

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
Image-guided core biopsy breast	1		Varies
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 examinations 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
Image-guided core biopsy breast	1		Varies
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
Image-guided core biopsy breast	1		Varies
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 examinations 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
Image-guided core biopsy breast	1		Varies
<u>Rating Scale:</u> 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 examination 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
Image-guided core biopsy breast	1		Varies
<u>Rating Scale:</u> 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
Image-guided core biopsy breast	1		Varies
<u>Rating Scale:</u> 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
Image-guided core biopsy breast	1		Varies
<u>Rating Scale:</u> 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 examinations. 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
Image-guided core biopsy breast	1		Varies
<u>Rating Scale:</u> 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

Introduction/Background

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 distortions. Benchmark data based on information from the Breast Cancer Surveillance Consortium (BCSC) report 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 can simulate a mass or focal asymmetry, and additional mammographic and/or ultrasound (US) evaluation may be necessary to determine the presence of a true finding. Masses are three-dimensional structures with convex outward contours. Focal asymmetries are seen on two views but are non-mass-like, often with concave outward contours. If new or enlarging on screening mammography, these should be further evaluated with diagnostic imaging and possibly US. [4-7]. When a mass is detected mammographically, its shape, margin, density, and size should be assessed as outlined in the *Breast Imaging Reporting and Data System: ACR BI-RADS-*

Mammography, 4th Edition (ACR BI-RADS® Atlas) [7-12].

Ultrasound

US can be used to evaluate the cystic versus solid nature of a breast mass. Adhering to strict criteria, this technique can separate cystic from solid masses with an accuracy approaching 100% [10]. Using good-quality, high-frequency equipment, cysts as small as 2-3 mm in diameter can be demonstrated. However, cysts 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, and solid masses [15]. Solid masses can often be further subcategorized as either probably benign (allowing short-term surveillance rather than biopsy) or suspicious, based on multiple sonographic parameters [15-17]. Masses with mammographic features 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].

US is also useful in evaluating architectural distortions and asymmetries that cannot be dismissed as superimposed tissue after diagnostic mammographic evaluation. US can often confirm the suspicious nature of the finding and can guide biopsy. In cases where the diagnostic workup of such a finding fails to show a persistent suspicious lesion, US can provide additional confirmation of the benign nature of the initial finding when thorough scanning is negative or when a benign sonographic explanatory correlate can be found. However, if a suspicious mammographic finding remains after diagnostic evaluation, negative US should not dissuade biopsy. Elastography, which examines the viscoelastic properties of tissue, is being evaluated as a way to increase the specificity of US, especially regarding evaluation and management of solid masses [18].

Magnetic Resonance Imaging

The use of magnetic resonance imaging (MRI) to evaluate nonpalpable noncalcified mammographic lesions is controversial. It is not needed in cases where a finding can be fully and confidently evaluated using the routine methods described above. MRI lacks a sufficiently high negative predictive value (NPV) to allow dismissal of a finding deemed suspicious on routine diagnostic evaluation but negative on MRI [19]. Therefore, MRI is not indicated for evaluating the vast majority of cases involving noncalcified mammographic findings. However, there may be a subset of equivocal or problem cases where MRI is of value. This group might include asymmetries and questioned architectural distortions where diagnostic mammography is inconclusive and there

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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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is no US correlate or definitive target for biopsy. In these selected cases, MRI may allow detection of a subtle cancer that might otherwise have been left to be followed or, when the MRI finding is negative, may add confidence to the decision to follow. However, as is seen with other MR indications, false positives unrelated to the initial site of concern can result in increased cost and unnecessary biopsies [20,21].

Biopsy

After appropriate workup of mammographically detected noncalcified suspicious lesions, which will usually include diagnostic mammography and US, a final assessment should be assigned according to the *ACR BI-RADS® Atlas* [8]. Articles have validated the approach of following probably benign lesions (category 3), as outlined in the *ACR BI-RADS® Atlas*, to decrease the number of biopsies of benign lesions and potentially substantially reduce cost [22-24]. If a noncalcified lesion is placed in category 4 or 5, a biopsy is warranted. This biopsy is most often performed as a percutaneous procedure using stereotactic or US guidance to obtain cores of tissue. Fine-needle aspiration biopsy is a less desirable approach to tissue sampling, requiring a trained cytopathologist for interpretation and showing suboptimal rates of accuracy and tissue sampling sufficiency compared to core needle biopsy [25-27]. Percutaneous biopsy should be done with the goal of 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.

Summary

- Screening mammography potentiates the detection of early, clinically occult cancers, with benchmark data demonstrating mean size at diagnosis to be 13 mm, and a detection rate of 4.7/1,000 screening examinations. While most lesions found on screening mammography are benign, a PPV3 of 33% can be achieved for lesions undergoing biopsy after diagnostic evaluation.
- 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® Atlas* criteria, terminology, and assessments helps guide management and optimizes communication of findings and recommendations.
- US is a useful adjunctive tool in evaluating abnormal mammographic findings, but it requires use of good-quality, high-frequency equipment and application of strict criteria, as 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. Elastography may improve specificity in evaluation of solid masses.

- Breast MRI may be useful as a problem-solving tool in a small, carefully selected group of patients who have inconclusive results after thorough diagnostic evaluation of mammographically detected noncalcified nonpalpable findings.
- Percutaneous biopsy of suspicious lesions can provide accurate tissue diagnosis at decreased cost, precluding the need for surgery in specific benign cases while 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 "Varies".		

Supporting Document(s)

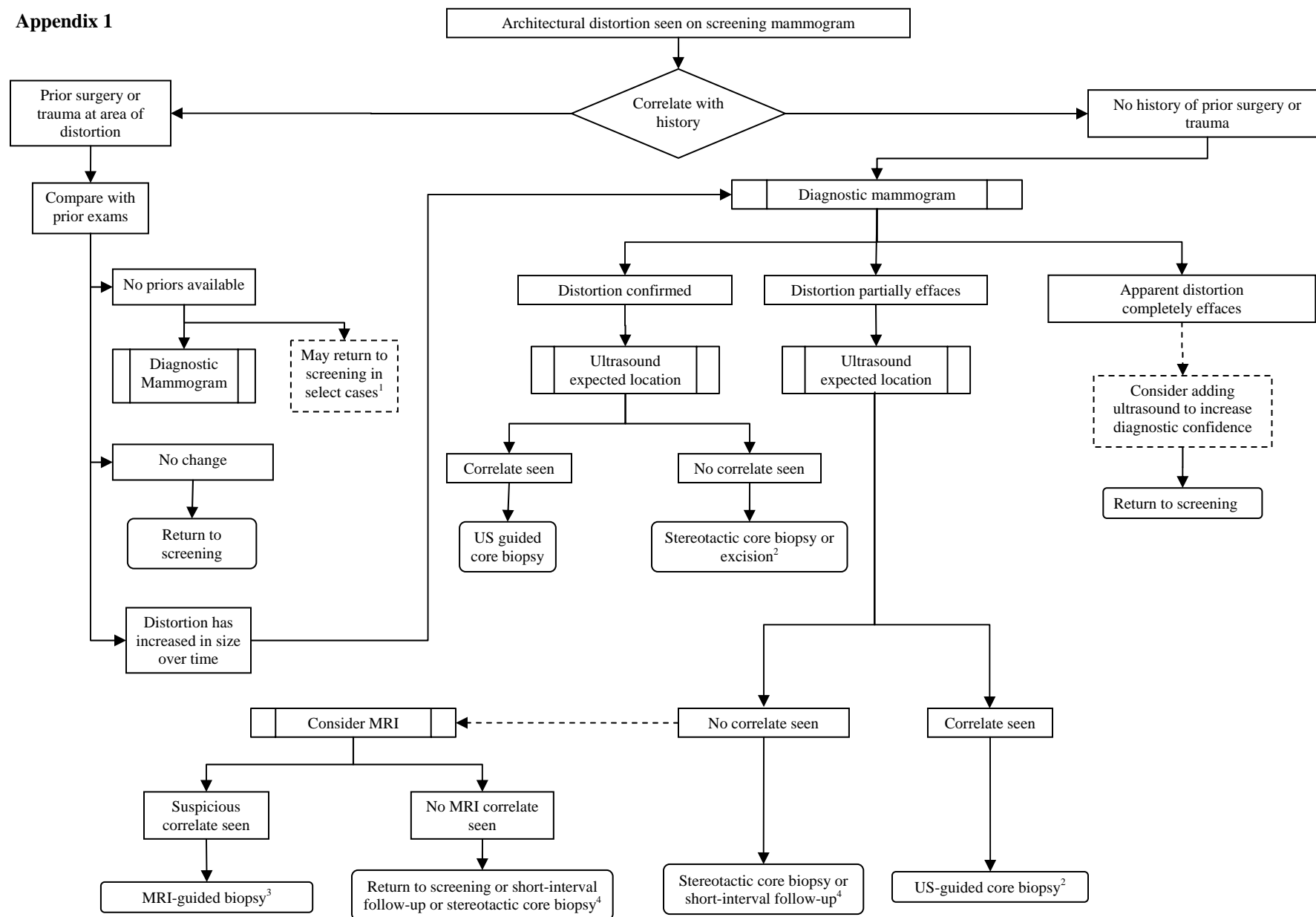
- [ACR Appropriateness Criteria® Overview](#)
- [Procedure Information](#)
- [Evidence Table](#)

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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



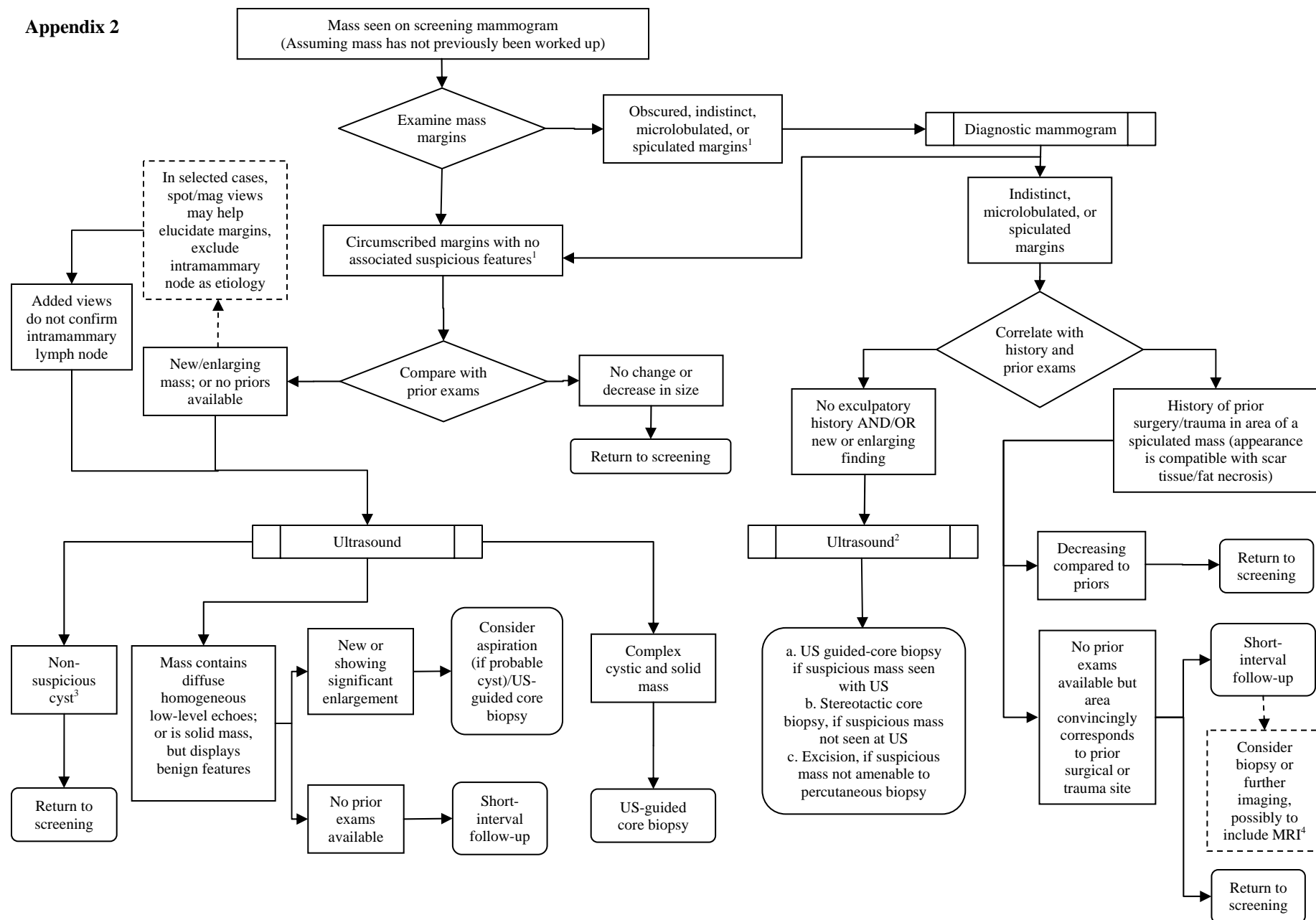
¹If the area can be confidently determined to be related to prior surgery (ie, by scar marker) or the sequelae of trauma (eg, presence of fat necrosis), consider return to screening mammography.

²Excision if distortion not amenable to percutaneous biopsy. If radial scar/complex sclerosing lesion is a likely diagnosis, advise patient that surgical excision will be performed. However, preoperative core biopsy is still appropriate, such that if malignancy is 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



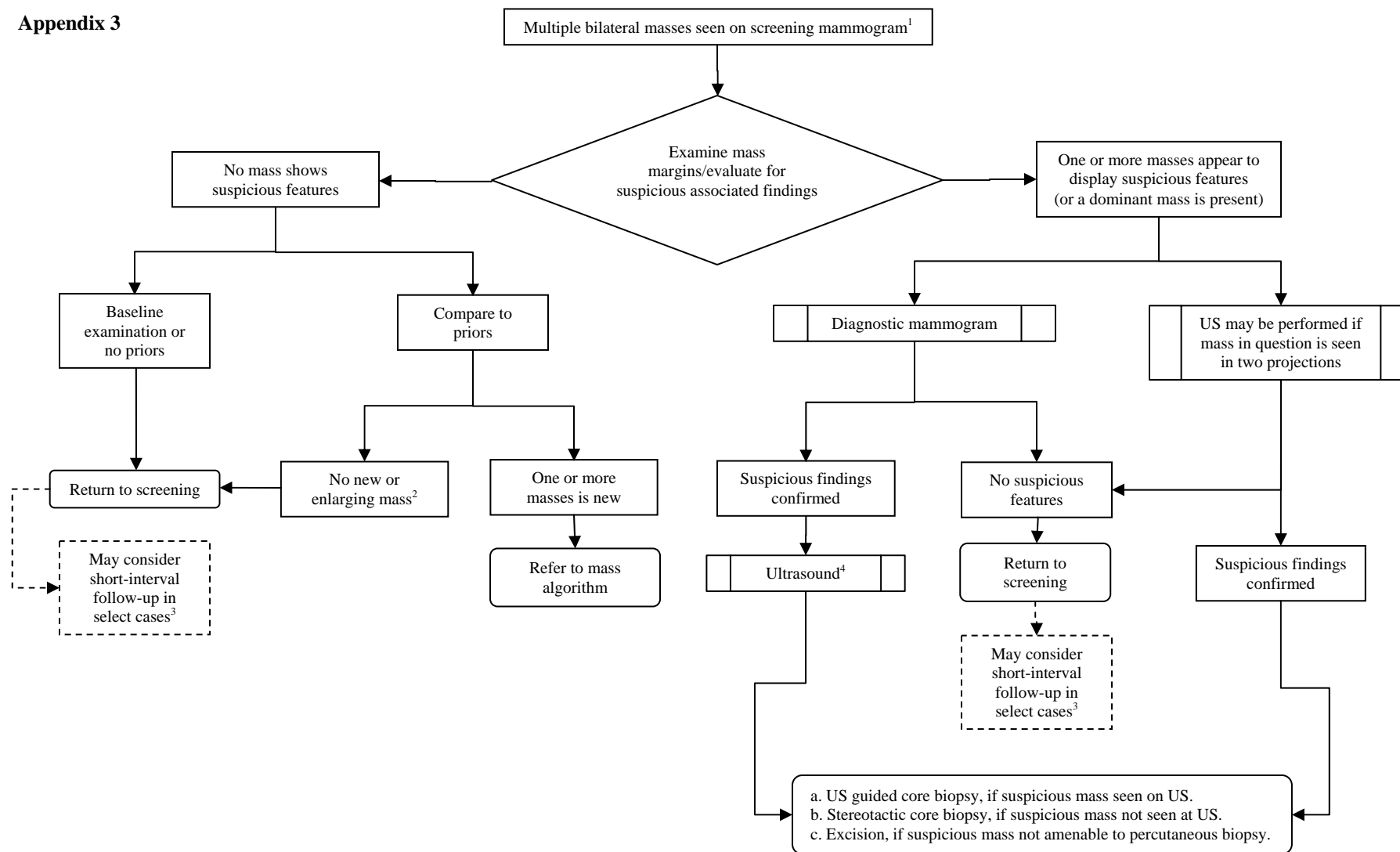
¹If suspicious calcifications are present in the mass; biopsy is indicated regardless of stability or margination.

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



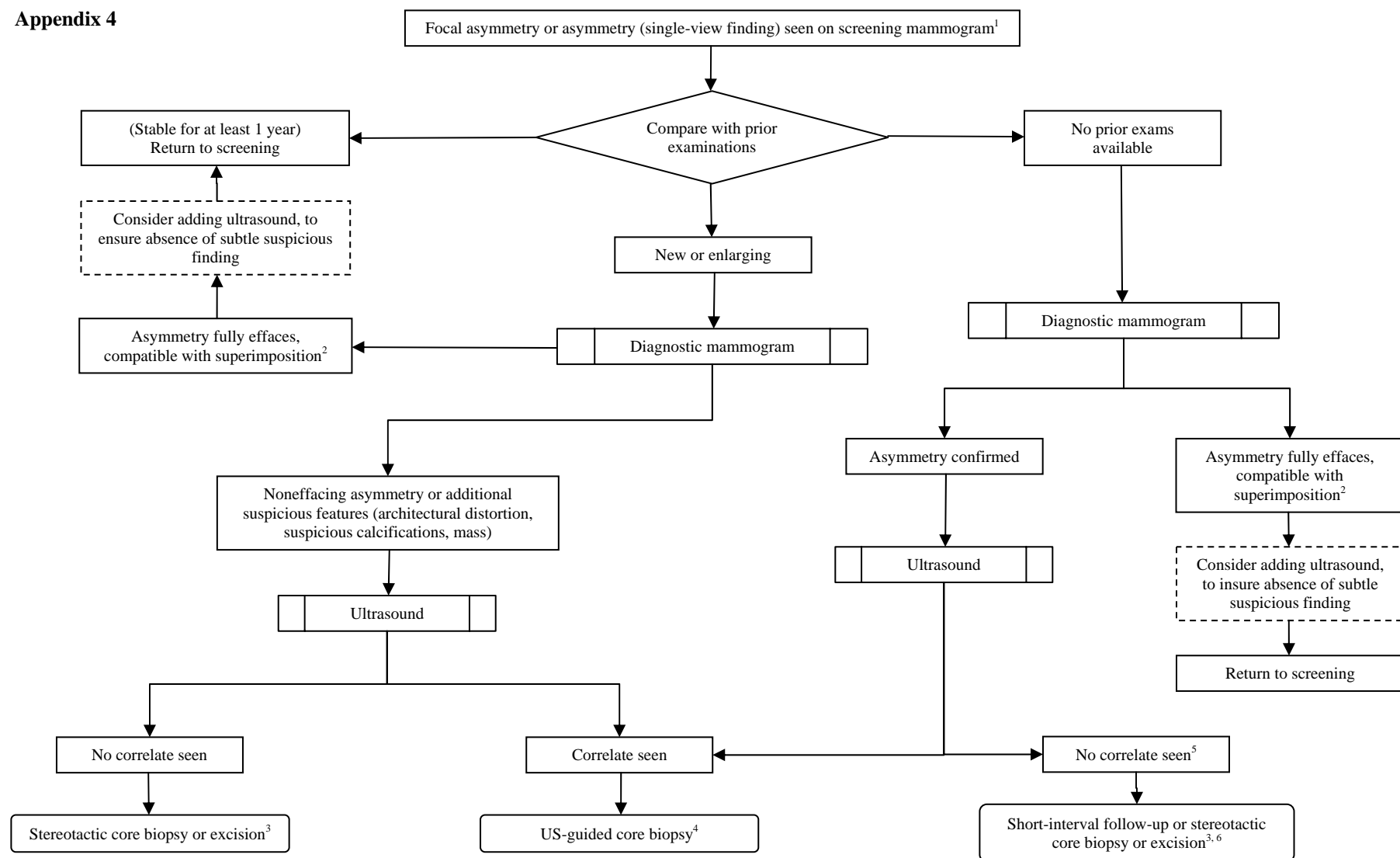
¹This should include at least two masses in one breast and at least one mass in the other breast.

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.