

**American College of Radiology
ACR Appropriateness Criteria®**

Clinical Condition: Nonpalpable Mammographic Findings (Excluding Calcifications)

Variant 1: Architectural distortion seen on screening mammogram. No history of prior surgery or trauma. Next examination to perform. (See [Appendix 1](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	9		☼☼
Mammography short-interval follow-up	1		☼☼
US breast	1		O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 2: Architectural distortion seen on screening mammogram. Prior surgery or trauma at area of distortion. No prior exams available. Next examination to perform. (See [Appendix 1](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
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		☼☼
US breast	1		O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 3: Mass seen on screening mammogram (assuming mass has not previously been worked up). Indistinct, microlobulated or spiculated margins. Next examination to perform. (See [Appendix 2](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	9		☼☼
Mammography short-interval follow-up	1		☼☼
US breast	1		O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition:**Nonpalpable Mammographic Findings (Excluding Calcifications)****Variant 4:**

Mass seen on screening mammogram (assuming mass has not previously been worked up). Circumscribed margins with no associated suspicious features. New or enlarging compared to prior exams or no priors available. Next examination to perform. (See [Appendix 2](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
US 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
MRI breast without contrast	1		O
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 5:

Multiple bilateral masses seen on screening mammogram. No suspicious features in any mass. Baseline exam or no priors available. Next examination to perform. (See [Appendix 3](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Return to screening mammography	8		☼☼
Mammography short-interval follow-up	3	In selected cases, may be appropriate.	☼☼
US breast	1		O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 6:

Multiple bilateral masses seen on screening mammogram. One or more masses suspicious or a dominant mass is present. Next examination to perform. (See [Appendix 3](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	9		☼☼
US breast	5	May proceed directly to US if mass in question is seen in two projections.	O
Mammography short-interval follow-up	1		☼☼
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition:**Nonpalpable Mammographic Findings (Excluding Calcifications)****Variant 7:**

Focal asymmetry or asymmetry (single-view finding) seen on screening mammogram. No priors available. Next examination to perform. (See [Appendix 4](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	8		☼☼
Mammography short-interval follow-up	1		☼☼
Return to screening mammography	1		☼☼
US breast	1		O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 8:

Focal asymmetry or asymmetry (single-view finding) seen on screening mammogram. New or enlarging from prior exams. Next examination to perform. (See [Appendix 4](#) for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	9		☼☼
Mammography short-interval follow-up	1		☼☼
Return to screening mammography	1		☼☼
US breast	1		O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Core biopsy breast	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

NONPALPABLE MAMMOGRAPHIC FINDINGS (EXCLUDING CALCIFICATIONS)

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Summary of Literature Review

With improved imaging techniques, screening mammograms enable early detection of smaller cancers. Most lesions detected mammographically are benign. Noncalcified lesions of concern on screening mammograms include masses, bilateral masses, focal asymmetries, and architectural distortion. Benchmark data based on information from the Breast Cancer Surveillance Consortium (BCSC) reports a positive predictive value (PPV₃) in 33% of biopsies performed [1]. The mean cancer detection rate reported for screening mammography is 4.7/1,000 mammograms, with a mean invasive cancer size of 13 mm [2-3].

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, 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 US [4-6]. When a mass is detected mammographically, assessment of its shape, margin, density, and size should be performed as outlined in the *ACR BI-RADS® Atlas* [7-12].

US 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 2-3 mm in diameter can be demonstrated. However, cysts that are smaller than 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 US to characterize simple cysts, complicated cysts, complex cystic and solid masses (a complex mass infers both cystic and solid components), and solid 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 US for assessment, although US can be used to guide needle biopsy if the mass is seen sonographically [15].

The use of magnetic resonance imaging (MRI) to evaluate nonpalpable mammographically occult, suspicious noncalcified lesions is being addressed. Although efficacy as to the reduction of numbers of deaths due to 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 synchronous breast cancer, and detection of primary occult breast cancer in cases presenting as axillary adenopathy [19-20]. The 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]. Because, in part, 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, based on peer-reviewed literature [23-24] or expert consensus, only for those women with a known or suspected gene mutation increasing their susceptibility to develop breast cancer, for those women with at least a 20%-25% lifetime risk assessment, and for those women who have been treated with chest or mediastinal radiation for Hodgkin's lymphoma at least 8 years earlier and prior to the age of 30. At this time, the ACS finds no compelling data to support or refute the performance of breast MRI for those women having only a personal history of breast cancer, a history 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 US, a final

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The American College of Radiology 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 individual or society endorsement of the final document.

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assessment should be assigned according to the BI-RADS guidelines [7]. Articles have validated the approach of following probably benign lesions (category 3), as outlined in the *ACR BI-RADS® Atlas–Mammography, 4th Edition*, to decrease the number of biopsies of benign lesions and potentially substantially reduce cost [25-27]. If the 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 US guidance to obtain a core of tissue or cellular aspirate via fine-needle technique. However, a core biopsy or needle aspirate should be done with the goal of either shortening the diagnostic process and/or providing a more cost-effective method of lesion diagnosis as 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, 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, avoiding separate trips to the operating room.

There are advantages and disadvantages to core and fine-needle aspiration biopsy (FNAB) techniques [30-31]. FNAB technique requires a trained cytopathologist. The report of a multicenter, randomized trial [32-34] demonstrated a 10% insufficiency rate for US-guided FNAB and up to a 39% insufficiency rate for stereotactically guided FNAB. The overall accuracy for US-guided FNAB was 77%, while 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]. US-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 four or more nonfragmented samples [39-41]. Similar to any percutaneous biopsy sampling, the final 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 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

mammogram, however, are benign, with a PPV of 33% for lesions undergoing biopsy (PPV₃).

- Additional workup, including diagnostic mammography and/or US, may be required to differentiate suspicious findings, such as masses and asymmetries/focal asymmetries, from normal breast tissue. Application of *ACR BI-RADS®* criteria, terminology and assessments helps guide management and optimizes communication of findings and recommendations.
- US is a useful adjunctive tool in evaluation of abnormal mammographic findings, but requires use of good-quality, high-frequency equipment and application of strict criteria, outlined in the *ACR BI-RADS® Atlas*. Breast US can help differentiate cysts from solid masses, aid in 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, based on 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 US guidance, is preferable to fine-needle aspiration cytology, based on sufficiency and accuracy of sampling.

Relative Radiation Level Information

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

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	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 NS (not specified).

Supporting Document(s)

- [ACR Appropriateness Criteria® Overview](#)
- [Procedure Information](#)
- [Evidence Table](#)

References

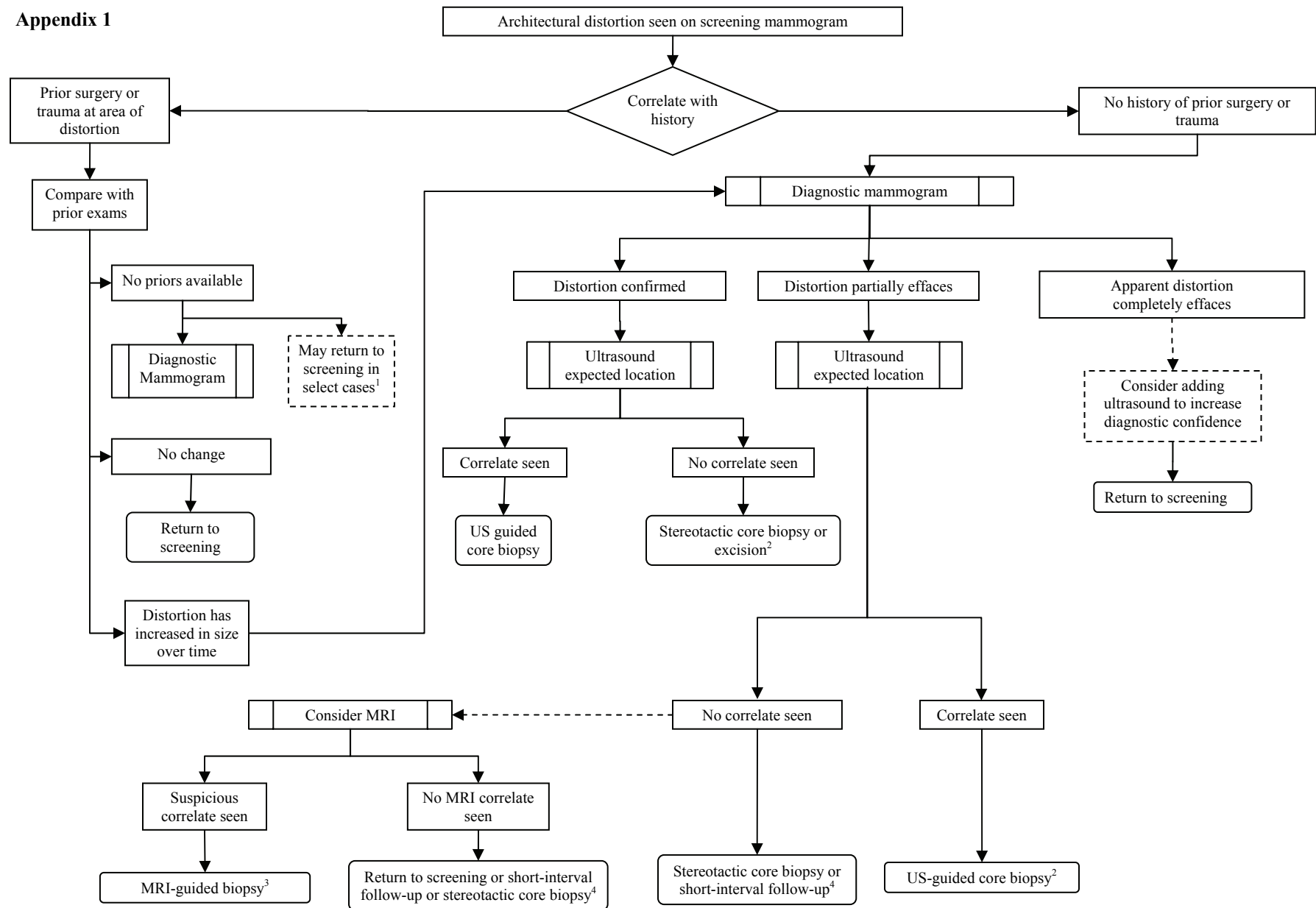
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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Appendix 1



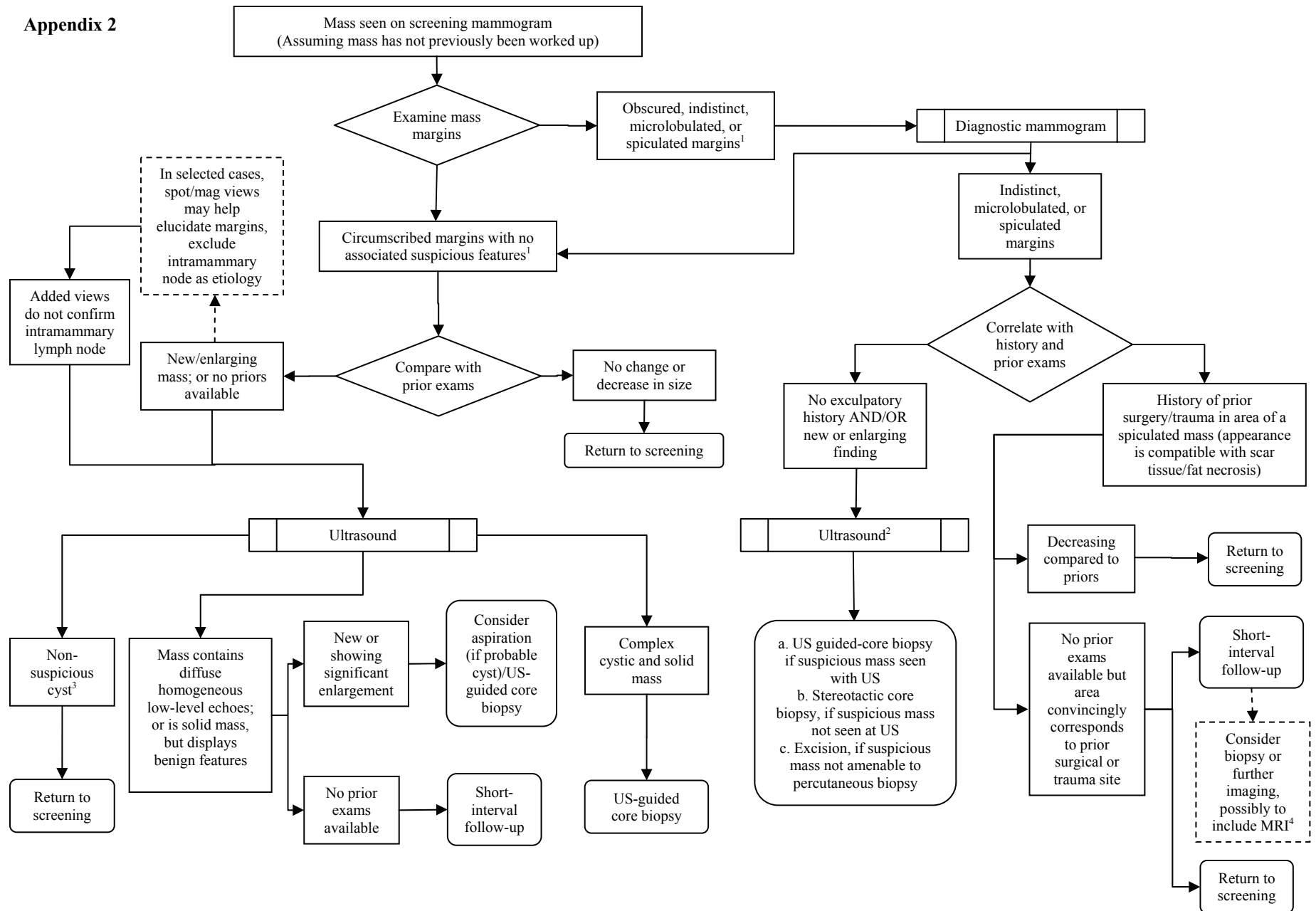
¹If the area can be confidently determined to be related to prior surgery (ie, by scar marker) or the sequelae of trauma (eg, presence of fat necrosis), consider return to screening mammography.

²Excision 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.

³Place a marking clip; obtain postprocedure mammogram to confirm concordance with original mammographic finding.

⁴Depends on initial level of suspicion.

Appendix 2



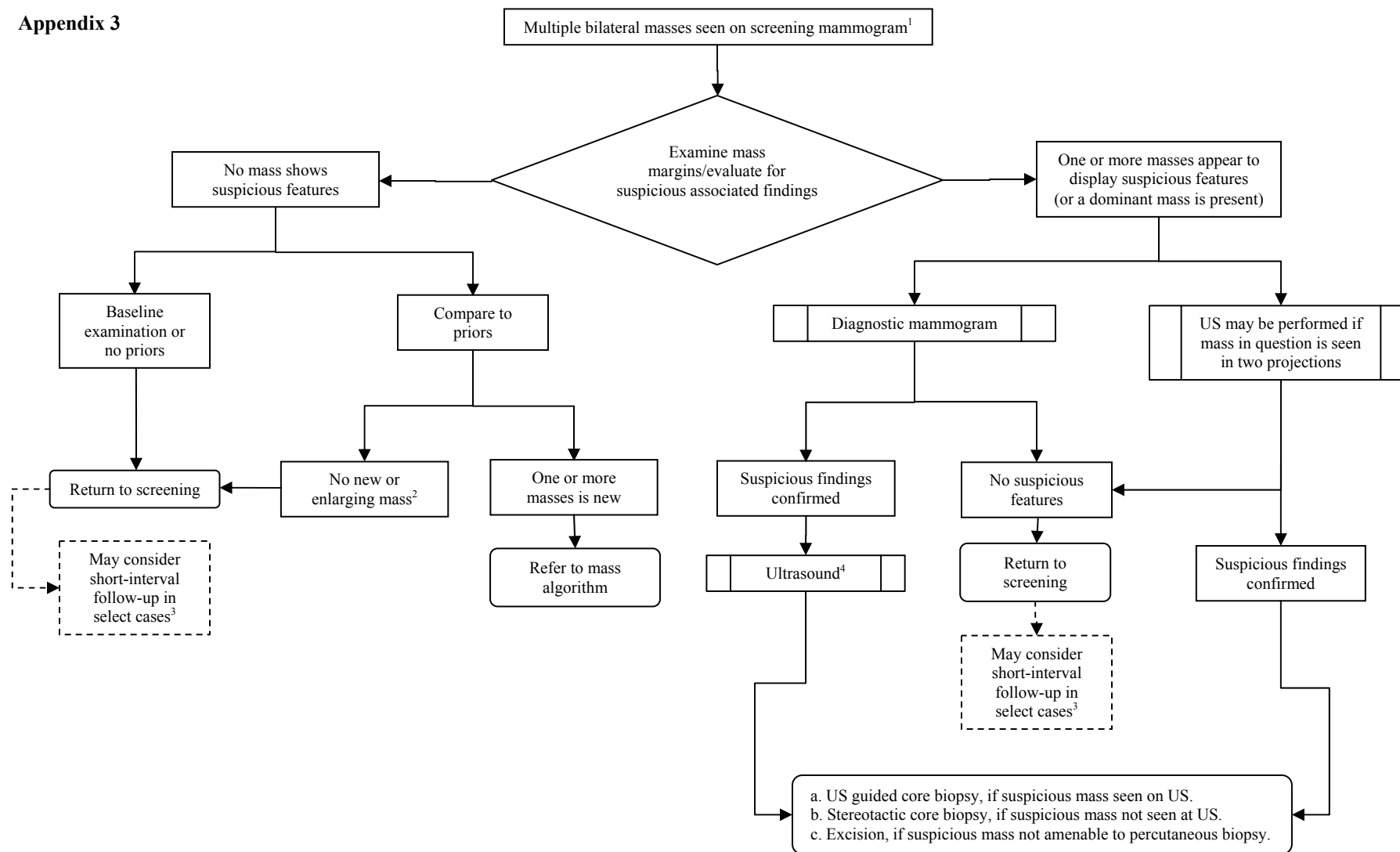
¹If suspicious calcifications are present in the mass; biopsy is indicated regardless of stability or margination.

²Ultrasound to exclude unlikely possibility of a nonsuspicious cyst. If cyst is documented, may return to screening or consider short-interval follow-up.

³Includes 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.

⁴If there is not exact concordance in location or characteristic appearance between mass and site of prior surgery/trauma, consider biopsy or further imaging.

Appendix 3



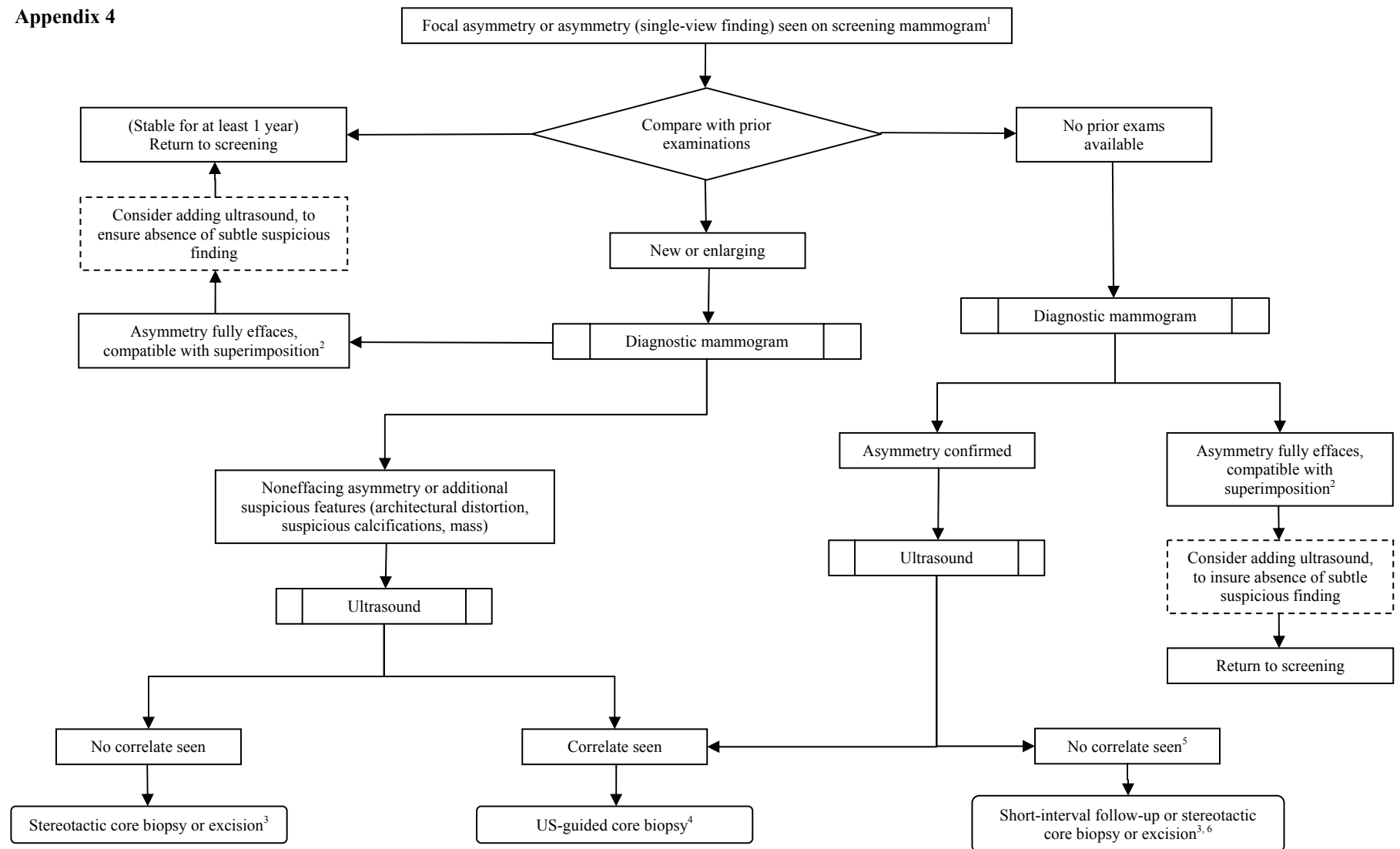
¹This should include at least two masses in one breast and at least one mass in the other breast.

²Enlargement of one or more masses over time, assuming circumscribed margins AND no suspicious features, can be considered normal variation and does not necessitate further evaluation.

³Short-interval follow-up to confirm stability if a more conservative approach is desired.

⁴If cyst is documented, may return to screening or consider short-interval follow-up.

Appendix 4



¹Global 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.

²Area should be carefully examined to exclude subtle suspicious findings (eg, low-density masses, distortions).

³Excision if asymmetry not amenable to percutaneous biopsy.

⁴Leave marking clip to confirm concordance with original mammographic finding.

⁵Meticulous 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.

⁶Depends on level of suspicion.