be Appropriate       | ○                        |
| Digital breast tomosynthesis screening     | Usually Not Appropriate  | ☼☼                       |
| Mammography screening                      | Usually Not Appropriate  | ☼☼                       |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☼☼☼                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☼☼☼☼                     |

**Variant 2:**                      **Adult female, 40 years of age or older. Palpable breast mass. Mammography findings are suspicious or highly suggestive of malignancy (BI-RADS 4 or 5). Next imaging study.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| US breast                                  | Usually Appropriate      | ○                        |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☼☼☼                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☼☼☼☼                     |

**Variant 3:**                      **Adult female, 40 years of age or older. Palpable breast mass. Diagnostic mammography, DBT, and US findings are probably benign (BI-RADS 3). Next imaging study.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☼☼☼                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☼☼☼☼                     |

**Variant 4:**                      **Adult female, 40 years of age or older. Palpable breast mass. Mammography findings are benign (BI-RADS 2) at the site of palpable mass. Next imaging study.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| US breast                                  | May Be Appropriate       | ○                        |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☢☢☢                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☢☢☢☢                     |

**Variant 5:**                      **Adult female, 40 years of age or older. Palpable breast mass. Mammography findings are negative (BI-RADS 1). Next imaging study.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| US breast                                  | Usually Appropriate      | ○                        |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☢☢☢                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☢☢☢☢                     |

**Variant 6:**                      **Adult female, younger than 30 years of age. Palpable breast mass. Initial imaging.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| US breast                                  | Usually Appropriate      | ○                        |
| Digital breast tomosynthesis diagnostic    | Usually Not Appropriate  | ☢☢                       |
| Digital breast tomosynthesis screening     | Usually Not Appropriate  | ☢☢                       |
| Mammography diagnostic                     | Usually Not Appropriate  | ☢☢                       |
| Mammography screening                      | Usually Not Appropriate  | ☢☢                       |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☢☢☢                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☢☢☢☢                     |

**Variant 7:**

**Adult female, younger than 30 years of age. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy (BI-RADS 4 or 5). Next imaging study.**

| Procedure                                  | Appropriateness Category          | Relative Radiation Level |
|--------------------------------------------|-----------------------------------|--------------------------|
| Digital breast tomosynthesis diagnostic    | Usually Appropriate               | ☼☼                       |
| Mammography diagnostic                     | Usually Appropriate               | ☼☼                       |
| Image-guided core biopsy breast            | Usually Appropriate               | Varies                   |
| Image-guided fine needle aspiration breast | May Be Appropriate (Disagreement) | Varies                   |
| Digital breast tomosynthesis screening     | Usually Not Appropriate           | ☼☼                       |
| Mammography screening                      | Usually Not Appropriate           | ☼☼                       |
| MRI breast without and with IV contrast    | Usually Not Appropriate           | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate           | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate           | ☼☼☼                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate           | ☼☼☼☼                     |

**Variant 8:**

**Adult female, younger than 30 years of age. Palpable breast mass. US findings probably benign (BI-RADS 3). Next imaging study.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| Digital breast tomosynthesis diagnostic    | Usually Not Appropriate  | ☼☼                       |
| Digital breast tomosynthesis screening     | Usually Not Appropriate  | ☼☼                       |
| Mammography diagnostic                     | Usually Not Appropriate  | ☼☼                       |
| Mammography screening                      | Usually Not Appropriate  | ☼☼                       |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☼☼☼                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☼☼☼☼                     |

**Variant 9:**                      **Adult female, younger than 30 years of age. Palpable breast mass. US findings benign (BI-RADS 2). Next imaging study.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| Digital breast tomosynthesis diagnostic    | Usually Not Appropriate  | ☢☢                       |
| Digital breast tomosynthesis screening     | Usually Not Appropriate  | ☢☢                       |
| Mammography diagnostic                     | Usually Not Appropriate  | ☢☢                       |
| Mammography screening                      | Usually Not Appropriate  | ☢☢                       |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☢☢☢                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☢☢☢☢                     |

**Variant 10:**                      **Adult female, younger than 30 years of age. Palpable breast mass. US findings negative (BI-RADS 1). Next imaging study.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| Digital breast tomosynthesis diagnostic    | Usually Not Appropriate  | ☢☢                       |
| Digital breast tomosynthesis screening     | Usually Not Appropriate  | ☢☢                       |
| Mammography diagnostic                     | Usually Not Appropriate  | ☢☢                       |
| Mammography screening                      | Usually Not Appropriate  | ☢☢                       |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☢☢☢                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☢☢☢☢                     |

**Variant 11:****Adult female, 30 to 39 years of age. Palpable breast mass. Initial imaging.**

| Procedure                                  | Appropriateness Category | Relative Radiation Level |
|--------------------------------------------|--------------------------|--------------------------|
| US breast                                  | Usually Appropriate      | ○                        |
| Digital breast tomosynthesis diagnostic    | Usually Appropriate      | ☢☢                       |
| Mammography diagnostic                     | Usually Appropriate      | ☢☢                       |
| Digital breast tomosynthesis screening     | Usually Not Appropriate  | ☢☢                       |
| Mammography screening                      | Usually Not Appropriate  | ☢☢                       |
| Image-guided core biopsy breast            | Usually Not Appropriate  | Varies                   |
| Image-guided fine needle aspiration breast | Usually Not Appropriate  | Varies                   |
| MRI breast without and with IV contrast    | Usually Not Appropriate  | ○                        |
| MRI breast without IV contrast             | Usually Not Appropriate  | ○                        |
| Sestamibi MBI                              | Usually Not Appropriate  | ☢☢☢                      |
| FDG-PET breast dedicated                   | Usually Not Appropriate  | ☢☢☢☢                     |

## PALPABLE BREAST MASSES

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### Summary of Literature Review

#### **Introduction/Background**

Breast cancer remains the most common female malignancy (excluding skin) and the second leading cause of female cancer death in the United States, with a woman's lifetime risk of breast cancer at approximately 12.8%. Palpable breast masses are more commonly from benign causes; however, a palpable mass is the most common symptom associated with cancer, and palpable cancers tend to be more aggressive with poorer prognoses compared with screen-detected cancers [1-3]. Palpable breast masses may present in various circumstances: during routine breast self-examination or clinical breast examination; between regular mammographic screens; before baseline mammogram; or after prolonged abstention from mammography due to advanced age or personal choice [4]. Detection and characterization of a breast mass at physical examination may be difficult, but masses are generally asymmetrical in relation to the other breast, distinct from the surrounding tissues, and 3-D. Malignant masses cannot be reliably differentiated from benign by physical examination, even among experienced clinicians [5]. More suspicious features of a cancerous mass may include firmness and fixation due to attachments to the skin or deep fascia with dimpling or nipple retraction. In contrast, benign masses typically are mobile and have discrete, well-defined margins, as well as a soft or rubbery texture. 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 [6].

Imaging evaluation is necessary to adequately characterize a palpable breast mass. After thorough clinical breast examination, usually by the referring clinician or by a specialist breast clinician, the radiologist must be able to establish concordance between the clinically detected mass and the imaging features at that location [2]. The negative predictive value of mammography with ultrasound (US) in the context of a palpable mass ranges from 97.4% to 100% [7-10]. Nevertheless, negative imaging evaluation should not deter biopsy when a strongly suspicious finding is present on physical examination.

#### **Initial Imaging Definition**

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

- There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

OR

- There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient's care).

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## **Discussion of Procedures by Variant**

### **Variant 1: Adult female, 40 years of age or older. Palpable breast mass. Initial imaging.**

#### **Digital Breast Tomosynthesis Diagnostic**

Diagnostic digital breast tomosynthesis (DBT) should be used for initial imaging evaluation. A small radio-opaque marker is placed on the skin over the palpable finding to identify its location. Several prior studies have shown the diagnostic accuracy of DBT is equivalent to or better than supplemental diagnostic mammographic views in the workup of women with clinical signs and symptoms and in women recalled from screening [11-14]. The added features of planar imaging and thin-section reconstructions allow further assessment of potential false-positive findings. In a recent study, DBT provided similarly accurate diagnostic results as compared with digital mammography (DM) in women with palpable breast masses for detecting breast cancer using either combination DM with DBT (DM/DBT) or DM alone [15]. Several small studies, which specifically included women presenting with clinical symptoms including palpable lumps, demonstrated increased accuracy on combination DM/DBT compared with DM alone [13,16,17]. Additionally, it was demonstrated that DBT may improve lesion detection and characterization with higher conspicuity scores as compared with conventional DM imaging, particularly for cancers presenting as spiculated masses and distortions [17].

#### **Digital Breast Tomosynthesis Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening DBT, with or without DM, is not useful as the initial imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

#### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG)-PET breast dedicated in the initial evaluation of a woman presenting with a palpable mass [2].

#### **Image-Guided Core Biopsy Breast**

There is no relevant literature to support the use of image-guided core biopsy in the initial evaluation of a woman presenting with a palpable mass. Because many breast masses may not exhibit distinctive physical findings, imaging evaluation is necessary in almost all patients  $\geq 40$  years of age to characterize the palpable lesion and screen the remainder of each breast for additional lesions. It is preferable for imaging to occur before biopsy because changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. However, negative imaging evaluation should not deter biopsy when a strongly suspicious finding is present on physical examination. There is no relevant literature to support the use of image-guided core biopsy in the initial evaluation of women  $\geq 40$  years of age with palpable mass.

#### **Image-Guided Fine Needle Aspiration Breast**

There is no relevant literature to support the use of image-guided fine needle aspiration (FNA) in the initial evaluation of a woman presenting with a palpable mass. 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. It is preferable for imaging to occur before biopsy because changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. There is no relevant literature to support the use of the use of image-guided FNA biopsy (FNAB) in the initial evaluation of women  $\geq 40$  years of age with palpable mass.

#### **Mammography Diagnostic**

Mammography should be using for initial imaging of a palpable breast mass in women  $\geq 40$  years of age. It is performed under the direct supervision of a radiologist and usually consists at a minimum of craniocaudal and mediolateral oblique views of each breast, enabling screening of the entire breast for additional lesions. The mammogram may only include 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, and 90° lateral views.

In several series evaluating palpable breast abnormalities [18-20], the sensitivity of mammography alone was 86% to 91%. Mammography likely does not need to be repeated if it was performed within the past 6 months [21]. This

modality may be particularly useful in women with almost entirely fatty breasts, in which mammography alone was shown to have a high sensitivity (96%) and specificity (93%) in the evaluation of palpable breast masses [22].

### **Mammography Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening mammography is not useful as the initial imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

### **MRI Breast**

There is no relevant literature to support the use of MRI breast with or without intravenous (IV) contrast in the initial evaluation of a woman presenting with a palpable mass [2,23-25].

### **Sestamibi MBI**

There is no relevant literature to support the use of Tc-99m sestamibi molecular breast imaging (MBI) in the initial evaluation of a woman presenting with a palpable mass.

### **US Breast**

US may be considered as an initial means of imaging if the patient has had a recent negative mammogram within the past 6 months. In a study of women presenting with a palpable breast mass with a negative mammogram within the previous 6 to 12 months, US detected a finding in 50.3% of 311 cases, whereas repeat mammography detected a change in 12.9% of cases [21]. US is more frequently used following DBT/mammography in this age group [2,26] (see Variants 2, 3, and 5). The negative predictive value of mammography with US in the context of a palpable mass ranges from 97.4% to 100% [7-9].

**Variant 2: Adult female, 40 years of age or older. Palpable breast mass. Mammography findings are suspicious or highly suggestive of malignancy (BI-RADS 4 or 5). Next imaging study.**

### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of FDG-PET breast dedicated as the next step in evaluating a palpable mass in the context of a suspicious mammographic finding [2].

### **Image-Guided Core Biopsy Breast**

It is preferable for imaging to occur before biopsy because 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, US is recommended as the next step in evaluation before image-guided core biopsy is pursued. However, the lack of sonographic correlate should not deter biopsy of a suspicious mammographic or DBT abnormality in this setting. Core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [27]. In addition, core biopsy allows for ready evaluation of tumor receptor status. When a mammographically or DBT-detected suspicious lesion is identified that correlates with a palpable mass, biopsy is warranted. If a lesion is only identified on mammography or DBT, mammographically or DBT-guided core biopsy may be pursued [28,29]. If the lesion can be seen with US, US-guided biopsy may be pursued [30]. At image-guided biopsy, a marker clip is placed, and a postbiopsy diagnostic mammogram confirms that the US and mammographic findings correlate. Similarly, a postbiopsy DBT confirms that the US and DBT findings correlate. US-guided core biopsy is also usually more easily tolerated because of a lack of breast compression and may allow biopsy of lesions difficult to access stereotactically (eg, far posterior lesions or axillary lesions) [30].

### **Image-Guided Fine Needle Aspiration Breast**

It is preferable for imaging to occur before biopsy because 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, US is recommended as the next step in evaluation before image-guided FNA is pursued. However, the lack of sonographic correlate should not deter biopsy of a suspicious mammographic or DBT abnormality in this setting. Core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [27]. In addition, core biopsy allows for ready evaluation of tumor receptor status. An additional consideration of FNAB over a core biopsy may be the faster turnover time for a pathology diagnosis without a difference in time to treatment [31]. At US-guided FNA, a marker clip is placed and a postprocedure mammogram confirms that the US and mammographic findings correlate. Similarly, a postprocedure DBT confirms that the US and DBT findings correlate.



## **MRI Breast**

There is no relevant literature to support the use of MRI of the breast with or without IV contrast as the next step in evaluating a palpable mass in the context of a suspicious mammographic finding [2,23-25]. If malignancy is subsequently established by biopsy, MRI may be useful in delineating extent of disease in certain circumstances [32].

## **Sestamibi MBI**

There is no relevant literature to support the use of the use of Tc-99m sestamibi MBI as the next step in evaluating a palpable mass in the context of a suspicious mammographic finding.

## **US Breast**

US may be helpful in characterizing a suspicious mammographic finding [33]. In a study of women presenting with palpable breast thickening, the sensitivity of diagnostic mammography for invasive cancer detection was 60%, whereas the sensitivity of US alone was 100% [34].

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 12 MHz [35]. Some mammographers also perform screening US of the remainder of the ipsilateral breast and the contralateral breast in the setting of a suspicious finding [33]. 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 (tomosynthesis-guided biopsy) should be guided by the suspicious DBT finding.

**Variant 3: Adult female, 40 years of age or older. Palpable breast mass. Diagnostic mammography, DBT, and US findings are probably benign (BI-RADS 3). Next imaging study.**

## **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of FDG-PET breast dedicated as the next step in evaluating a palpable mass in the context of a probably benign mammographic finding for women  $\geq 40$  years of age [2].

## **Image-Guided Core Biopsy Breast**

If a palpable mass has probably benign features as identified on mammogram and/or US, imaging follow-up may be appropriate. However, if a mass is new on imaging or increasing by  $>20\%$  in volume or  $>20\%$  in each diameter in a 6-month period, the mass is considered suspicious, and image-guided biopsy is recommended [36]. Core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [27]. In addition, there are certain cases in which 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 for tissue sampling. In addition, situations in which biopsy may alleviate extreme patient anxiety may prompt tissue sampling [30,37]. If an image-guided biopsy is pursued, a marker clip is placed and a postbiopsy mammogram/DBT confirms that the clip placement and mammographic/DBT findings correlate.

## **Image-Guided Fine Needle Aspiration Breast**

If a palpable mass has probably benign features as identified on mammogram and/or US, imaging follow-up may be appropriate. However, if a mass is new on imaging or increasing by  $>20\%$  in volume or  $>20\%$  in each diameter in a 6-month period, image-guided biopsy is recommended [36]. In addition, there are certain cases in which 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 for tissue sampling. In addition, situations in which biopsy may alleviate extreme patient anxiety may prompt tissue sampling [30,37]. Large series have demonstrated core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [27]. In addition, core biopsy allows for ready evaluation of tumor receptor status. FNAB; however, may allow a faster turnover time as compared with core biopsy for a pathology diagnosis without a difference in time to treatment [31]. At image-guided FNA, a marker clip is placed and a postprocedure mammogram/DBT confirms that the marker clip and mammographic/DBT findings correlate.

## **MRI Breast**

There is no relevant literature to support the use of the use of MRI of the breast with or without IV contrast as the next step in evaluating a palpable mass in the context of a probably benign mammographic finding for women  $\geq 40$  years of age [2,23-25].

### **Sestamibi MBI**

There is no relevant literature to support the use of the use of Tc-99m sestamibi MBI as the next step in evaluating a palpable mass in the context of a probably benign mammographic finding for women  $\geq 40$  years of age.

**Variant 4: Adult female, 40 years of age or older. Palpable breast mass. Mammography findings are benign (BI-RADS 2) at the site of palpable mass. Next imaging study.**

### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of FDG-PET breast dedicated as the next step in evaluating a palpable mass in the context of a benign mammographic finding [2].

### **Image-Guided Core Biopsy Breast**

There is no relevant literature to support the use of image-guided core biopsy breast as the next step in evaluating a palpable mass in the context of a benign mammographic finding.

### **Image-Guided Fine Needle Aspiration Breast**

There is no relevant literature to support the use of image-guided FNAB as the next step in evaluating a palpable mass in the context of a benign mammographic finding. However, image-guided aspiration can be considered for symptomatic relief of a palpable simple cyst.

### **MRI Breast**

There is no relevant literature to support the use of MRI of the breast with or without IV contrast of the breast as the next step in evaluating a palpable mass in the context of a benign mammographic finding.

### **Sestamibi MBI**

There is no relevant literature to support the use of Tc-99m sestamibi MBI as the next step in evaluating a palpable mass in the context of a benign mammographic finding.

### **US Breast**

When the mammogram shows a definite benign mass (eg, lymph node, hamartoma, lipoma, calcified fibroadenoma, or oil cyst), US is not necessary as long as the benign mass identified on mammography is a definitive correlate of the clinical finding.

If correlation between the mammographic finding and the palpable lesion is uncertain, US is useful. US is preferably targeted specifically to the palpable finding [33]. When both mammography and US are negative or benign in the evaluation of a palpable breast mass, the negative predictive value exceeds 97% [8,9,38]. 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 benign imaging findings [38].

**Variant 5: Adult female, 40 years of age or older. Palpable breast mass. Mammography findings are negative (BI-RADS 1). Next imaging study.**

### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of FDG-PET breast dedicated as the next step in the evaluation of a woman presenting with a negative mammogram and a palpable mass [2].

### **Image-Guided Core Biopsy Breast**

There is no relevant literature to support the use of image-guided core biopsy as the next step in the evaluation of a woman presenting with a negative mammogram and a palpable mass. US should be performed, and if a suspicious correlate is identified, then US-guided core biopsy is recommended. However, a suspicious physical examination should prompt biopsy guided by palpation, regardless of negative imaging findings [38].

### **Image-Guided Fine Needle Aspiration Breast**

There is no relevant literature to support the use of image-guided FNAB as the next step in the evaluation of a woman presenting with a negative mammogram and a palpable mass. US should be performed, and if a suspicious correlate is identified, then US-guided core biopsy is recommended. However, a suspicious physical examination should prompt biopsy guided by palpation, regardless of negative imaging findings [38].

### **MRI Breast**

MRI of the breast with or without IV contrast for women with a palpable mass and negative mammography is not recommended as the next imaging study [2,23-25]. US should be performed next [8,9,19].

## **Sestamibi MBI**

There is no relevant literature to support the use of the use of Tc-99m sestamibi MBI as the next step in the evaluation of a woman presenting with a negative mammogram and a palpable mass.

## **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 [18-20], the sensitivity of mammography was 86% to 91%. The addition of US detects 93% to 100% of cancers [8,9,19]. The addition of US to mammography may also improve detection of a benign etiology for a palpable finding and may also identify lesions that are mammographically occult [26]. In a series, 40% of benign palpable masses were identified only on US [20]. In another study of 375 palpable masses in 320 women, 68.8% of the masses (n = 258) were only identified with US and were typically oval (n = 275, 73.3%) and hypoechoic (n = 336 in 372 US examinations, 90.3%) [39]. When both mammography and US are negative or benign in the evaluation of a palpable breast mass, the negative predictive value is very high, more than 97% [8,9,38,40]. Together, these imaging modalities can be reassuring when the physical examination is not highly suspicious and clinical follow-up is planned.

If almost entirely fatty tissue is identified in the palpable region of concern, US may not be necessary [2]. In a study that included 323 palpable masses in 271 women with almost entirely fatty tissue on diagnostic mammography, mammography alone yielded a negative predictive value of 99.6% [22]. Of the 294 (91%) of women with almost entirely fatty breasts who also underwent targeted US for the evaluation of palpable symptoms, US yielded 11 false-positives and 8 benign correlates at sites with no mammographic findings [22].

## **Variant 6: Adult female, younger than 30 years of age. Palpable breast mass. Initial imaging.**

### **Digital Breast Tomosynthesis Diagnostic**

Because of the low incidence of breast cancer (<1%) in younger women, the recommended initial imaging differs from older patients [41-44]. Younger women tend to have relatively denser breast tissue [45], which is associated with decreased mammographic/DBT sensitivity [46]. DBT is not useful as the initial imaging modality in younger women.

### **Digital Breast Tomosynthesis Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening DBT, with or without DM, is not useful as the initial imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of FDG-PET breast dedicated as the initial imaging workup in women <30 years of age with a palpable mass [2].

### **Image-Guided Core Biopsy Breast**

There is no relevant literature to support the use of image-guided core biopsy as the initial imaging workup in women <30 years of age with a palpable mass.

### **Image-Guided Fine Needle Aspiration Breast**

There is no relevant literature to support the use of image-guided FNAB as the initial imaging workup in women <30 years of age with a palpable mass.

### **Mammography Diagnostic**

Because of the low incidence of breast cancer (<1%) in younger women, the recommended initial imaging differs from older patients [41-44]. Younger women tend to have relatively denser breast tissue [45], which is associated with decreased mammographic/DBT sensitivity [46]. Most benign lesions in young women are not visualized on mammography [41,43]. Diagnostic mammography is not useful as the initial imaging modality in younger women.

### **Mammography Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening mammography is not useful as the initial imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

## **MRI Breast**

There is no relevant literature to support the use of the use of MRI of the breast with or without IV contrast as the initial imaging workup in women <30 years of age with a palpable mass [2,23-25].

## **Sestamibi MBI**

There is no relevant literature to support the use of the use of Tc-99m sestamibi MBI as the initial imaging workup in women <30 years of age with a palpable mass.

## **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 with a 1 in 15 chance at  $\geq 70$  years of age [47]. Diagnostic mammography is useful as the initial examination in the evaluation of a palpable breast finding for women aged  $\geq 40$  years of age. However, because of the low incidence of breast cancer (<1%) in younger women, their imaging evaluation differs from that performed for older patients [41-44]. In addition, most benign lesions in young women are not visualized on mammography [41,43], and US is therefore used as the initial imaging modality in younger women. US is preferably targeted specifically to the palpable finding [33]. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

**Variant 7: Adult female, younger than 30 years of age. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy (BI-RADS 4 or 5). Next imaging study.**

### **Digital Breast Tomosynthesis Diagnostic**

DBT may be useful in a woman <30 years of age with a suspicious sonographic finding that correlates to a palpable mass. DBT may demonstrate findings not readily detected at US (calcifications or subtle architectural distortion); this may provide a more accurate assessment of the extent of disease in the ipsilateral breast and can identify contralateral lesions as well. In addition, DBT may have relatively high diagnostic accuracy in dense breast tissue, often encountered in younger patients [48,49].

### **Digital Breast Tomosynthesis Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening DBT, with or without DM, is not useful as the next imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of FDG-PET breast dedicated as the next step in evaluating a palpable mass with suspicious sonographic features in women <30 years of age [2].

### **Image-Guided Core Biopsy Breast**

If a suspicious mass has been identified on US, tissue sampling (US guided) is warranted. It may be appropriate to proceed directly to image-guided biopsy if a palpable lesion has suspicious features on US followed by placement of a biopsy clip. If US findings are particularly worrisome for malignancy, diagnostic mammography or DBT may be performed prior to tissue sampling to delineate disease extent (eg, calcifications extending beyond the margins of the US-identified solid mass) and identify any additional suspicious findings in the ipsilateral or contralateral breast. Core-needle biopsy has been shown in large series to be superior to FNA in terms of sensitivity, specificity, and correct histological grading [27]. Some practices have had good results using FNAB, but this may be facility specific, and a lower threshold for radiologic-pathologic discordance may need to be applied [50,51].

### **Image-Guided Fine Needle Aspiration Breast**

If a suspicious mass has been identified on US, tissue sampling (US guided) is warranted. It may be appropriate to proceed directly to image-guided biopsy if a palpable lesion has suspicious features on US. If US findings are particularly worrisome for malignancy, diagnostic mammography or DBT may be performed before tissue sampling to delineate disease extent (eg, calcifications extending beyond the margins of the US-identified solid mass) and identify any additional suspicious findings in the ipsilateral or contralateral breast. Core-needle biopsy has been shown in large series to be superior to FNA in terms of sensitivity, specificity, and correct histological grading [27]. Some practices have had good results using FNAB, but this may be facility specific, and a lower threshold for radiologic-pathologic discordance may need to be applied [50,51]. US-guided FNAB may be preferred over core biopsy in rare situations but should be used judiciously.

### **Mammography Diagnostic**

Mammography may be useful in a woman <30 years of age with a suspicious sonographic finding that correlates to a palpable mass. If US findings are particularly worrisome for malignancy, mammography diagnostic or diagnostic DBT would usually be performed before tissue sampling to identify any additional suspicious findings and/or delineate the extent of disease (eg, calcifications extending beyond the margins of the US-identified solid mass) in the ipsilateral breast. Mammography diagnostic is recommended as a prebiopsy assessment in cases in which cancer is strongly suspected clinically [41].

### **Mammography Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening mammography is not useful as the next imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

### **MRI Breast**

There is no relevant literature to support the use of the use of MRI of the breast with or without IV contrast as the next step in evaluating a palpable mass with suspicious sonographic features in women <30 years of age [2,23-25].

### **Sestamibi MBI**

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

**Variant 8: Adult female, younger than 30 years of age. Palpable breast mass. US findings probably benign (BI-RADS 3). Next imaging study.**

### **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 DBT to further evaluate the palpable mass in women <30 years of age.

### **Digital Breast Tomosynthesis Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening DBT, with or without DM, is unnecessary for imaging surveillance. Screening mammography is provided to women without signs or symptoms of breast disease.

### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of FDG-PET breast dedicated in women <30 years of age with probably benign sonographic findings in the setting of a palpable mass [2].

### **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 in some cases. 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 for biopsy instead of imaging follow-up. In addition, situations in which biopsy may alleviate extreme patient anxiety may prompt tissue sampling and a biopsy marker clip should be placed [30].

### **Image-Guided Fine Needle Aspiration Breast**

If a palpable mass has probably benign features as identified on US, US follow-up is recommended. Image-guided FNAB may be performed after complete imaging assessment in some cases. 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 for tissue sampling. In addition, situations in which biopsy may alleviate extreme patient anxiety may prompt tissue sampling, and a biopsy marker clip should be placed [30]. However, large series demonstrate that core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses [27]. In addition, core biopsy allows for ready evaluation of tumor receptor status. US-guided FNAB may be preferred in rare situations (lesion abuts an implant).

### **Mammography Diagnostic**

If a correlate for a palpable mass has been identified on US and is probably benign, there is no indication for diagnostic mammography to further evaluate the palpable mass in women <30 years of age.

### **Mammography Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening mammography is unnecessary for imaging surveillance. Screening mammography is provided to women without signs or symptoms of breast disease.

### **MRI Breast**

There is no relevant literature to support the use of the use of MRI of the breast with or without IV contrast in women <30 years of age with probably benign sonographic findings in the setting of a palpable mass [2,23-25].

### **Sestamibi MBI**

There is no relevant literature to support the use of the use of Tc-99m sestamibi MBI in women <30 years of age with probably benign sonographic findings in the setting of a palpable mass.

**Variant 9: Adult female, younger than 30 years of age. Palpable breast mass. US findings benign (BI-RADS 2). Next imaging study.**

### **Digital Breast Tomosynthesis Diagnostic**

If a benign entity has been found on US and is the definitive correlate for a palpable mass, there is no role for further evaluation with diagnostic DBT in women <30 years of age.

### **Digital Breast Tomosynthesis Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening DBT, with or without DM, is unnecessary for confirmation of benignity. Screening mammography is provided to women without signs or symptoms of breast disease.

### **FDG-PET Breast Dedicated**

If a benign entity has been found on US and is the definitive correlate for a palpable mass, there is no role for FDG-PET breast dedicated in women <30 years of age [2].

### **Image-Guided Core Biopsy Breast**

If a benign entity has been found on US and is the definitive correlate for a palpable mass, there is no role for tissue sampling. The likelihood of a palpable mass in a young woman that is benign on both clinical examination and US resulting in a cancer is extremely low; one study prospectively evaluating US-guided core biopsy in 248 young women <25 years of age with clinically benign masses and predominantly benign findings found no cancers in this group [52].

### **Image-Guided Fine Needle Aspiration Breast**

If a benign entity has been found on US and is the definitive correlate for a palpable mass, there is no role for image-guided FNAB in women <30 years of age.

### **Mammography Diagnostic**

If a benign entity has been found on US and is the definitive correlate for a palpable mass, there is no role for further evaluation with diagnostic mammography in women <30 years of age.

### **Mammography Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening mammography is unnecessary for confirmation of benignity. Screening mammography is provided to women without signs or symptoms of breast disease.

### **MRI Breast**

If a benign entity has been found on US and is the definitive correlate for a palpable mass, there is no role for MRI of the breast with or without IV contrast in women <30 years of age [2,23-25].

### **Sestamibi MBI**

If a benign entity has been found on US and is the definitive correlate for a palpable mass, there is no evidence for Tc-99m sestamibi MBI in women <30 years of age.

**Variant 10: Adult female, younger than 30 years of age. Palpable breast mass. US findings negative (BI-RADS 1). Next imaging study.**

### **Digital Breast Tomosynthesis Diagnostic**

DBT is not useful unless the clinical findings are suspicious. DBT or mammography diagnostic is recommended as a prebiopsy assessment in cases in which cancer is strongly suspected clinically [41]. As with women ≥40 years of

age, if physical examination is highly suspicious and DBT and US are negative, tissue sampling with core biopsy or surgical biopsy is warranted.

### **Digital Breast Tomosynthesis Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening DBT, with or without DM, is not useful as the next imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of the use of FDG-PET breast dedicated in women <30 years of age with negative US findings [2].

### **Image-Guided Core Biopsy Breast**

There is no relevant literature to support the use of the use of image-guided core biopsy in women <30 years of age with negative US findings.

### **Image-Guided Fine Needle Aspiration Breast**

There is no relevant literature to support the use of the use of image-guided FNAB in women <30 years of age with negative US findings.

### **Mammography Diagnostic**

Mammography is not useful unless the clinical findings are suspicious. Mammography is recommended as a prebiopsy assessment in cases in which cancer is strongly suspected clinically [41]. If a mammographic correlate to a suspicious finding is identified, then stereotactic biopsy is recommended. As with women  $\geq 40$  years of age, if physical examination is highly suspicious and mammography and US are negative, tissue sampling with core biopsy or surgical biopsy is warranted.

### **Mammography Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening mammography is not useful as the next imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

### **MRI Breast**

There is no relevant literature to support the use of the use of MRI of the breast with or without IV contrast in women in women <30 years of age with negative US findings [2,23-25].

### **Sestamibi MBI**

There is no relevant literature to support the use of the use of Tc-99m sestamibi MBI in women <30 years of age with negative US findings.

## **Variant 11: Adult female, 30 to 39 years of age. Palpable breast mass. Initial imaging.**

### **Digital Breast Tomosynthesis Diagnostic**

Diagnostic mammography, DBT, or US can be useful as initial imaging for women 30 to 39 years of age with a palpable breast mass. DBT may demonstrate subtle architectural distortion or calcifications, findings not readily detected by US. DBT and diagnostic mammography can also provide more information regarding the extent of disease and the presence of additional findings in the ipsilateral breast [22]. In the absence of DBT data for women 30 to 39 years of age, the utility of DBT can be extrapolated from the diagnostic mammography data. Mammography has been shown to add clinical value for women  $\geq 30$  years of age with a palpable breast mass. Mammographic sensitivity is dependent on the tumor size on palpation, ranging from 78% for a palpable tumor size of  $\leq 2$  cm to 97% for a palpable tumor size between 2 and 5 cm [53]. DBT provided similarly accurate diagnostic results as compared to DM in women with palpable breast masses [15]. Several small studies that specifically included women presenting with clinical symptoms including palpable lumps demonstrated increased accuracy on combination DM/DBT compared with DM alone [13,16,17]. In one recent study, mammography contributed to the workup of palpable malignant masses in 16.7% of cases in women 30 to 39 years of age [54].

### **Digital Breast Tomosynthesis Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening DBT, with or without DM, is not useful as the initial imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

### **FDG-PET Breast Dedicated**

There is no relevant literature to support the use of the use of FDG-PET breast dedicated in the initial evaluation of women 30 to 39 years of age with a palpable mass [2].

### **Image-Guided Core Biopsy Breast**

There is no relevant literature to support the use of the use of image-guided core biopsy in the initial evaluation of women 30 to 39 years of age with a palpable mass.

### **Image-Guided Fine Needle Aspiration Breast**

There is no relevant literature to support the use of the use of image-guided FNAB in the initial evaluation of women 30 to 39 years of age with a palpable mass.

### **Mammography Diagnostic**

Diagnostic mammography, DBT, or US can be useful as initial imaging for women 30 to 39 years of age with a palpable breast mass. Mammography has been shown to add clinical value for women  $\geq 30$  years of age with a palpable breast mass. Mammographic sensitivity is dependent on the tumor size on palpation, ranging from 78% for a palpable tumor size of  $\leq 2$  cm to 97% for a palpable tumor size between 2 and 5 cm [53]. In one recent study, it was demonstrated that in 16.7% of cases in women 30 to 39 years of age, mammography contributed in the workup of malignant palpable masses [54]. For example, mammography revealed calcifications that extended outside of the mass or associated satellite lesions. The overall contribution of diagnostic mammography for palpable breast masses is the characterization of benign disease, evaluating the overall extent of disease and assessing the remainder of the ipsilateral breast [22].

One study of 1,208 women 30 to 39 years of age presenting with focal breast symptoms found a higher sensitivity for US compared with mammography (95.7% versus 60.9%) but with a similar specificity (89.2% and 94.4%, respectively), negative predictive value (99.9% and 99.2%, respectively), and positive predictive value (13.2% and 18.4%, respectively) [40].

### **Mammography Screening**

In women presenting with signs or symptoms, including a palpable breast mass, screening mammography is not useful as the initial imaging study. Screening mammography is provided to women without signs or symptoms of breast disease.

### **MRI Breast**

There is no relevant literature to support the use of MRI of the breast with or without IV contrast in the initial evaluation of women 30 to 39 years of age with palpable mass [2,23-25].

### **Sestamibi MBI**

There is no relevant literature to support the use of Tc-99m sestamibi MBI in the initial evaluation of women 30 to 39 years of age with palpable mass.

### **US Breast**

Diagnostic mammography, DBT, or US can be useful as initial imaging for women 30 to 39 years of age with a palpable breast mass. Most benign lesions in young women are not visualized on mammography [41,43], and US is therefore frequently used as the initial imaging modality in younger women. The criterion for “young” has historically been considered  $<30$  years of age. However, the risk of breast cancer remains relatively low for women 30 to 39 years of age. The sensitivity of US may be higher than mammography for women  $<40$  years of age [53]. One study of 1,208 women 30 to 39 years of age 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) [40]. US is a reasonable initial imaging study for women  $<40$  years of age, with a low threshold for using mammography if the clinical examination or other risk factors are concerning. If the mass has probably benign US features, then short-term interval follow-up with US only may be appropriate. If a suspicious mass is identified on US in this group, bilateral mammography is useful.

### **Summary of Recommendations**

- **Variante 1:** DBT diagnostic or mammography diagnostic are usually appropriate for the initial imaging of a female patient 40 years of age or older with a palpable breast mass. These procedures can be complementary (ie, more than one procedure is ordered as a set or simultaneously in which each procedure provides unique clinical information to effectively manage the patient’s care).



- **Variant 2:** US breast is usually appropriate as the next imaging study for a female patient 40 years of age or older with a palpable breast mass in which mammography findings are suspicious or highly suggestive of malignancy (BI-RADS 4 or 5).
- **Variant 3:** Imaging is usually not appropriate as the next study for a female patient 40 years of age or older with a palpable breast mass in which the diagnostic mammography, DBT, and US findings are probably benign (BI-RADS 3).
- **Variant 4:** US breast maybe appropriate as the next imaging study for a female patient 40 years of age or older with a palpable breast mass in which mammography findings are benign (BI-RADS 2) at the site of palpable mass.
- **Variant 5:** US breast is usually appropriate as the next imaging study of a female patient 40 years of age or older with a palpable breast mass in which mammography findings are negative (BI-RADS 1).
- **Variant 6:** US breast is usually appropriate as the initial imaging of a female patient younger than 30 years of age with a palpable breast mass.
- **Variant 7:** DBT diagnostic, mammography diagnostic, or image-guided core biopsy breast are usually appropriate as the next imaging study of a female patient younger than 30 years of age with a palpable breast mass in which US findings are suspicious or highly suggestive of malignancy (BI-RADS 4 or 5). These procedures can be complementary (ie, more than one procedure is ordered as a set or simultaneously in which each procedure provides unique clinical information to effectively manage the patient's care). The panel did not agree on recommending image-guided fine needle aspiration breast for this clinical scenario. There is insufficient medical literature to conclude whether or not these patients would benefit from this procedure. This procedure in this patient population is controversial but may be appropriate.
- **Variant 8:** Imaging is usually not appropriate as the next study in a female patient younger than 30 years of age with a palpable breast mass in which US findings are probably benign (BI-RADS 3).
- **Variant 9:** Imaging is usually not appropriate as the next study in a female patient younger than 30 years of age with a palpable breast mass in which US findings are benign (BI-RADS 2).
- **Variant 10:** Imaging is usually not appropriate as the next study in a female patient younger than 30 years of age with a palpable breast mass in which US findings are negative (BI-RADS 1).
- **Variant 11:** US breast, DBT diagnostic, or mammography diagnostic are usually appropriate as the initial imaging of a female patient 30 to 39 years of age with palpable breast mass. These procedures can be complementary (ie, more than one procedure is ordered as a set or simultaneously in which each procedure provides unique clinical information to effectively manage the patient's care).

### Supporting Documents

The evidence table, literature search, and appendix for this topic are available at <https://acsearch.acr.org/list>. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents go to [www.acr.org/ac](http://www.acr.org/ac).

## Appropriateness Category Names and Definitions

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

## Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document [55].

| 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."

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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.