ACR Appropriateness Criteria® on Nonpalpable Mammographic Findings (Excluding Calcifications)

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Screening mammography can detect breast cancer before it becomes clinically apparent. However, the screening process identifies many false-positive findings for each cancer eventually confirmed. Additional tools are available to help differentiate spurious findings from real ones and to help determine when tissue sampling is required, when short-term follow-up will suffice, or whether the finding can be dismissed as benign. These tools include additional diagnostic mammographic views, breast ultrasound, breast MRI, and, when histologic evaluation is required, percutaneous biopsy. The imaging evaluation of a finding detected at screening mammography proceeds most efficiently, cost-effectively, and with minimization of radiation dose when approached in an evidence-based manner. The appropriateness of the above-referenced tools is presented here as they apply to a variety of findings often encountered on screening mammography; an algorithmic approach to workup of these potential scenarios is also included. The recommendations put forth represent a compilation of evidence-based data and expert opinion of the ACR Appropriateness Criteria® Expert Panel on Breast Imaging.

Key Words: Appropriateness Criteria®, breast imaging, mammography, breast ultrasound, breast MRI, percutaneous breast biopsy

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SUMMARY OF LITERATURE REVIEW

With improved imaging techniques, screening mammography enables the early detection of smaller cancers. Most lesions detected mammographically are benign. Noncalcified lesions of concern on screening mammography include masses, bilateral masses, focal asymmetries, and architectural distortion. Benchmark data based on information from the Breast Cancer Surveillance Consortium report a positive predictive value in 33% of biopsies performed [1]. The mean cancer detection rate reported for screening mammography is 4.7/1,000

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The ACR seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria® through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply society endorsement of the final document.

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Variant 1. Architectural distortion seen on screening mammography; no history of prior surgery or trauma; next examination to perform

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Mammography diagnostic	9		☢☢
Mammography short-interval follow-up	1		☢☢
Ultrasound breast	1		O
MRI breast without and with contrast	1		O
Core biopsy breast	1		Not specified

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. See Appendix A for additional steps in the workup of these patients.

mammograms, with a mean invasive cancer size of 13 mm [2,3].

Normal soft-tissue densities can simulate a mass, and additional mammographic or ultrasound evaluation may be necessary to determine the presence of a true mass. Masses are 3-D structures with convex outward contours. Asymmetric breast tissue is planar, often with concave outward contours and if new or enlarging on screening mammography should be further evaluated with diagnostic imaging. Similarly, when a new or enlarging mass is suspected, additional imaging is necessary, using additional views and possibly ultrasound [4-6]. When a mass is detected mammographically, assessment of its shape, margin, density, and size should be performed as outlined in the ACR Breast Imaging Reporting and Data System® (BI-RADS®) atlas [7-12] (see Variants 1-8).

Ultrasound has the ability to determine the cystic or solid nature of a breast mass and may be helpful in directing biopsy of architectural distortion and suspicious focal asymmetries. 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 to 3 mm in diameter can be demonstrated. However, cysts that are <8 mm or deeper than 3 cm from the skin can be difficult to characterize as anechoic [13,14]. After final mammographic evaluation, round or oval masses with circumscribed, partially obscured, indistinct, or microlobulated margins can be further investigated with ultrasound to characterize simple cysts, complicated cysts, complex cystic and solid masses (a complex mass implies both cystic and solid components), and solid

Variant 2. Architectural distortion seen on screening mammography; prior surgery or trauma area of distortion; no prior examinations available; next examination to perform

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Mammography diagnostic	6	Use of a scar marker on the original screening study may preclude the need for diagnostic evaluation.	☢☢
Return to screening mammography	4	If the area can be confidently determined to be related to prior surgery (ie, by scar marker) or the sequelae of trauma (eg, presence of fat necrosis), consider return to screening mammography.	☢☢
Mammography short-interval follow-up	1		☢☢
Ultrasound breast	1		O
MRI breast without and with contrast	1		O
Core biopsy breast	1		Not specified

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. See Appendix A for additional steps in the workup of these patients.

Variant 3. Mass seen on screening mammography (assuming mass has not previously been worked up); indistinct, microlobulated or spiculated margins; next examination to perform

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Mammography diagnostic	9		☢☢
Mammography short-interval follow-up	1		☢☢
Ultrasound breast	1		O
MRI breast without and with contrast	1		O
Core biopsy breast	1		Not specified

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. See Appendix B for additional steps in the workup of these patients.

masses [15]. Masses with mammographic findings that are suspicious or highly suggestive of malignancy, or masses with suspicious or typically benign calcifications, do not require ultrasound for assessment, although it can be used to guide needle biopsy if the mass is seen sonographically [15].

The use of MRI to evaluate nonpalpable mammographically occult, suspicious noncalcified lesions is being addressed. Although efficacy as to the reduction of numbers of deaths from breast cancer has not been demonstrated, some of the current uses of MRI include the evaluation of the extent of recently diagnosed breast cancer within the ipsilateral breast [16-18], the assessment of the contralateral breast for clinically and mammographically occult synchronous breast cancer, and the detection of primary occult breast cancer in cases presenting as axillary adenopathy [19,20]. A multi-institutional trial reported in 2007 discovered clinically and mammographically occult breast cancer in 3% of the 969 women who had recent diagnoses of breast cancer in the opposite breast [21]. In part because of the relatively low specificity of breast MRI, screening for breast cancer has only recently been recommended by the American Cancer Society (ACS) [22] and, on the basis of peer-reviewed literature [23,24] or expert consensus, only for those women with known or suspected gene mutations increasing their susceptibility to develop breast cancer, for those women with at least a 20% to 25% lifetime risk assessment, and for those women who have been treated with chest or mediastinal radiation for Hodgkin's lymphoma $\geq$ 8 years earlier and before the age of 30 years. At this time, the ACS finds no compelling data to support or refute the performance of breast MRI for those women having only personal histories of breast cancer, histories of biopsy-proven lobular neoplasia or atypical ductal hyperplasia, or dense breast tissue. Finally, the ACS recommends against the performance of screening MRI for those women with a $<$15% lifetime risk.

After appropriate workup of a mammographically detected noncalcified suspicious lesion, which will usually include diagnostic mammography and ultrasound, a final assessment should be assigned according to the BI-RADS guidelines [7]. Articles have validated the approach of following probably benign lesions (category 3),

Variant 4. Mass seen on screening mammography (assuming mass has not previously been worked up); circumscribed margins with no associated suspicious features; new or enlarging compared with prior examinations or no prior examinations available; next examination to perform

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Ultrasound breast	9		O
Mammography diagnostic	5	In selected cases, spot/magnification views may help elucidate margins, exclude intramammary node as etiology.	☢☢
Mammography short-interval follow-up	1		☢☢
MRI breast without and with contrast	1		O
Core biopsy breast	1		Not specified

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. See Appendix B for additional steps in the workup of these patients.

Variant 5. Multiple bilateral masses seen on screening mammography; no suspicious features in any mass; baseline examination or no prior examinations available; next examination to perform.

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Return to screening mammography	8		☢☢
Mammography short-interval follow-up	3	In selected cases, may be appropriate.	☢☢
Ultrasound breast	1		O
MRI breast without and with contrast	1		O
Core biopsy breast	1		Not specified

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. See Appendix C for additional steps in the workup of these patients.

as outlined in the BI-RADS atlas, to decrease the number of biopsies of benign lesions and potentially substantially reduce cost [25-27]. If a noncalcified lesion is placed in category 4 or 5, a biopsy is warranted. This biopsy is most often performed as a sampling or incisional procedure using stereotactic or ultrasound guidance to obtain a core of tissue or cellular aspirate via the fine-needle technique. However, a core biopsy or needle aspirate should be done with the goal of either shortening the diagnostic process or providing a more cost-effective method of lesion diagnosis compared with excisional biopsy [28,29]. 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, cost has been added and the diagnostic procedure lengthened 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, avoiding separate trips to the operating room.

There are advantages and disadvantages to core needle biopsy and fine-needle aspiration biopsy (FNAB) techniques [30,31]. The FNAB technique requires a trained cytopathologist. The report of a multicenter, randomized trial [32-34] demonstrated a 10% insufficiency rate for ultrasound-guided FNAB and up to a 39% insufficiency rate for stereotactically guided FNAB. The overall accuracy for ultrasound-guided FNAB was 77%, whereas for stereotactically guided FNAB, accuracy was only 58%. Percutaneous core biopsy provides tissue samples allowing accurate distinction between in situ and invasive carcinoma. Stereotactic core biopsies may be performed with the patient sitting or on specialized prone tables, and the most commonly sampled lesion type is calcifications. Issues of potential sampling error must be addressed with careful evaluation of imaging-histologic concordance. Technical success is reported in as many as 98% of cases [35], and an average of ≥10 samples using 11-gauge vacuum-assisted needles improves accuracy and decreases (but does not eliminate) possible upgrades from atypical ductal hyperplasia to cancer or ductal carcinoma in situ to invasive carcinoma [36-38]. Ultrasound-guided core biopsy, typically used to sample masses, may be successfully performed using either automated 14-gauge needles or vacuum-assisted devices and should include ≥4 nonfragmented samples [39-41]. Similar to any percutaneous biopsy sampling, the final

Variant 6. Multiple bilateral masses seen on screening mammography; one or more masses suspicious or a dominant mass is present; next examination to perform

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Mammography diagnostic	9		☢☢
Ultrasound breast	5	May proceed directly to ultrasound if mass in question is seen in two projections.	O
Mammography short-interval follow-up	1		☢☢
MRI breast without and with contrast	1		O
Core biopsy breast	1		Not specified

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. See Appendix C for additional steps in the workup of these patients.

Variant 7. Focal asymmetry or asymmetry (single-view finding) seen on screening mammography; no prior examinations available; next examination to perform

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Mammography diagnostic	8		☢☢
Mammography short-interval follow-up	1		☢☢
Return to screening mammography	1		☢☢
Ultrasound breast	1		O
MRI breast without and with contrast	1		O
Core biopsy breast	1		Not specified

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. See Appendix D for additional steps in the workup of these patients.

assessment as to follow-up recommendations must include strict vigilance regarding imaging and pathology correlation.

SUMMARY

Screening mammography potentiates the detection of early, clinically occult cancers, with benchmark data demonstrating the mean size at diagnosis to be 13 mm and cancers detected at a rate of 4.7/1,000 screening examinations. Most lesions found on screening mammography, however, are benign, with positive predictive value of 33% for lesions undergoing biopsy.

Additional workup, including diagnostic mammography or ultrasound, may be required to differentiate suspicious findings, such as masses and asymmetries or focal asymmetries, from normal breast tissue. Application of the ACR BI-RADS criteria, terminology, and assessments helps guide management and optimizes communication of findings and recommendations.

Ultrasound is a useful adjunctive tool in the evaluation of abnormal mammographic findings but requires the use of good-quality, high-frequency equipment and application of strict criteria, outlined in the BI-RADS atlas. Breast ultrasound can help differentiate cysts from solid masses, aid in the characterization of solid masses, and guide percutaneous biopsy.

Breast MRI is a technology whose roles and indications are still evolving. Its effectiveness in outlining extent of disease and detecting occult contralateral cancers in newly diagnosed breast cancer patients has been demonstrated; however, mortality reduction has not been confirmed. The ACS has recommended its use as a screening tool in select populations, on the basis of evidence and expert consensus. The ACS recommends against MRI screening in women with a <15% estimated lifetime risk.

Percutaneous biopsy of suspicious lesions can provide accurate tissue diagnosis at decreased cost, precluding the need for surgery in benign, specific cases and allowing definitive single-stage surgical treatment in cases returned as malignant. Core needle biopsy, using either stereotactic or ultrasound guidance, is preferable to fine-needle aspiration cytology, on the basis of sufficiency and accuracy of sampling.

Variant 8. Focal asymmetry or asymmetry (single-view finding) seen on screening mammography; new or enlarging from prior examination; next examination to perform

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Mammography diagnostic	9		☢☢
Mammography short-interval follow-up	1		☢☢
Return to screening mammography	1		☢☢
Ultrasound breast	1		O
MRI breast without and with contrast	1		O
Core biopsy breast	1		Not specified

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. See Appendix D for additional steps in the workup of these patients.

Table 9. Relative radiation level designations

Relative Radiation Level	Adult Effective Dose Estimate Range (mSv)	Pediatric Effective Dose Estimate Range (mSv)
O	0	0
☢	<0.1	<0.03
☢☢	0.1-1	0.03-0.3
☢☢☢	1-10	0.3-3
☢☢☢☢	10-30	3-10
☢☢☢☢☢	30-100	10-30

Note: Relative radiation level 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 relative radiation levels for these examinations are designated as not specified.

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 indication has been included for each imaging examination. The relative radiation levels 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 relative radiation level dose estimate ranges for pediatric examinations are lower compared with those specified for adults (Table 9). Additional information regarding radiation dose assessment for imaging examinations can be found in *ACR Appropriateness Criteria®: Radiation Dose Assessment Introduction* [42].

Disclaimer: *The ACR Committee on Appropriateness Criteria® and its expert panels have developed criteria for determining appropriate imaging examinations for the diagnosis and treatment of specified medical conditions. 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 the evaluation of a patient's condition are ranked. Other imaging studies necessary to evaluate other coexistent 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 US Food and Drug Administration have not been considered in developing these criteria, but the 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.*

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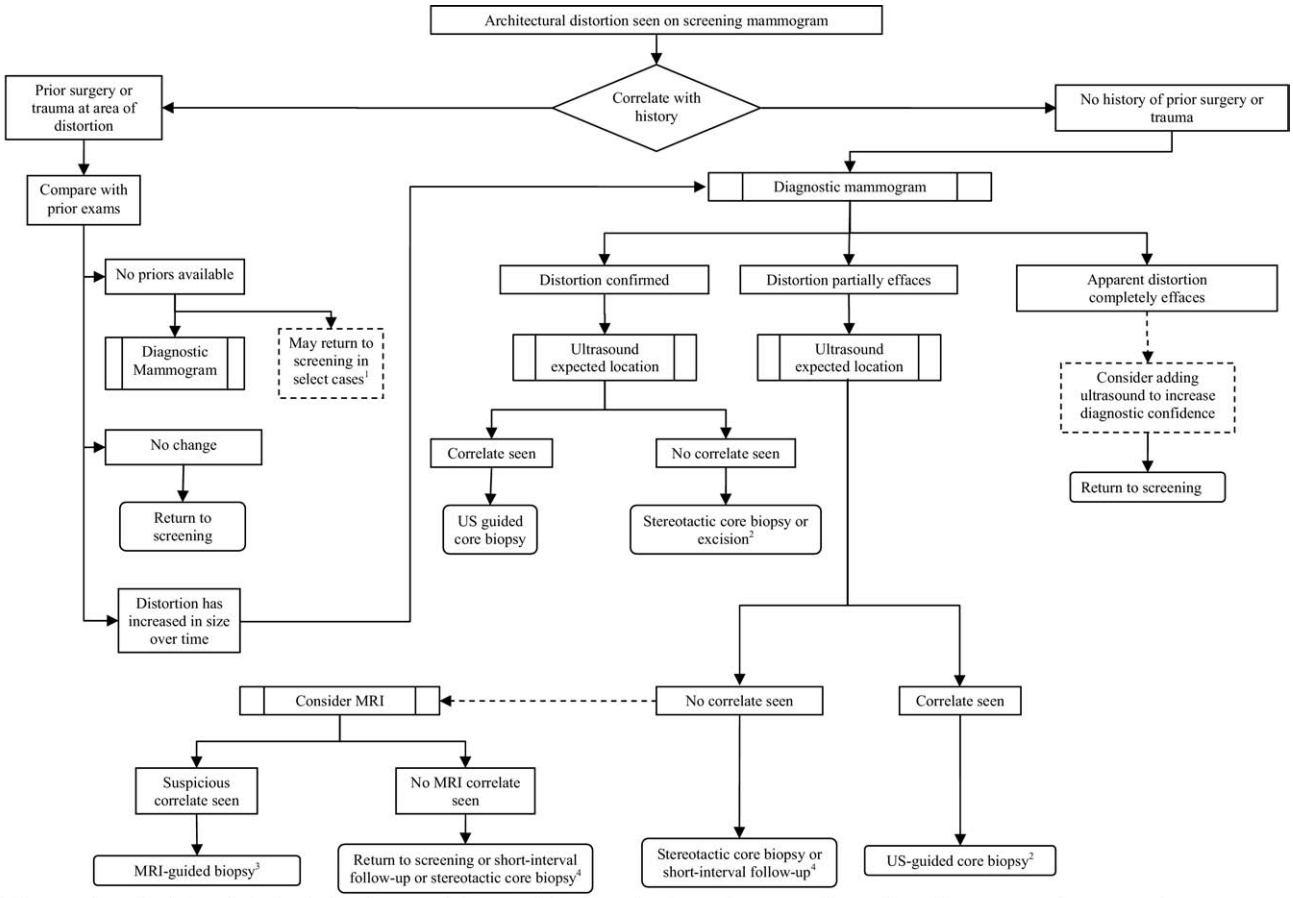
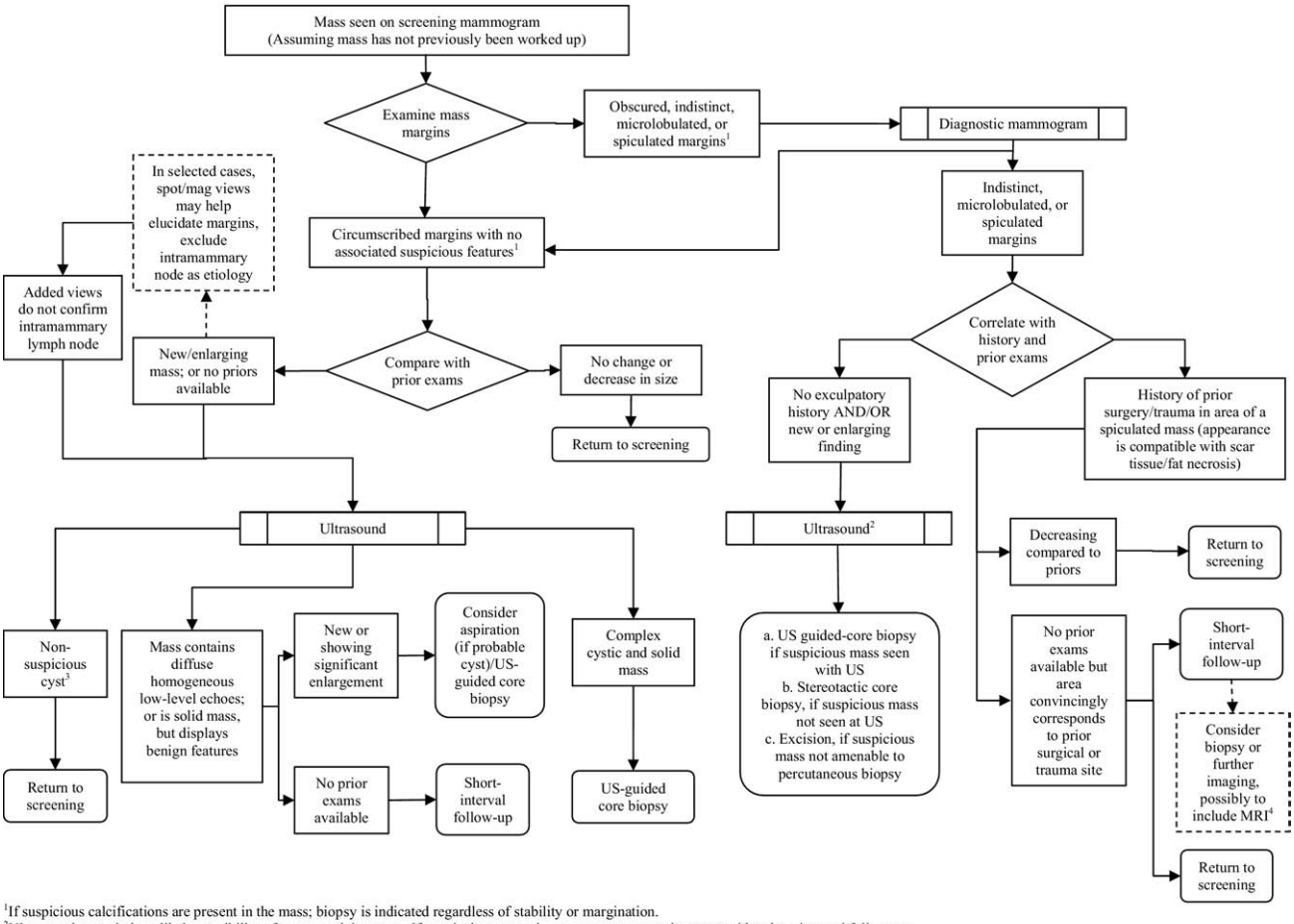
APPENDIX A



[1]If the area can be confidently determined to be related to prior surgery (ie, by scar marker) or the sequelae of trauma (eg, presence of fat necrosis), consider return to screening mammography.
[2]Excision if distortion not amenable to percutaneous biopsy. If radial scar/complex sclerosing lesion is a likely diagnosis, consider excision rather than percutaneous biopsy. However, preoperative core biopsy may still be appropriate, such that if malignancy is unexpectedly found, a comprehensive surgical approach can be undertaken prospectively.
[3]Place a marking clip; obtain postprocedure mammogram to confirm concordance with original mammographic finding.
[4]Depends on initial level of suspicion.

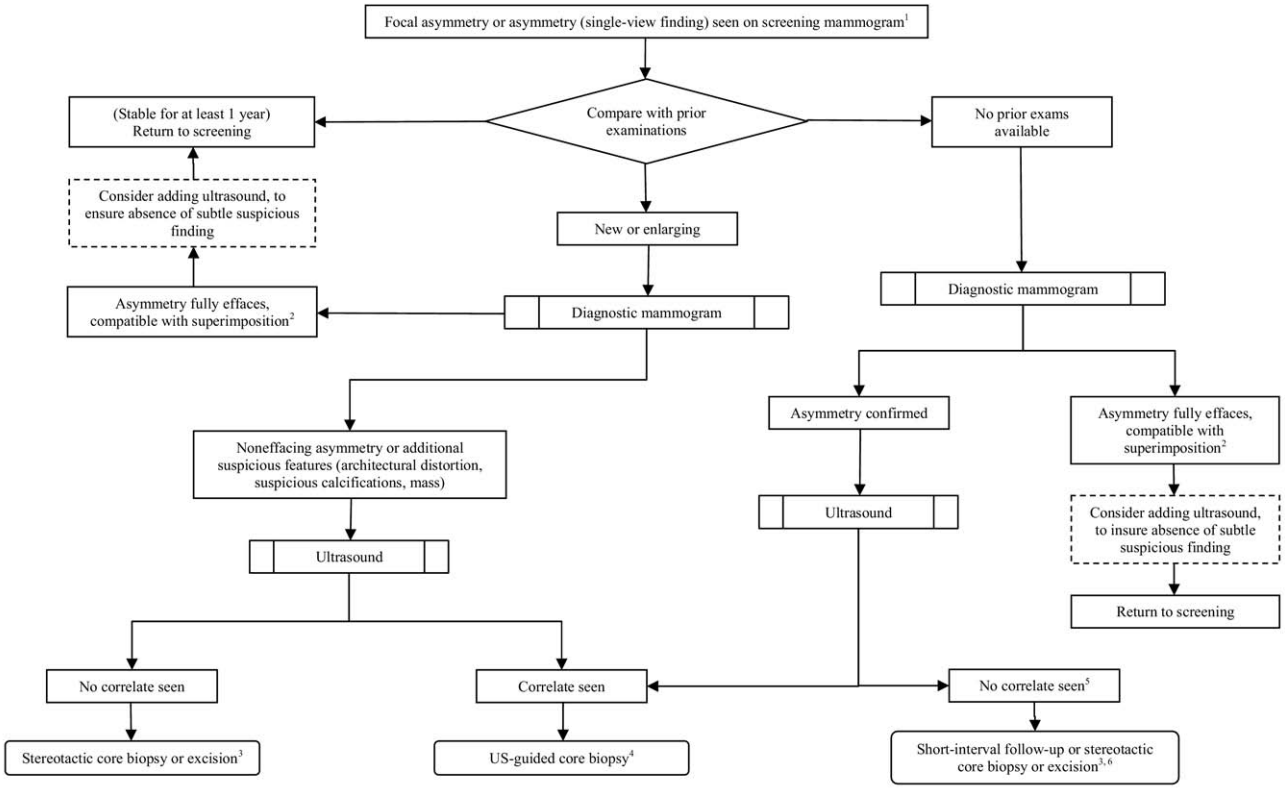
APPENDIX B



[1]If suspicious calcifications are present in the mass; biopsy is indicated regardless of stability or margination.
[2]Ultrasound to exclude unlikely possibility of a nonsuspicious cyst. If cyst is documented, may return to screening or consider short-interval follow-up.
[3]Includes simple cysts, clustered microcysts, cysts with mobile debris, fluid/debris levels, and thin (<0.5 mm) septa; however, the sonographic identification of a cyst in the region of a spiculated mass should NOT be considered concordant; stereotactic biopsy should be pursued.
[4]If there is not exact concordance in location or characteristic appearance between mass and site of prior surgery/trauma, consider biopsy or further imaging.

APPENDIX C

APPENDIX D



[1]Global asymmetries — in the absence of a suspicious correlate on physical examination or change over time — represent normal anatomic variants and can be dismissed as BI-RADS 2 benign. Premenopausal status/hormone replacement therapy may account for developing focal/global asymmetries; consider such history when evaluating an asymmetry.
[2]Area should be carefully examined to exclude subtle suspicious findings (eg, low-density masses, distortions).
[3]Excision if asymmetry not amenable to percutaneous biopsy.
[4]Leave marking clip to confirm concordance with original mammographic finding.
[5]Meticulous sonographic examination of area is required to exclude subtle areas of shadowing, which may signal the presence of a cancer. Identification of a hyperechoic correlate (ie, normal fibroglandular tissue) of similar size and shape may preclude the need for short-term follow-up or biopsy.
[6]Depends on level of suspicion.