American College of Radiology
ACR Appropriateness Criteria®

Clinical Condition: **Nonpalpable Breast Masses**

Variant 1: **Focal asymmetries.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray supplemental mammographic views	9		Low
US breast	8		None
X-ray diagnostic mammography short interval follow-up	4	Restricted to lesions that meet the criteria specified in the literature review.	Low
MRI breast	3		None
Percutaneous tissue sampling breast	2	A developing asymmetry may require sampling after appropriate evaluation.	NS
CT breast	2		Med
Excisional biopsy breast	2		None
Sestamibi scan breast	2		High
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Clinical Condition: **Nonpalpable Breast Masses**

Variant 2: **Round, oval or lobular mass with circumscribed, partially obscured margin on baseline screening mammogram.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray diagnostic mammography	9		Low
US breast	9		None
Percutaneous tissue sampling breast when US shows complex mass	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.	NS
Percutaneous tissue sampling breast when US suspicious for malignancy	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.	NS
Fine needle aspiration breast when US shows complex cyst	4		NS
Percutaneous tissue sampling breast when US shows solid mass	3	Patient may wish biopsy or biopsy may circumvent excision.	NS
X-ray diagnostic mammography short interval follow-up	3	Restricted to lesions that meet the criteria specified in the literature review.	Low
Percutaneous tissue sampling breast when US shows clustered microcysts	2		NS
Fine needle aspiration breast when US shows simple cyst	2	For pain control.	NS
Fine needle aspiration breast when US shows clustered microcysts	2		NS
Fine needle aspiration breast when US shows complex mass	2		NS
CT breast	2		Med
MRI breast	2		None
Excisional biopsy breast	2		None
Sestamibi scan breast	2		High
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Clinical Condition: **Nonpalpable Breast Masses**

Variant 3: **Spiculated and/or ill-defined masses.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray diagnostic mammography	9		Low
Percutaneous tissue sampling breast	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.	NS
US breast	5	The use of US here is primarily to guide tissue sampling procedures.	None
Excisional biopsy breast	4		None
Sestamibi scan breast	2		High
CT breast	2		Med
X-ray diagnostic mammography short interval follow-up	1		Low
MRI breast	No Consensus	Data are being collected. Appropriateness of MRI will be determined at a future date.	None
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Variant 4: **Circumscribed (≥75%), partially obscured mass with coarse, dystrophic and/or "popcorn" calcification.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray diagnostic mammography	4	May be indicated if mass is not clearly benign on screening mammogram.	Low
CT breast	2		Med
Percutaneous tissue sampling breast	2		NS
Sestamibi scan breast	2		High
US breast	2		None
Excisional biopsy breast	2		None
MRI breast	2		None
X-ray diagnostic mammography short interval follow-up	1		Low
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Clinical Condition: **Nonpalpable Breast Masses**

Variant 5: **Circumscribed/partially obscured mass with pleomorphic/amorphous and/or heterogeneous calcifications.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray diagnostic mammography	9		Low
Percutaneous tissue sampling breast	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.	NS
US breast	7	To further characterize the partially obscured mass and to evaluate the possibility of using ultrasound to guide biopsy.	None
CT breast	2		Med
Excisional biopsy breast	2		None
Sestamibi scan breast	2		High
MRI breast	2		None
X-ray diagnostic mammography short interval follow-up	1		Low
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Variant 6: **Irregular spiculated/indistinct mass with coarse/dystrophic and/or "popcorn" calcification.**

Radiologic Procedure	Rating	Comments	RRL*
Percutaneous tissue sampling breast	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.	NS
US breast	8	Used to evaluate the extent of local disease and to evaluate the possibility of using ultrasound to guide biopsy.	None
X-ray diagnostic mammography	8		Low
Excisional biopsy breast	4	In some circumstances, excisional biopsy for diagnosis may be used as the initial diagnostic biopsy.	None
MRI breast	2		None
CT breast	2		Med
Sestamibi scan breast	2		High
X-ray diagnostic mammography short interval follow-up	1		Low
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Clinical Condition: **Nonpalpable Breast Masses**

Variant 7: **Irregular spiculated/indistinct mass with pleomorphic/amorphous and/or heterogeneous calcification.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray diagnostic mammography	9		Low
Percutaneous tissue sampling breast	9	While the majority of experts prefer core biopsy, the use of FNAB could be a site-specific decision.	NS
US breast	5	The use of US here is primarily to guide tissue sampling procedures.	None
Excisional biopsy breast	4	In some circumstances, excisional biopsy for diagnosis may be used as the initial diagnostic biopsy.	None
CT breast	2		Med
Sestamibi scan breast	2		High
X-ray diagnostic mammography short interval follow-up	1		Low
MRI breast	No Consensus	Evolving technology; indications currently being defined.	None
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Expert Panel on Women's Imaging–Breast Work Group: Carl J. D'Orsi, MD[1]; Lawrence W. Bassett, MD[2]; Wendie A. Berg, MD, PhD[3]; Marcela Bohm-Velez, MD[4]; W. Phil Evans III, MD[5]; Dione Marie Farria, MD, MPH[6]; Carol Lee, MD[7]; Ellen B. Mendelson, MD[8]; Steven Goldstein, MD.[9]

Summary of Literature Review

With improved imaging techniques, screening mammograms enable early detection of smaller cancers. Most lesions detected mammographically are benign. The positive predictive value of mammography for breast cancer ranges from 10%-15% to 34%-40% depending on age and type of population examined [1,2].

Normal soft-tissue densities can simulate a mass, and additional mammographic and/or ultrasound (US) evaluation may be necessary to determine the presence of a true mass. Masses are three-dimensional structures with convex outward contours. Asymmetric breast tissue is planar, often with concave outward contours. When a new mass is suspected, additional imaging is necessary using additional views and possibly ultrasound [3-5]. When a mass is detected mammographically, assessment of its shape, margin, density, and size should be done as outlined in the ACR BI-RADS® Atlas [6], Appendix 1 [7-9].

Ultrasound has the ability to determine the cystic or solid nature of a breast mass. Adhering to strict criteria, this technique can separate cystic from solid masses with an accuracy approaching 100% [9]. Using good-quality, high-frequency equipment, cysts as small as 2-3 mm in diameter can be demonstrated. After final mammographic evaluation, round, oval, or lobular masses with circumscribed or partially obscured or ill-defined margins can be further investigated with US to identify simple cysts, complicated cysts, complex masses, and solid masses. Masses with mammographic findings that are suspicious or highly suggestive of malignancy, or masses with suspicious or typically benign calcifications, do not require US for assessment, though US can be used to guide needle biopsy if the mass is seen sonographically [10].

[1]Principal Author, The Emory Clinic, Atlanta, Georgia.
[2]Panel Chair, David Geffen School of Medicine at UCLA, Los Angeles, California.
[3]Breast Imaging Consultant, Lutherville, Maryland.
[4]Weinstein Imaging Associates, Pittsburgh, Pennsylvania.
[5]University of Texas, Southwestern Center for Breast Care, Dallas, Texas.
[6]Mallinckrodt Institute of Radiology, Saint Louis, Missouri.
[7]Yale University School of Medicine, New Haven, Connecticut.
[8]Northwestern Memorial Hospital, Chicago, Illinois.
[9]New York University Medical Center, New York, New York, American College of Obstetrics and Gynecology.

Reprint requests to: Department of Quality & Safety, American College of Radiology, 1891 Preston White Drive, Reston, VA 20191-4397.

The data on the use of magnetic resonance imaging (MRI) to evaluate nonpalpable masses is being addressed. Current uses of MRI include evaluation of disease extent in the ipsilateral and contralateral breasts in women with known malignancy [11-13] and screening of high-risk women with dense breasts [14,15], although benefit has not been established.

After appropriate work-up of a mass, which will usually include diagnostic mammography and US, a final assessment following BI-RADS® guidelines should be assigned [6]. Articles have validated the approach of following probably benign lesions, as outlined in the ACR BI-RADS® Atlas–Mammography, 4th Edition guidance chapter, to decrease the number of biopsies of benign lesions and potentially substantially reduce cost [16-18]. If the mass is placed in category 4 or 5, a biopsy is warranted. This biopsy may be incisional using stereotactic or US guidance to obtain a core of tissue or cellular aspirate via fine-needle technique. An incisional biopsy should only be done if the diagnostic process is shortened and/or more cost effective with comparable outcome to an excisional biopsy [19-20]. For example, if a solid mass is diagnosed as fibroadenoma on core biopsy and then undergoes surgical excision for any of a variety of reasons, we have added cost and lengthened the diagnostic procedure with no gain. On the other hand, a core biopsy may be used to provide histology for a category 5 lesion so that excision and sentinel node biopsy can be done simultaneously. Where sentinel node biopsy will not be performed, a category 5 lesion may be directed to excision without a prior core biopsy.

There are advantages and disadvantages to core and fine-needle aspiration biopsy (FNAB) techniques [21,22]. An advantage to core biopsy is that it does not require a trained cytopathologist for review; in cases of malignancy it will frequently indicate the presence of invasion; and, for calcifications, it may demonstrate visual target removal. However, the procedure may be more traumatic than FNAB and requires more post-procedure vigilance. With incisional image-guided biopsy procedures, one must pay attention to what is present behind the target by using some automated core devices to insure that inadvertent puncture of the pleura or pectoralis muscle does not occur, or that there is adequate breast tissue behind the mass to prevent impingement of the needle onto the cassette with sterotactic guidance.

Fine-needle aspiration biopsy technique requires a trained cytopathologist. The report of a multi-center randomized trial [23-25] demonstrated a 10%-11% insufficiency rate for US-guided FNAB and up to 39% for stereotactically guided procedures. The overall accuracy for US-guided FNAB was 77%, while for stereotactically guided FNAB, accuracy was only 58%. There were also 9% false positive exams, which could lead to unnecessary treatment. Unlike FNAB, core biopsy allows accurate distinction between in situ and invasive carcinoma.

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. 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*	**Effective Dose Estimate Range**
None	0
Minimal	< 0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv
*The 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, the region of the body exposed to ionizing radiation, the imaging guidance that is used, etc). The RRLs for these examinations are designated as NS (not specified).	

Supporting Document(s)

- ACR Appropriateness Criteria® Overview
- Evidence table under review

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Appendix 1. ACR Breast Imaging Reporting and Data System, Breast Imaging Atlas

***BREAST IMAGING LEXICON—Mammography* (terms in parentheses are acceptable, although not as desirable).**	
A. MASSES	
A "MASS" is a space-occupying lesion seen in two different projections. If a potential mass is seen in only a single projection it should be called an "ASYMMETRY" until its three-dimensionality is confirmed.	
1. Shape	
Round:	A mass that is spherical, ball-shaped, circular, or globular in shape.
Oval:	A mass that is elliptical or egg-shaped.
Lobular:	A mass that has an undulating contour.
Irregular:	The lesion's shape cannot be characterized by any of the above.
2. Margins (these modify the shape of the mass)	
Circumscribed (well-defined or sharply-defined):	The margin is sharply demarcated (at least 75% of the margin must be well defined, with the remainder no worse than obscured by overlying tissue, for a mass to qualify as "circumscribed") with an abrupt transition between the lesion and the surrounding tissue. Without additional modifiers, there is nothing to suggest infiltration. A mass where any portion of the border is indistinct or spiculated should be classified on the basis of the latter.
Microlobulated:	The margins undulate with short cycles producing small undulations.
Obscured:	A margin that is hidden by superimposed or adjacent normal tissue. This is used when interpreting physician believes that the mass is circumscribed, but the margin is hidden.
Indistinct (ill-defined) Margin:	The poor definition of the margin or any portion of margin raises concern that there may be infiltration by the lesion and this appearance is not likely due to superimposed normal breast tissue.
Spiculated:	The lesion is characterized by lines radiating from the margin of a mass.
3. Density	
This is used to define the x-ray attenuation of the lesion relative to the expected attenuation of an equal volume of fibroglandular breast tissue. It is important that most breast cancers that form a visible mass are of equal or higher density than an equal volume of fibroglandular tissue. It is rare (although not impossible) for breast cancer to be lower in density. Breast cancers are never fat containing (radiolucent) although they may trap fat.	
High-density	
Equal density (isodense)	
Low density, but not fat-containing	
Fat containing radiolucent: This includes all lesions containing fat such as an oil cyst, lipoma or galactocele as well as mixed lesions such as the hamartoma or fibroadenolipoma. Since specificity is lower than sensitivity, it is important to stress the benign nature of mammographic features when possible. A fat containing mass will overwhelmingly represent a benign mass.	
B. ARCHITECTURAL DISTORTION	
The normal architecture is distorted with no definite mass visible. This includes thin lines or spiculations radiating from a point and focal retraction or distortion of the edge of the parenchyma. Architectural distortion can also be associated with a mass, asymmetry or calcifications. In the absence of appropriate history of trauma or surgery, architectural distortion is suspicious for malignancy or radial scar and biopsy is appropriate.	
C. SPECIAL CASES	
Asymmetric tubular structure/solitary dilated duct:	This is a tubular or branching structure that likely represents a dilated or otherwise enlarged duct. If unassociated with other suspicious clinical or mammographic findings, it is usually of minor significance.
Intramammary lymph node:	These are typically reniform or have a radiolucent notch due to fat at the hilum and are generally 1 cm or smaller in size. They may be larger than 1 cm and identified as normal when fat replacement is pronounced. They may be multiple, or marked fat replacement may cause a single lymph node to look like several rounded masses. This specific diagnosis is usually reserved for masses in the lateral and usually upper portions of the breast, although they may occur anywhere in the breast.
Global asymmetry:	Asymmetric breast tissue is judged relative to the corresponding area in the contralateral breast and represents a greater volume of breast tissue over a significant portion of the breast. There is no mass, distorted architecture or associated suspicious calcifications. Global asymmetric breast tissue usually represents a normal variation, but may be significant when it corresponds to a palpable abnormality.
Focal asymmetry:	This is a density that does not fit criteria for a mass. It is visible as a confined asymmetry with similar shape on two views, but completely lacking borders and the conspicuity of a true mass. It could represent an island of normal breast tissue, particularly when there is interspersed fat, but its lack of specific benign characteristics may warrant further evaluation.
(From the American College of Radiology (ACR). ACR BI-RADS® – Mammography. 4th Edition. In: *ACR Breast Imaging Reporting and Data System, Breast Imaging Atlas*. Reston, VA: American College of Radiology; 2003.)	

Appendix 2. ACR Breast Imaging Reporting and Data System, Breast Imaging Atlas

BREAST IMAGING LEXICON — Ultrasound	
A. Masses	
A mass occupies space and should be seen in two different projections.	
1. Shape	
Oval:	Elliptical or egg-shaped (may include 2 or 3 undulations, i.e., "gently lobulated" or "macrolobulated").
Round:	Spherical, ball-shaped, circular, or globular.
Irregular:	Neither round nor oval in shape.
2. Orientation	
Parallel:	Long axis of lesion parallels the skin line ("wider than tall" or horizontal).
Not parallel:	Long axis, not oriented along the skin line ("taller than wide" or vertical, includes round).
3. Margin	
Circumscribed:	A margin that is well defined or sharp, with an abrupt transition between the lesion and surrounding tissue.
Not circumscribed:*	The mass has one or more of the following features: indistinct, angular, microlobulated or spiculated.
Indistinct:	No clear demarcation between a mass and its surrounding tissue.
Angular:	Some or all of the margin has sharp corners, often forming acute angles.
Microlobulated:	Short cycle undulations impart a scalloped appearance to the margin of the mass.
Spiculated:	Margin is formed or characterized by sharp lines projecting from the mass.
(Note: "Irregular" is used as descriptor of shape rather than margin.)*	
4. Lesion Boundary	
Abrupt interface:	The sharp demarcation between the lesion and surrounding tissue can be imperceptible or a distinct well-defined echogenic rim of any thickness.
Echogenic halo:	No sharp demarcation between the mass and surrounding tissue, which is bridged by an echogenic transition zone.
5. Echo Pattern	
Anechoic:	Without internal echoes.
Hyperechoic:	Having increased echogenicity relative to fat or equal to fibroglandular tissue.
Complex:	Mass contains both anechoic and echogenic components.
Hypoechoic:	Defined relative to fat; masses are characterized by low-level echoes throughout (e.g., appearance of a complicated cyst or fibroadenoma).
Isoechoic:	Having the same echogenicity as fat. (A complicated cyst or fibroadenoma may be isoechoic or hypoechoic.)
6. Posterior Acoustic Features	
No posterior acoustic features:	No posterior shadowing or enhancement.
Enhancement:	Increased posterior echoes.
Shadowing:	Decreased posterior echoes; edge shadows are excluded.
Combined pattern:	More than one pattern of posterior attenuation, both shadowing and enhancement.
7. Surrounding Tissue Description	
Identifiable effect	
Duct changes:	Abnormal caliber and/or arborization.
Cooper's ligament changes:	Straightening or thickening of Cooper's ligaments.
Edema:	Increased echogenicity of surrounding tissue; reticulated pattern of angular, hypoechoic lines.
Architectural distortion:	Disruption of normal anatomic planes.
Skin thickening:	Focal or diffuse skin thickening. (Normal skin is 2 mm or less in thickness except in the periareolar area and lower breasts.)
Skin retraction /irregularity:	Skin surface is concave or ill-defined, and appears pulled in

B. Calcifications	
Calcifications are poorly characterized with ultrasound but can be recognized particularly in a mass.	
If present:	
Macrocalcifications:	Greater than or equal to 0.5 mm in diameter.
Microcalcifications out of mass:	Echogenic foci that do not occupy the entire acoustic beam and do not shadow. Less than 0.5 mm in diameter.
Microcalcifications in mass:	Embedded in a mass, microcalcifications are well depicted. The punctate, hyperechoic foci will be conspicuous in a hypoechoic mass.
C. Special Cases	
Special cases are those with a unique diagnosis or finding.	
Clustered microcysts:	A cluster of tiny anechoic foci each smaller than 2-3 mm in diameter with thin (less than 0.5 mm) intervening septations and no discrete solid components.
Complicated cysts:	Most commonly characterized by homogeneous low-level internal echoes. Complicated cysts may also have fluid-fluid, or fluid-debris levels that may shift with changes in patient's position.
Mass in or on skin:	These masses are clinically apparent and may include sebaceous or epidermal inclusion cysts, keloids, moles and neurofibromas.
Foreign body:	May include marker clips, coil, wire, catheter sleeves, silicone, and metal or glass related to trauma.
Lymph nodes – intramammary:	Lymph nodes resemble small kidneys with an echogenic hilus and hypoechoic surrounding cortex. Found in the breast, including axilla.
Lymph nodes – axillary:	Lymph nodes resemble small kidneys with an echogenic hilus and hypoechoic surrounding cortex. Found in the breast, including axilla.
D. Vascularity	
Not Present or not assessed	
Present in lesion	
Present immediately adjacent to lesion	
Diffusely increased vascularity in surrounding tissue	
(From the American College of Radiology (ACR). ACR BI-RADS® –Ultrasound. In: *ACR Breast Imaging Reporting and Data System, Breast Imaging Atlas*. Reston, VA: American College of Radiology; 2003.)	