



**NCCN Clinical Practice Guidelines in Oncology™**

# **Breast Cancer Screening and Diagnosis Guidelines**

V.1.2007

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This manuscript is being updated to correspond with the newly updated algorithm.

**Clinical Trials:** The NCCN believes that the best management for any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

To find clinical trials online at NCCN member institutions, [click here: nccn.org/clinical\\_trials/physician.html](#)

**NCCN Categories of Consensus:** All recommendations are Category 2A unless otherwise specified.

See [NCCN Categories of Consensus](#)

[Summary of Guidelines Updates](#)

These guidelines are a statement of consensus of the authors regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The National Comprehensive Cancer Network makes no representations nor warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way. These guidelines are copyrighted by National Comprehensive Cancer Network. All rights reserved. These guidelines and the illustrations herein may not be reproduced in any form without the express written permission of NCCN. ©2007.

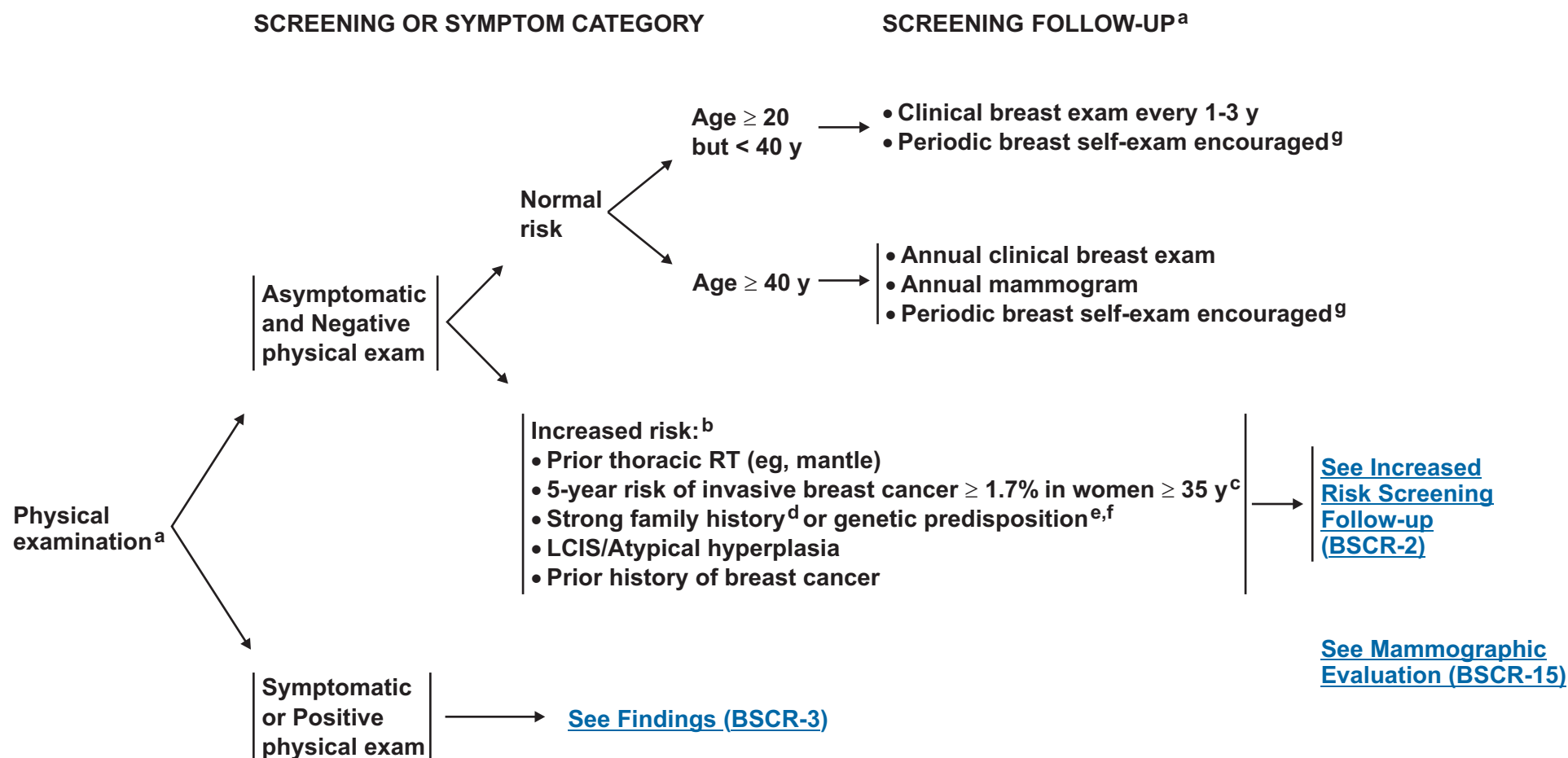
## Summary of the Guidelines updates

Summary of changes in the 1.2007 version of the Breast Cancer Screening and Diagnosis Guidelines from the 1.2006 version include:

- Strong family history or genetic predisposition, Age  $\geq$  25 y, Consider MRI as an adjunct to mammogram and clinical breast exam: The panel removed the quantifier ‘annual’ from the bullet ([BSCR-2](#)).
- Lump/mass Age  $\geq$  30 y, ultrasound, ‘Lesion not visualized’ was replaced by ‘No ultrasonographic abnormality’ ([BSCR-4](#)).
- Follow-up evaluation, Tissue biopsy or Observe every 3-6 mo  $\pm$  imaging for 1-2 y to assess stability: ‘Progression or enlargement of clinical exam’ replaced ‘Increase in size’ ([BSCR-4](#)).
- Footnote o was modified to include radial scar ([BSCR-5](#), [BSCR-6](#), [BSCR-7](#), [BSCR-10](#), [BSCR-11](#) and [BSCR-16](#)).
- Tissue diagnosis, Core needle biopsy: Panel added ‘preferred’ after core need biopsy. In addition, after Excision, the panel added the phrase, ‘If core needle biopsy not available’ ([BSCR-6](#)).
- Follow-up evaluation, mass recurs, ultrasound: Removed ‘preferred’ as a recommendation after ultrasound ([BSCR-7](#)).
- Histology/Cytology: ‘Benign’ replaced ‘fibroadenoma’ and ‘Malignant’ replaced ‘cancer’ ([BSCR-10](#)).
- Histology/Cytology: Insufficient tissue was added as a new category ([BSCR-10](#)).
- Follow-up evaluation, observe every 3-6 months for 1-2 years: The quantifier ‘only if < 2 cm’ was removed. In addition, after Surgical excision, the panel added ‘for larger masses’ as a quantifier ([BSCR-10](#)).
- Nipple discharge, no palpable mass: Bilateral milky pathway was removed ([BSCR-12](#)).
- Non-spontaneous, multiduct, Age  $\geq$  40 y: See Mammogram evaluation ([BSCR-15](#)) was added as a link ([BSCR-12](#)).
- Nipple discharge, no palpable mass: Persistent was clarified by adding ‘reproducible on exam’ ([BSCR-12](#)).
- BI-RADS<sup>®</sup> Category 4-5 and/or solid or non-simple cyst, surgical excision was clarified by adding ‘intracystic mass, wall thickening’ ([BSCR-14](#)).
- Pathology/image concordant: Removed radial scar from the list ([BSCR-16](#)).
- A new breast screening consideration, ‘A single study (DMIST) suggested benefit of digital mammography in young women and women with dense breasts’ was added to the page ([BSCR-A](#)).

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<sup>a</sup>See [Breast Screening Considerations \(BSCR-A\)](#).

<sup>b</sup>Refer to the [NCCN Breast Cancer Risk Reduction Guidelines](#) for a detailed qualitative and quantitative assessment.

<sup>c</sup>See [Risk Factors Used in the Modified Gail Model \(BSCR-B\)](#).

<sup>d</sup>For a definition of strong family history, see [NCCN Genetic/Familial High Risk Assessment Guidelines](#).

<sup>e</sup>As currently defined in the American Society of Clinical Oncology Policy Statement Update: Genetic testing for cancer susceptibility. J Clin Oncol 2003, 21:2397-2406.

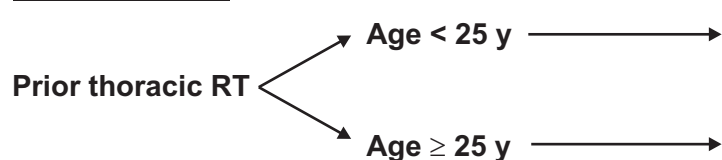
<sup>f</sup>See [NCCN Genetic/Familial High Risk Assessment Guidelines](#).

<sup>g</sup>Women should be familiar with their breasts and promptly report changes to their healthcare provider. Periodic, consistent BSE may facilitate breast self awareness. Premenopausal women may find BSE most informative when performed at the end of menses.

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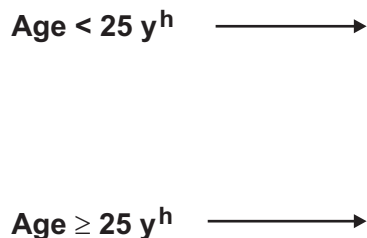
SCREENING OR SYMPTOM CATEGORY

Increased Risk:



5-year risk of  
invasive breast  
cancer ≥ 1.7%<sup>c</sup> in  
women ≥ 35 y

Strong family  
history<sup>d</sup> or  
genetic  
predisposition<sup>e,f</sup>



LCIS/Atypical  
hyperplasia

Prior history of breast cancer

SCREENING FOLLOW-UP

- Annual clinical breast exam
- Periodic breast self-exam encouraged<sup>g</sup>

- Annual mammogram + clinical breast exam every 6-12 mo
  - ▶ Begin 8-10 y after RT or age 40, whichever first
- Periodic breast self-exam encouraged<sup>g</sup>

- Annual mammogram + clinical breast exam every 6-12 mo
- Periodic breast self-exam encouraged<sup>g</sup>
- Consider risk reduction strategies  
([See NCCN Breast Cancer Risk Reduction Guidelines](#))

- Annual clinical breast exam
- Periodic breast self-exam encouraged<sup>g</sup>

- Annual mammogram + clinical breast exam every 6-12 mo
  - ▶ Starting at age 25 y for Hereditary Breast and Ovarian Cancer (HBOC)<sup>f</sup> patients
  - ▶ 5-10 y prior to youngest breast cancer case for strong family history or other genetic predispositions
- Periodic breast self-exam encouraged<sup>g</sup>
- Consider MRI as an adjunct to mammogram and clinical breast exam
- Consider risk reduction strategies  
([See NCCN Breast Cancer Risk Reduction Guidelines](#))

- Annual mammogram + clinical breast exam every 6-12 mo
- Consider risk reduction strategies  
([See NCCN Breast Cancer Risk Reduction Guidelines](#))
- Periodic breast self-exam encouraged<sup>g</sup>

[See NCCN Breast Cancer Treatment Guidelines Surveillance Section](#)

[See Physical Exam \(BSCR-1\)](#)

[See Mammographic Evaluation \(BSCR-15\)](#)

<sup>c</sup>See Risk Factors Used in the Modified Gail Model (BSCR-B).

<sup>d</sup>For a definition of strong family history, see [NCCN Genetic/Familial High Risk Assessment Guidelines](#).

<sup>e</sup>As currently defined in the American Society of Clinical Oncology Guidelines (Statement of the American Society of Clinical Oncology: Genetic testing for cancer susceptibility, adopted on February 20, 1996. J Clin Oncol 14(5):1730-1736, 1996.)

<sup>f</sup>See [NCCN Genetic/Familial High Risk Assessment Guidelines](#).

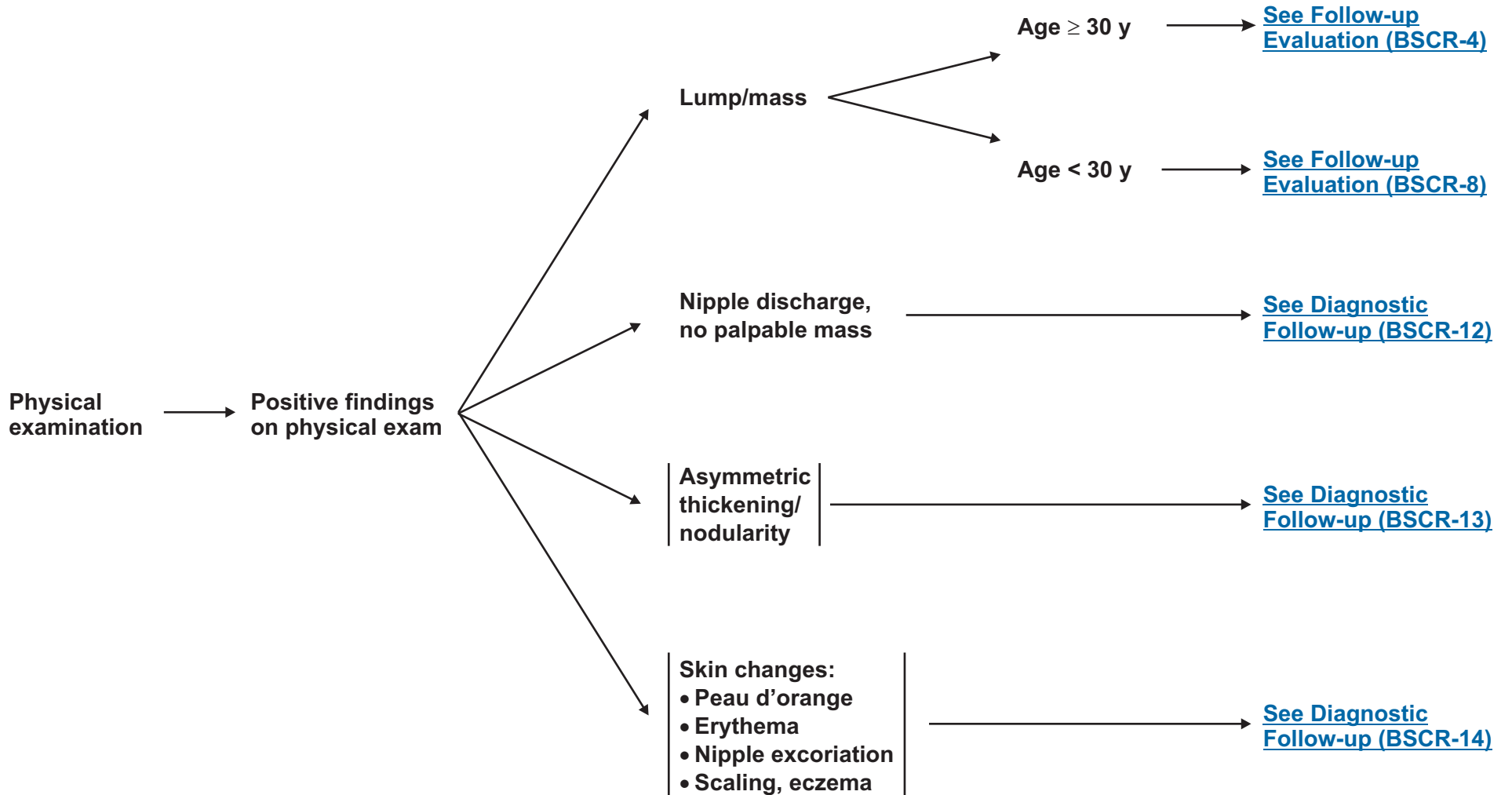
<sup>g</sup>Women should be familiar with their breasts and promptly report changes to their healthcare provider. Periodic, consistent BSE may facilitate breast self awareness. Premenopausal women may find BSE most informative when performed at the end of menses.

<sup>h</sup>Earlier screening may be appropriate in some patients.

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DIAGNOSTIC CATEGORY

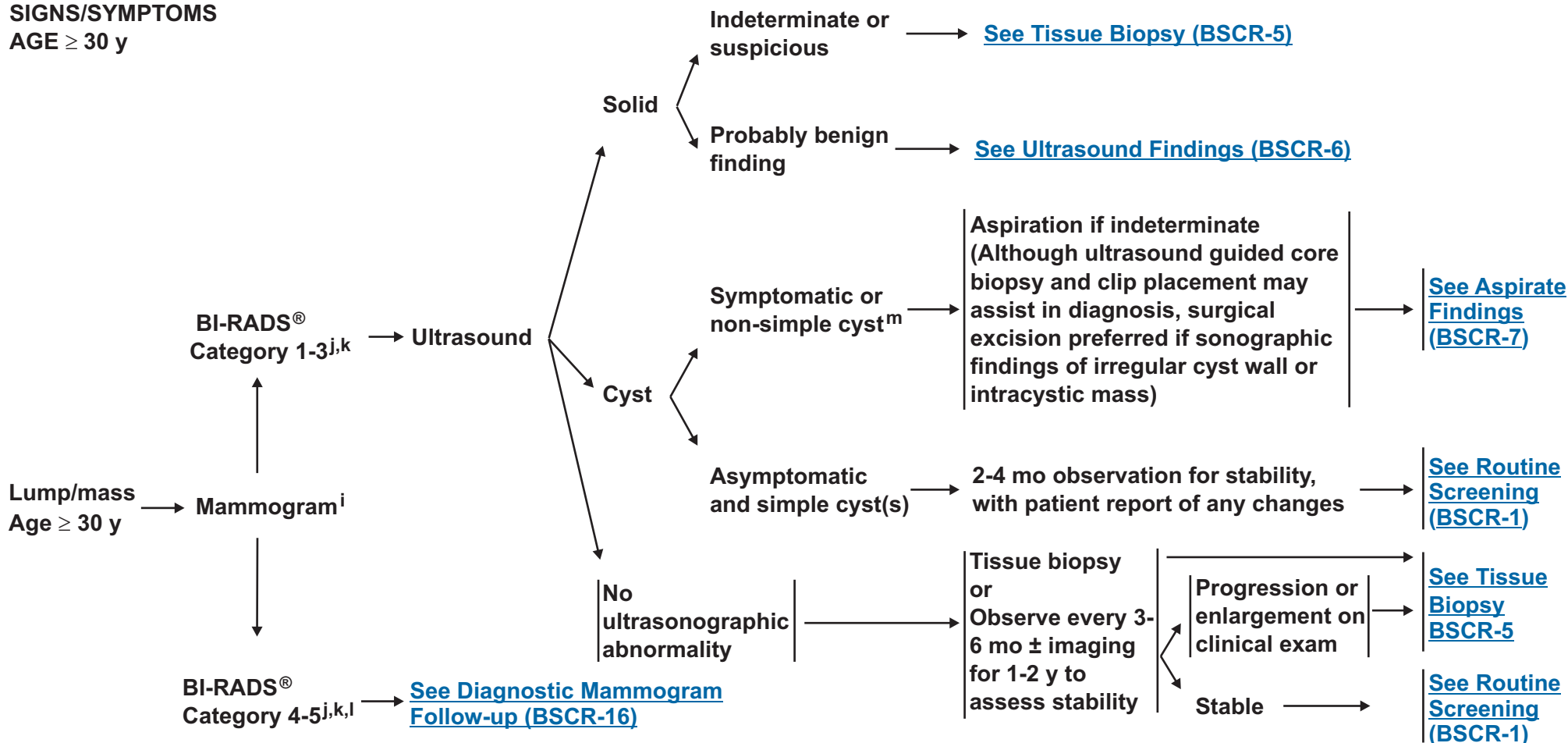


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PRESENTING  
SIGNS/SYMPTOMS  
AGE ≥ 30 y

INITIAL EVALUATION

FOLLOW-UP EVALUATION



<sup>i</sup>There are a few clinical circumstances in which ultrasound would be preferred (eg, suspected simple cyst).

<sup>j</sup>[See Mammographic Assessment Category Definitions \(BSCR-C\)](#).

<sup>k</sup>Mammography results are mandated to be reported using Final Assessment categories (Mammography Quality Standards Act, Final Rule. Federal Register 62(208):55988,1997).

<sup>l</sup>Assess geographic correlation between clinical and imaging findings. If there is a lack of correlation return to Category 1-3 for further work-up of palpable lesion. If imaging findings correlate with the palpable finding, workup of the imaging problem will answer the palpable problem.

<sup>m</sup>Round, circumscribed mass containing low level echoes without vascular flow, fulfilling most but not all criteria for simple cyst.

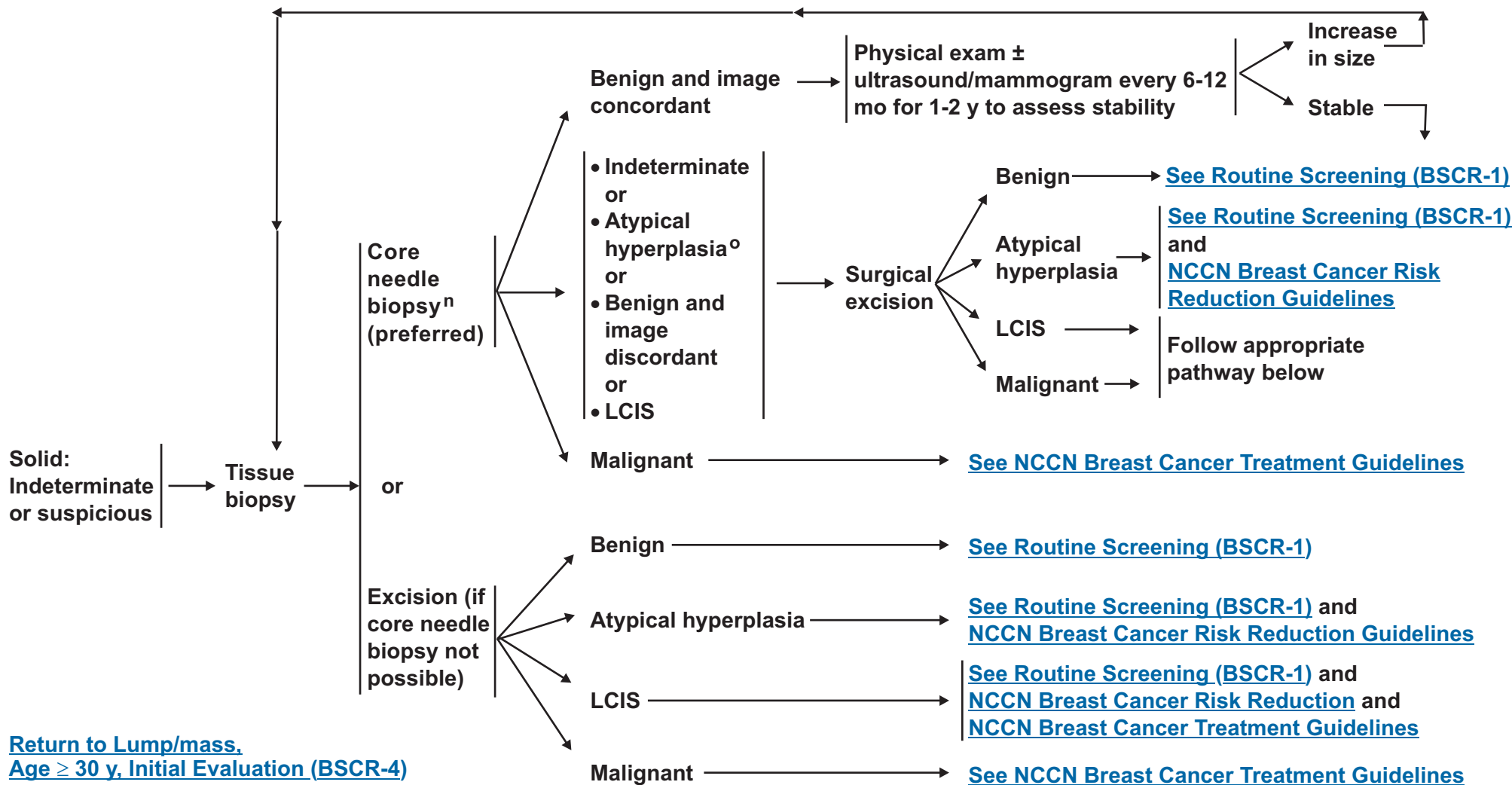
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ULTRASOUND FINDINGS

FOLLOW-UP EVALUATION

AGE ≥ 30 y



<sup>n</sup>FNA and core (needle or vacuum-assisted) biopsy are both valuable. FNA requires cytologic expertise.

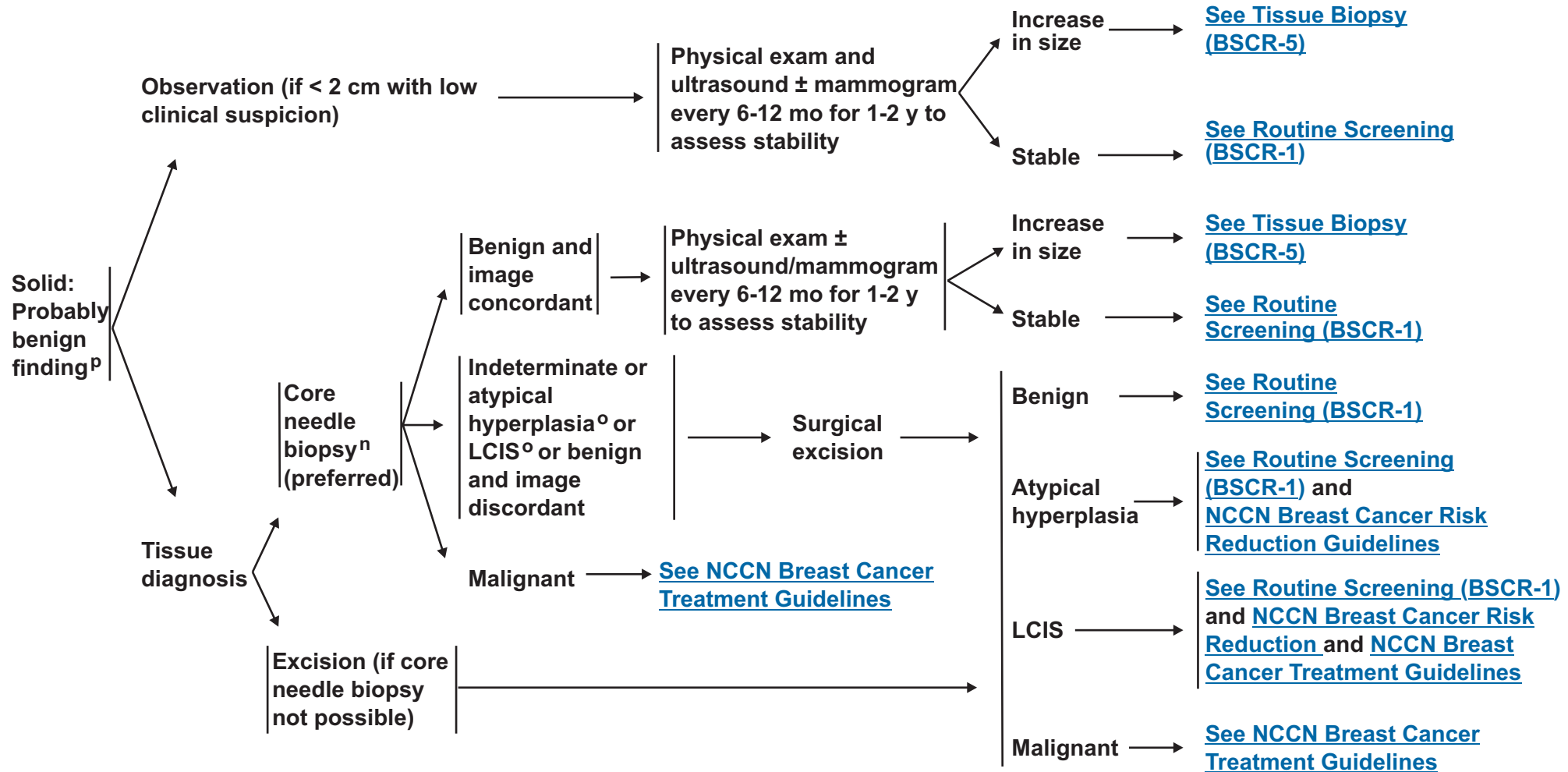
<sup>o</sup>Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesions, radial scar or other histologies of concern to pathologist.

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ULTRASOUND FINDINGS  
PALPABLE LUMP/MASS

FOLLOW-UP EVALUATION



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<sup>o</sup>Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesions, radial scar or other histologies of concern to pathologist.

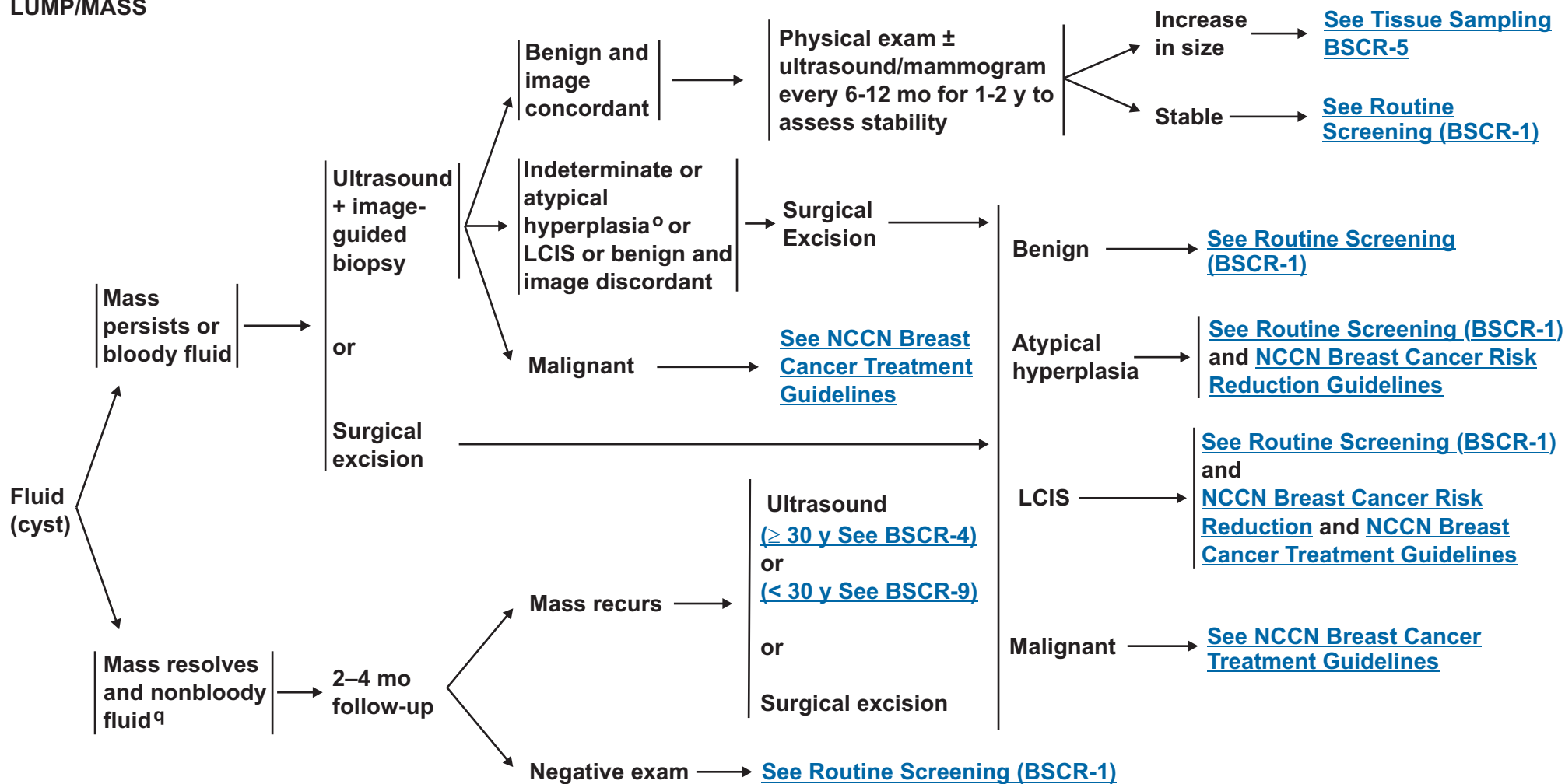
<sup>p</sup>Stavros A, Thickman D, Rapp C et al. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. Radiology 1995;196:123-124.

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ASPIRATE FINDINGS  
LUMP/MASS

FOLLOW-UP EVALUATION



°Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesion, radial scar or other histologies of concern to pathologist.

¶Routine cytology not recommended.

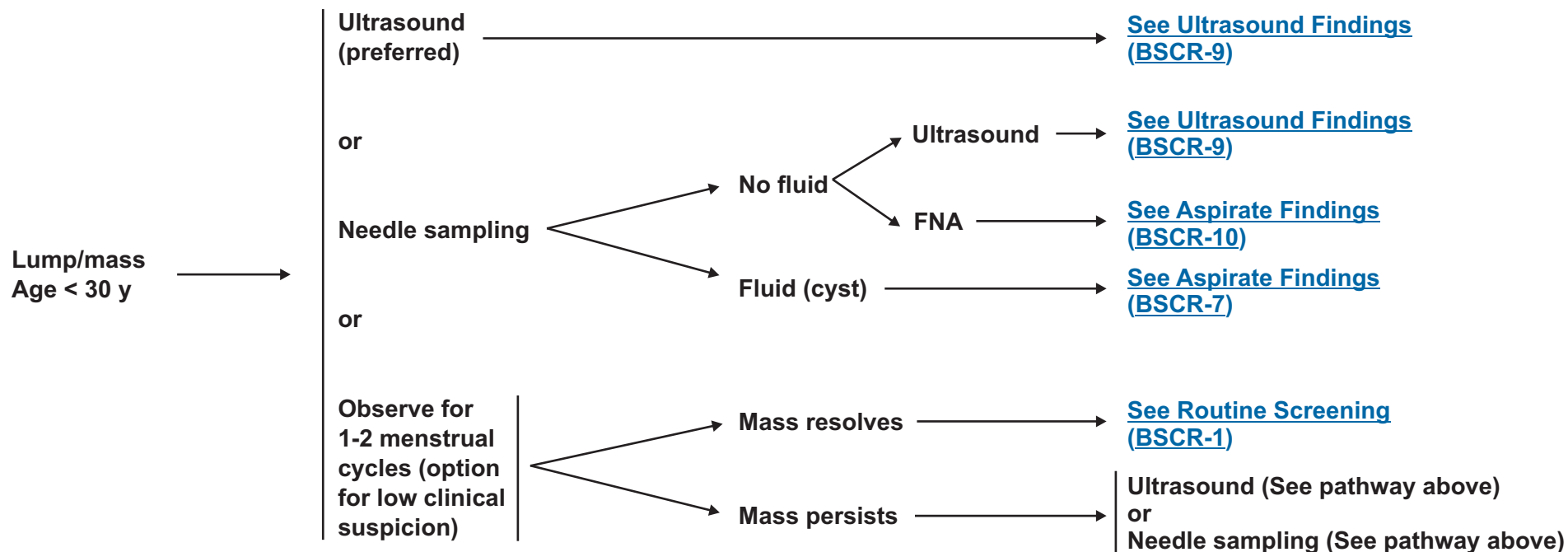
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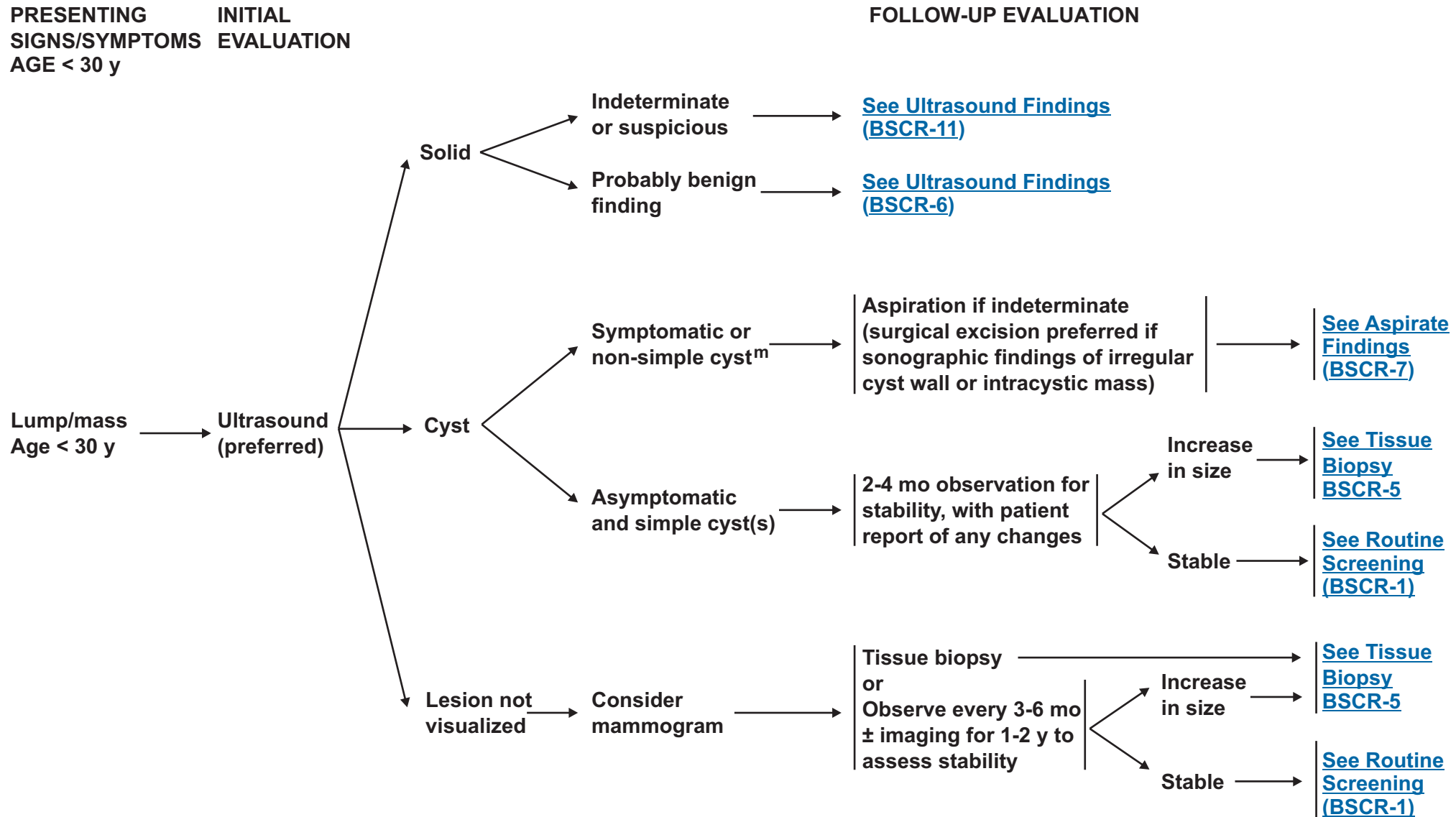
PRESENTING  
SIGNS/SYMPTOMS  
AGE < 30 y

INITIAL EVALUATION

FOLLOW-UP EVALUATION



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<sup>m</sup>Round, circumscribed mass containing low level echoes without vascular flow, fulfilling most but not all criteria for simple cyst.

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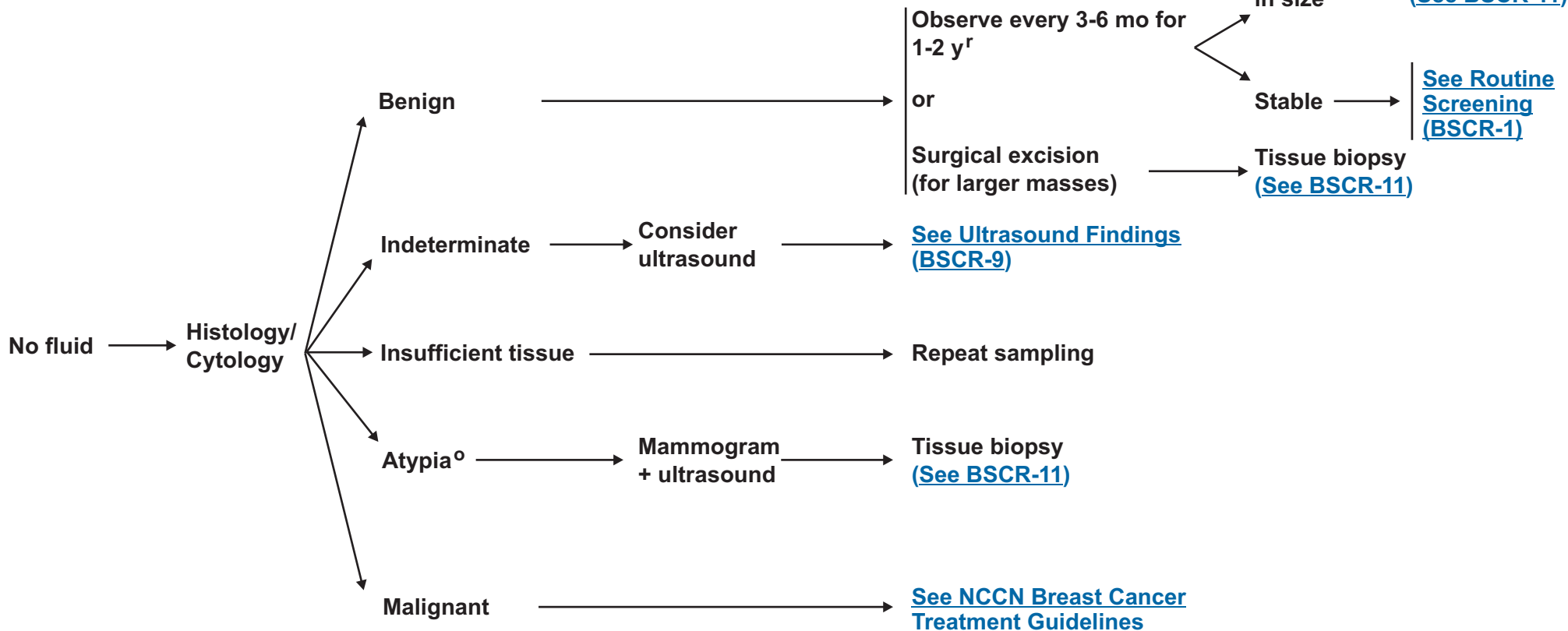
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[Return to Lump/mass, Age < 30 y, Initial Evaluation \(BSCR-8\)](#)

ASPIRATE FINDINGS

LUMP/MASS

Age < 30 y



<sup>o</sup>Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesions, radial scar or other histologies of concern to pathologist.

<sup>r</sup>Consider an ultrasound to obtain size measurement for accurate monitoring of stability.

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ULTRASOUND FINDINGS  
PALPABLE LUMP/MASS  
AGE < 30 y

Solid:  
Indeterminate  
or suspicious

Mammogram → Tissue biopsy

or

Core needle biopsy<sup>n</sup> (preferred)

FOLLOW-UP EVALUATION

Benign and image concordant

Physical exam ± ultrasound/mammogram every 6-12 mo for 1-2 y to assess stability

Increase in size → Return to tissue biopsy  
Stable →

Indeterminate or atypical hyperplasia<sup>o</sup> or LCIS or benign and image discordant

Surgical excision

Benign → [See Routine Screening \(BSCR-1\)](#)  
Atypical hyperplasia → [See Routine Screening \(BSCR-1\) and NCCN Breast Cancer Risk Reduction Guidelines](#)  
LCIS → [See Routine Screening \(BSCR-1\) and NCCN Breast Cancer Risk Reduction and NCCN Breast Cancer Treatment Guidelines](#)  
Malignant → [See NCCN Breast Cancer Treatment Guidelines](#)

Malignant → [See NCCN Breast Cancer Treatment Guidelines](#)

Excision

Benign → [See Routine Screening \(BSCR-1\)](#)  
Atypical hyperplasia → [See Routine Screening \(BSCR-1\) and NCCN Breast Cancer Risk Reduction Guidelines](#)  
LCIS → [See Routine Screening \(BSCR-1\) and NCCN Breast Cancer Risk Reduction and NCCN Breast Cancer Treatment Guidelines](#)  
Malignant → [See NCCN Breast Cancer Treatment Guidelines](#)

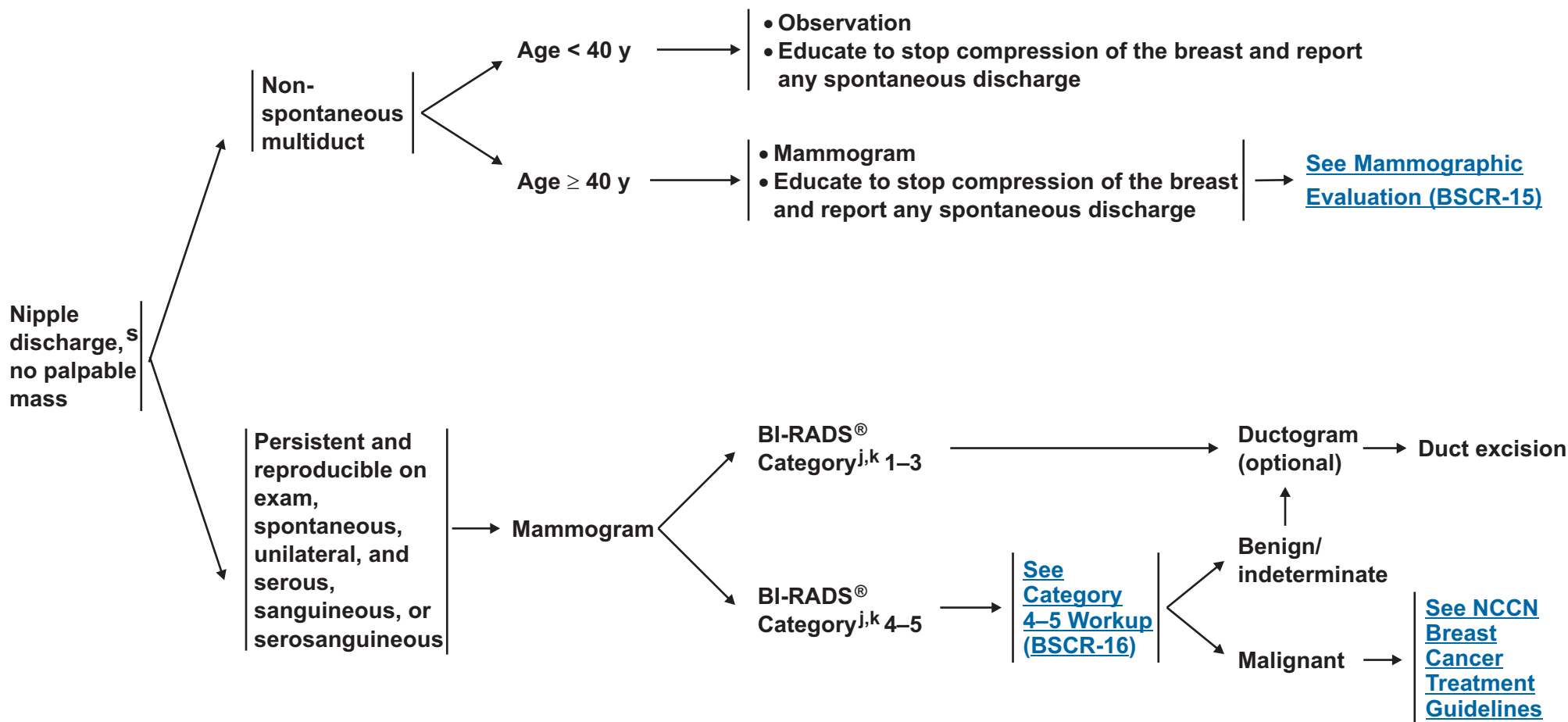
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[Return to Screening Category \(BSCR-4\)](#)

DIAGNOSTIC  
CATEGORY

DIAGNOSTIC FOLLOW-UP



<sup>s</sup>A list of drugs that can cause nipple discharge (not all inclusive): Psychoactive drugs, antihypertensive medications, opiates, oral contraceptives, and estrogen.

<sup>j</sup>See [Mammographic Assessment Category Definitions \(BSCR-C\)](#).

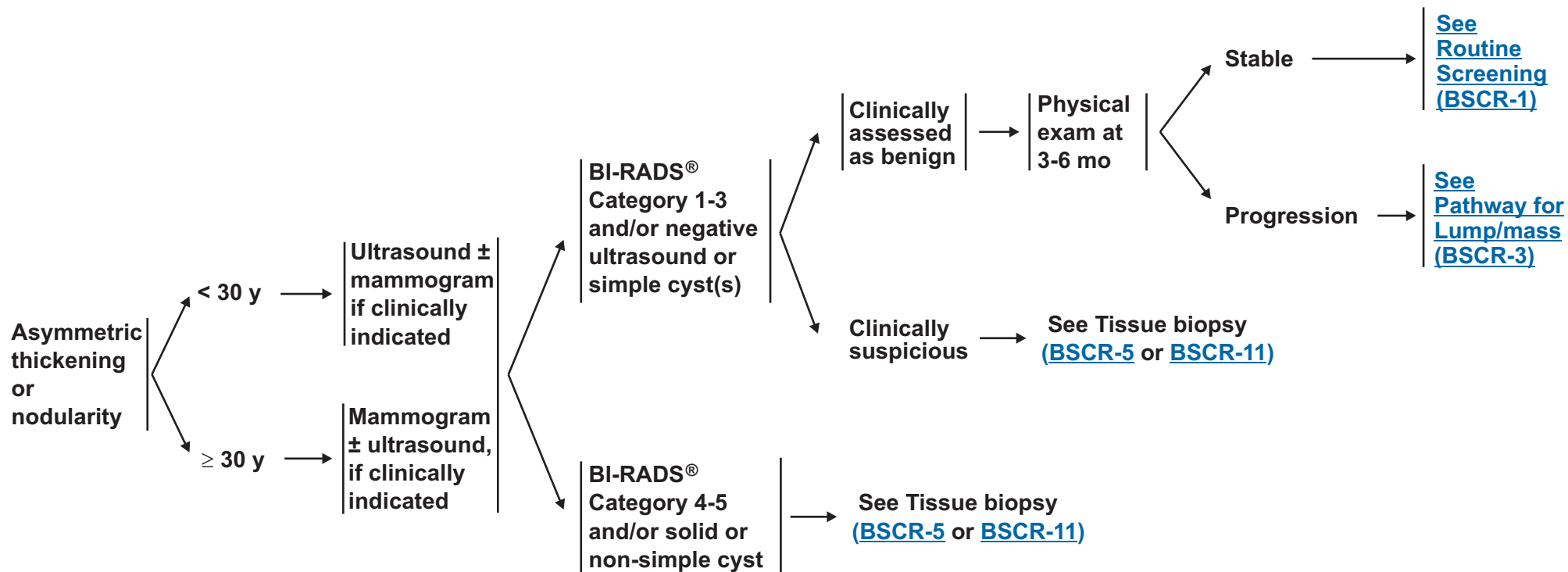
<sup>k</sup>Mammography results are mandated to be reported using Final Assessment categories (Mammography Quality Standards Act, Final Rule. Federal Register 62(208):55988, 1997).

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DIAGNOSTIC  
CATEGORY

DIAGNOSTIC FOLLOW-UP

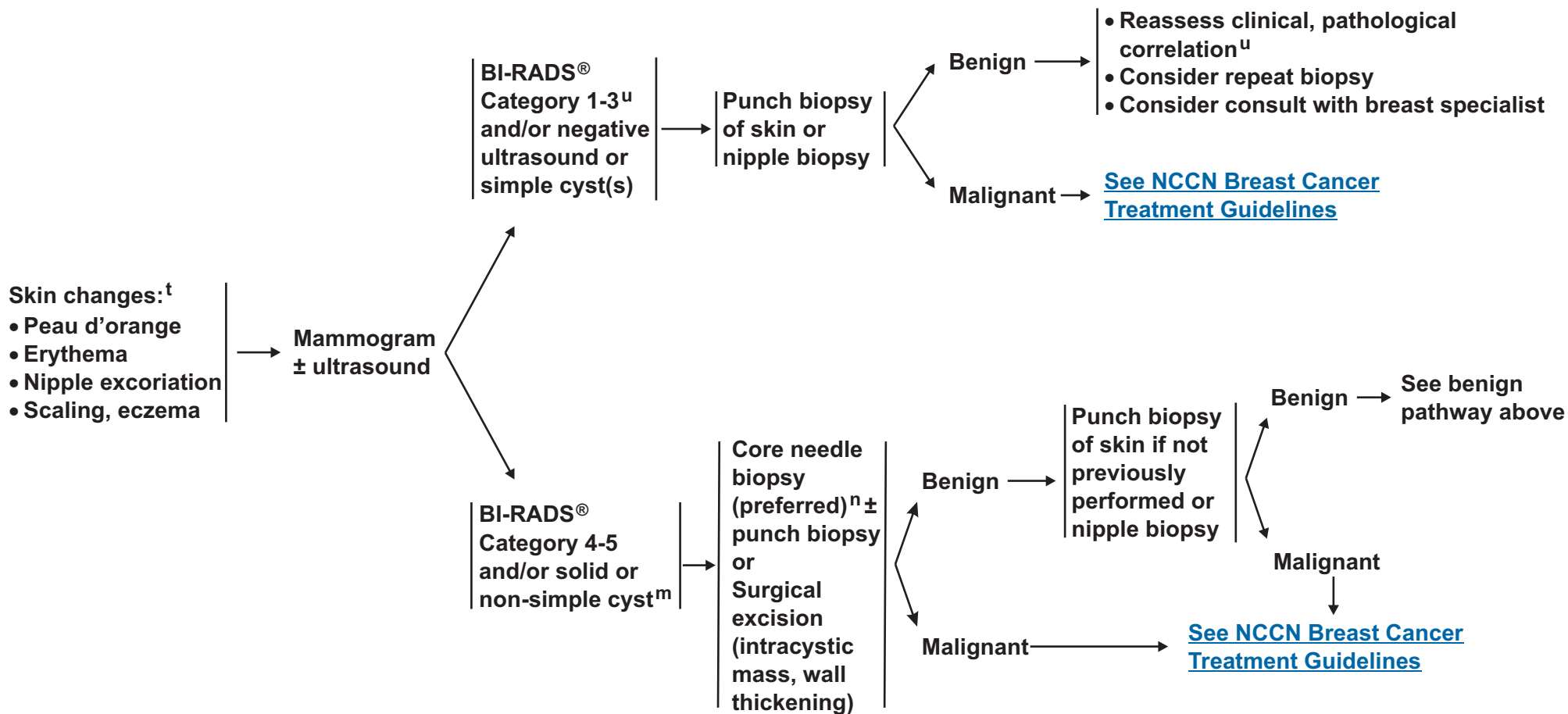


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DIAGNOSTIC  
CATEGORY

DIAGNOSTIC FOLLOW-UP



<sup>m</sup>Round, circumscribed mass containing low level echoes without vascular flow, fulfilling most but not all criteria for simple cyst.

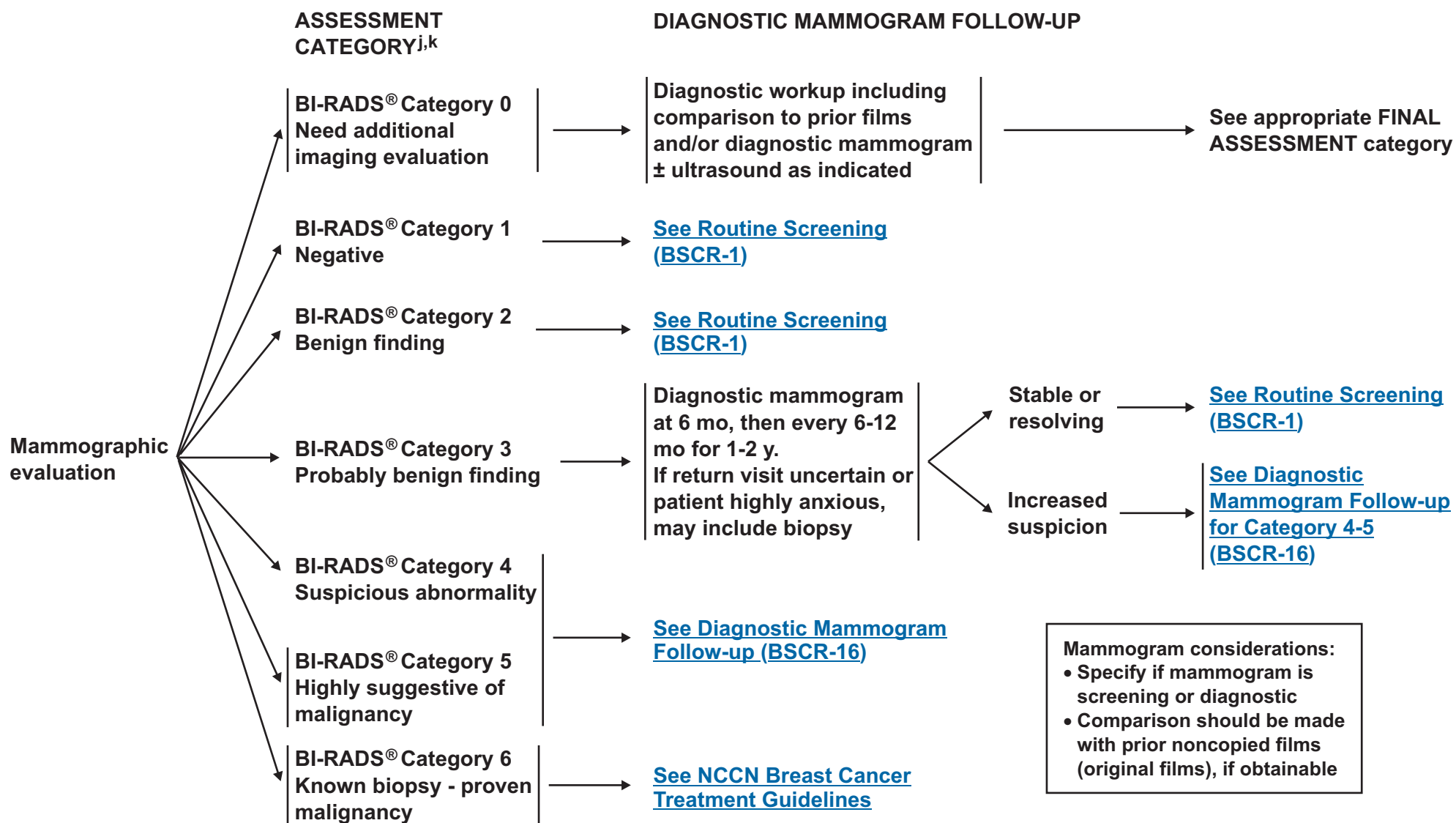
<sup>n</sup>FNA and core (needle or vacuum-assisted) biopsy are both valuable. FNA requires cytologic expertise.

<sup>t</sup>This may represent serious disease of the breast and needs evaluation.

<sup>u</sup>If clinically of low suspicion, a short trial (7-10 days) of antibiotics for mastitis may be indicated.

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<sup>j</sup>See [Mammographic Assessment Category Definitions \(BSCR-C\)](#).

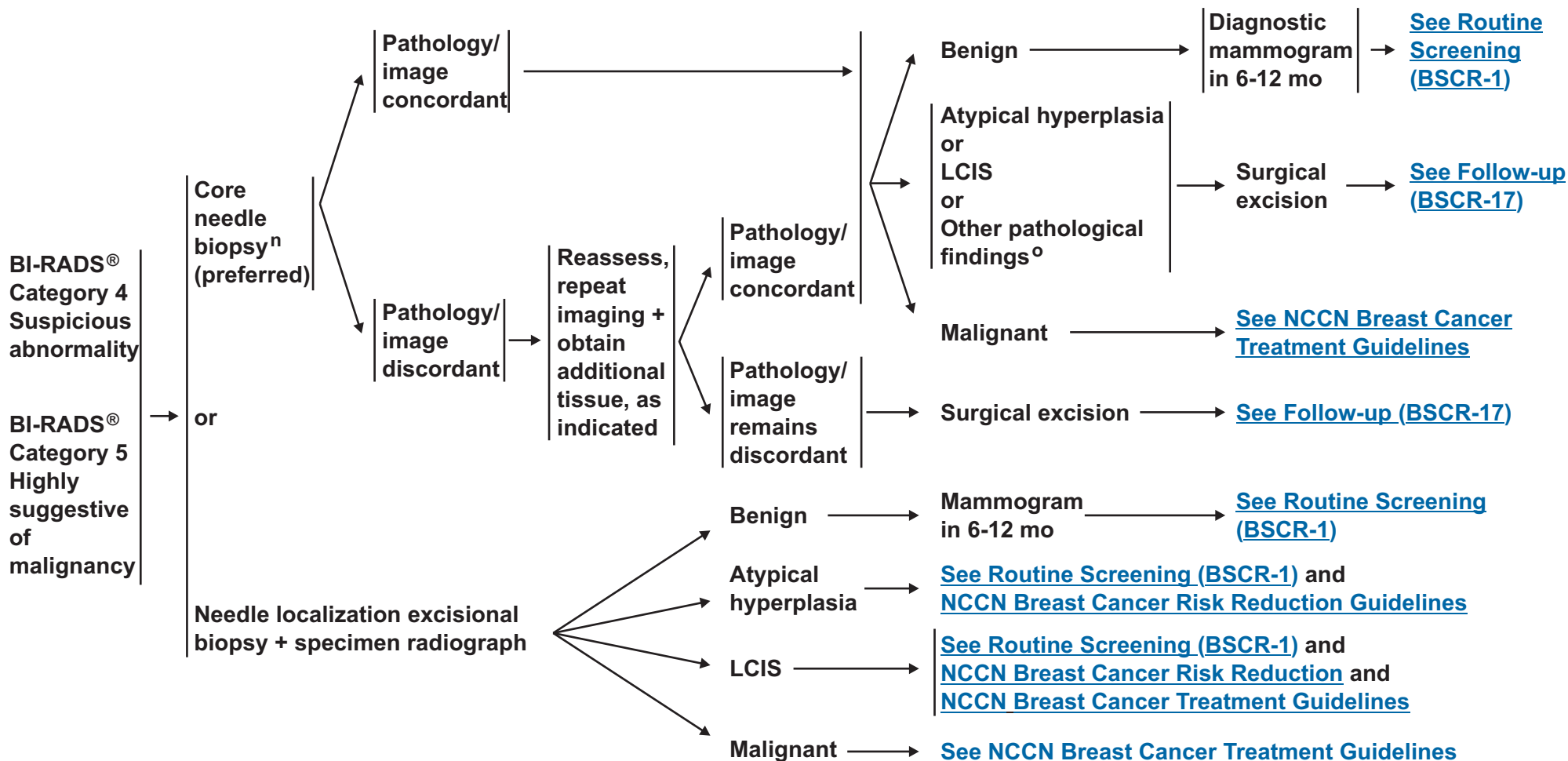
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ASSESSMENT  
CATEGORY<sup>j,k</sup>

DIAGNOSTIC MAMMOGRAM FOLLOW-UP



<sup>j</sup>See [Mammographic Assessment Category Definitions \(BSCR-C\)](#).

<sup>k</sup>Mammography results are mandated to be reported using Final Assessment categories (Mammography Quality Standards Act, Final Rule. Federal Register 62(208):55988, 1997).

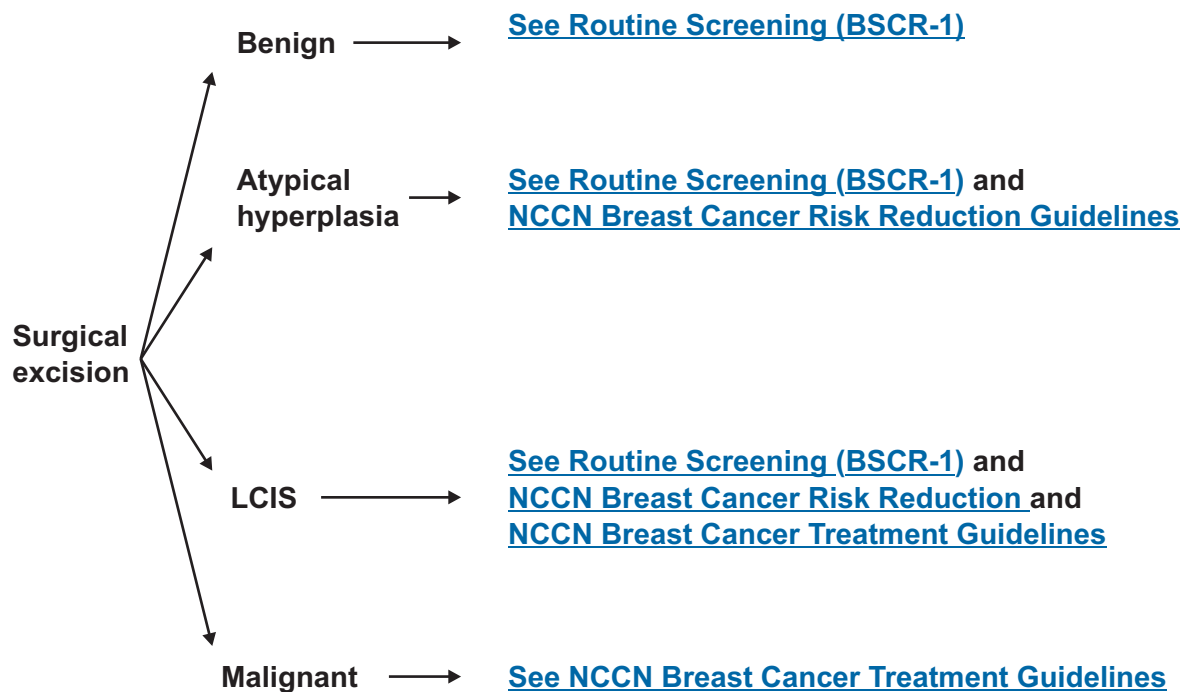
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## FOLLOW-UP EVALUATION



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**BREAST SCREENING CONSIDERATIONS**

- Consider severe comorbid conditions limiting life expectancy and whether therapeutic interventions are planned.
- Upper age limit for screening is not yet established.
- Current evidence does not support the routine use of breast scintigraphy (eg, sestamibi scan), or ductal lavage as screening procedures.
- Current evidence does not support the routine use of breast MRI as a screening procedure, in average risk women.
- There are limited data supporting the use of MRI for breast cancer screening as an adjunct to mammography for high risk women.
- There are limited data supporting the use of ultrasound for breast cancer screening as an adjunct to mammography for high risk women or women with dense breast tissue.
- A single study (DMIST) suggested benefit of digital mammography in young women and women with dense breasts<sup>1</sup>.

<sup>1</sup>Pisano ED, Gatsonis C, Hendrick E et al for the Digital Mammographic Imaging Screening Trial (DMIST) Investigators. Diagnostic performance of digital versus film mammography for breast cancer screening. N Engl J Med 2005;353:1773-1783.

[Back to Physical Examination \(BSCR-1\)](#)

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**RISK FACTORS USED IN THE MODIFIED GAIL MODEL<sup>1</sup>**

- Current age
- Age at menarche
- Age at first live birth or nulliparity
- Number of first-degree relatives with breast cancer
- Number of previous benign breast biopsies
- Atypical hyperplasia in a previous breast biopsy
- Race<sup>2</sup>

For calculation of risk, based on the modified Gail model, see [www.nci.nih.gov](http://www.nci.nih.gov).

<sup>1</sup>For detailed information, see [www.nci.nih.gov](http://www.nci.nih.gov).

<sup>2</sup>The current Gail model may not accurately assess breast cancer risk in non-Caucasian women.

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MAMMOGRAPHIC ASSESSMENT CATEGORY DEFINITIONS<sup>1,2</sup>**A. Assessment Is Incomplete:****Category 0- Need Additional Imaging Evaluation and/or Prior Mammograms For Comparison:**

Finding for which additional evaluation is needed. This is almost always used in a screening situation. Under certain circumstances this category may be used after a full mammographic workup. A recommendation for additional imaging evaluation may include, but is not limited to spot compression, magnification, special mammographic views and ultrasound. Whenever possible, if the study is not negative and does not contain a typically benign finding, the current examination should be compared to previous studies. The radiologist should use judgment on how vigorously to attempt obtaining previous studies. Category 0 should only be used for old film comparison when such comparison is required to make a final assessment.

**B. Assessment Is Complete - Final Assessment Categories:****Category 1: Negative:**

There is nothing to comment on. The breasts are symmetric and no masses, architectural distortion, or suspicious calcifications are present.

**Category 2: Benign Finding(s):**

Like Category 1, this is a "normal" assessment, but here, the interpreter chooses to describe a benign finding in the mammography report. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions such as oil cysts, lipomas, galactoceles, and mixed-density hamartomas all have characteristically benign appearances, and may be labeled with confidence. The interpreter may also choose to describe intramammary lymph nodes, vascular calcifications, implants or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy.

Note that both Category 1 and Category 2 assessments indicate that there is no mammographic evidence of malignancy. The difference is that Category 2 should be used when describing one or more specific benign mammographic findings in the report, whereas Category 1 should be used when no such findings are described.

[See Mammographic Assessment Category Definitions \(page 2 of 2\)](#)

<sup>1</sup>Mammography results are mandated to be reported using Final Assessment categories (Mammography Quality Standards Act, Final Rule. Federal Register 62(208):55988, 1997).

<sup>2</sup>Terminology in this table is reflective of the American College of Radiology (ACR). ACR-BI-RADS<sup>®</sup> - Mammography. 4th Edition. In: *ACR Breast Imaging Reporting and Data System*, Breast Imaging Atlas. Reston VA. American College of Radiology, 2003. For more information, see [www.acr.org](http://www.acr.org).

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**Note:** All recommendations are category 2A unless otherwise indicated.

**Clinical Trials:** NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

MAMMOGRAPHIC ASSESSMENT CATEGORY DEFINITIONS<sup>1,2</sup>  
(continued)**Category 3: Probably Benign Finding - Short Interval Follow-Up Suggested:**

A finding placed in this category should have less than a 2% risk of malignancy. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability.

There are several prospective clinical studies demonstrating the safety and efficacy of initial short-term follow-up for specific mammographic findings.

Three specific findings are described as being probably benign (the noncalcified mass, the focal asymmetry and the cluster of round [punctate] calcifications; the latter is anecdotally considered by some radiologists to be an absolutely benign feature). All the published studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (Category 3) assessment; hence it is inadvisable to render such an assessment when interpreting a screening examination. Also, all the published studies exclude palpable lesions, so the use of a probably benign assessment for a palpable lesion is not supported by scientific data. Finally, evidence from all published studies indicate the need for biopsy rather than continued follow-up when most probably benign findings increase in size or extent.

While the vast majority of findings in this category will be managed with an initial short-term follow-up (6 mo) examination followed by additional examinations until longer-term (2 y or longer) stability is demonstrated, there may be occasions where biopsy is done (patient wishes or clinical concerns).

**Category 4: Suspicious Abnormality - Biopsy Should Be Considered:**

This category is reserved for findings that do not have the classic appearance of malignancy but have a wide range of probability of malignancy that is greater than those in Category 3. Thus, most recommendations of breast interventional procedures will be placed within this category. It is encouraged that the relevant probabilities be indicated so the patient and her physician can make an informed decision on the ultimate course of action.

**Category 5: Highly Suggestive of Malignancy - Appropriate Action Should Be Taken:**

These lesions have a high probability ( $\geq 95\%$ ) of being cancer. This category contains lesions for which one-stage surgical treatment could be considered without preliminary biopsy. However, current oncologic management may require percutaneous tissue sampling as, for example, when sentinel node imaging is included in surgical treatment or when neoadjuvant chemotherapy is administered at the outset.

**Category 6: Known Biopsy - Proven Malignancy - Appropriate Action Should Be Taken:**

This category is reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

<sup>1</sup>Mammography results are mandated to be reported using Final Assessment categories (Mammography Quality Standards Act, Final Rule. Federal Register 62(208):55988, 1997).

<sup>2</sup>Terminology in this table is reflective of the American College of Radiology (ACR). ACR-BI-RADS<sup>®</sup> - Mammography. 4th Edition. In: *ACR Breast Imaging Reporting and Data System*, Breast Imaging Atlas. Reston VA. American College of Radiology, 2003. For more information, see [www.acr.org](http://www.acr.org).

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**Manuscript** This manuscript is being updated to correspond with the newly updated algorithm.

### NCCN Categories of Consensus

**Category 1:** There is uniform NCCN consensus, based on high-level evidence, that the recommendation is appropriate.

**Category 2A:** There is uniform NCCN consensus, based on lower-level evidence including clinical experience, that the recommendation is appropriate.

**Category 2B:** There is nonuniform NCCN consensus (but no major disagreement), based on lower-level evidence including clinical experience, that the recommendation is appropriate.

**Category 3:** There is major NCCN disagreement that the recommendation is appropriate.

**All recommendations are category 2A unless otherwise noted.**

### Overview

The lifetime risk of a woman developing breast cancer in the United States has increased over the past 5 years. One of seven women is at risk based on a life expectancy of 85 years. In 2006, an estimated 214,640 new cases of breast cancer (212,920 women and 1,720 men) will be diagnosed in the United States with 41,430 deaths (40,970 women and 460 men) from this disease are predicted.<sup>1</sup> The good news is that mortality from breast cancer has dropped slightly. This decrease had been attributed, in part, to mammographic screening.<sup>2,3</sup>

A critical key to a continued reduction in mortality is early detection and accurate diagnosis made in a cost-effective manner. Practice

guidelines developed by the National Comprehensive Cancer Network (NCCN) Breast Cancer Screening and Diagnosis Panel are designed to facilitate clinical decision-making.

### Physical Examination

The starting point of these guidelines for screening and evaluating breast abnormalities is physical examination. The general public and health care providers need to be aware that mammography is not a stand-alone procedure. Neither the current technology of mammography nor its subsequent interpretation is foolproof. Clinical judgment is needed to ensure appropriate management. The patient's concerns and physical findings must be considered along with the radiographic and histologic assessment.

### Asymptomatic Women with Negative Physical Findings

If the physical examination is negative in an asymptomatic woman, the next decision point is based on risk stratification. Women can be stratified into two basic categories for the purpose of screening recommendations: those at normal risk and those at increased risk. The increased risk category consists of five groups: (1) women who have previously received therapeutic thoracic irradiation or mantle irradiation; (2) women of 35 years or older with a 5-year risk of invasive breast carcinoma greater than or equal to 1.7%; (3) women with a strong family history or genetic predisposition; (4) women with lobular carcinoma in situ (LCIS) or atypical hyperplasia; and (5) women with a prior history of breast cancer.

Strictly speaking, breast self-examination (BSE) is considered optional in all risk groups because data from a large, randomized trial of BSE screening in Shanghai, China, has shown that instruction in BSE has no effect on reducing breast cancer mortality.

In this study, 266,064 women were randomly assigned to either receive instruction in BSE or not. Compliance was encouraged through feedback and reinforcement sessions. After 10 to 11 years of follow-up, 135 breast cancer deaths in the instruction group and 131 in the control group were observed and the cumulative breast cancer mortality rates were not significantly different between the two arms. The number of benign breast lesions detected in the BSE instruction group was higher than that detected in the control group.<sup>4</sup> However, BSE may detect interval cancers between routine screenings and, therefore, should be encouraged. Periodic, consistent BSE may facilitate breast self-awareness. Premenopausal women may find BSE most informative when performed at the end of menses.

#### Women at Normal Risk

For women between ages 20 and 39 years, a clinical breast examination every 1 to 3 years is recommended, with periodic BSE encouraged. For women ages 40 and older, annual clinical breast examination and screening mammography are recommended, with periodic BSE encouraged. Although controversies persist regarding cost-effectiveness of screening in certain age categories and the diagnostic work-up required of false positives, most medical experts reaffirmed current recommendations supporting screening mammography. This recommendation that women begin annual screening at age 40 is based on a consensus statement from the American Cancer Society. The National Cancer Institute also agreed that screening in this younger age group does decrease mortality from breast cancer.<sup>5</sup> Recent studies have reported a survival benefit in younger women that is equivalent to that seen in women over age 50.<sup>6</sup>

#### Women at Increased Risk

*Women Who Have Received Prior Thoracic Irradiation:* For women aged 25 years and older who have received prior thoracic irradiation, annual mammograms and a clinical breast examination every 6 to 12 months are recommended. Periodic BSE is encouraged. For these patients mammogram screening is usually initiated 8 to 10 years after radiation exposure or after age 40. For women younger than 25, an annual clinical breast examination is recommended and periodic BSE is encouraged.

Results from the Late Effects Study Group<sup>7</sup> indicate that women who received thoracic irradiation in their second or third decade of life have a 35% risk of developing breast cancer by the age of 40. The overall risk associated with prior thoracic irradiation at a young age is 75 times greater than the risk of breast cancer in the general population. Although there is a concern that the cumulative radiation exposure from mammography in a young woman may itself pose a risk for cancer, the benefit of early detection of breast cancer in this high-risk group would outweigh the potential side effect.<sup>8</sup>

*Women Aged 35 Years or Older with a 5-Year Risk of Invasive Breast Carcinoma Greater Than or Equal to 1.7%:* For women age 35 and older, risk assessment tools are available to identify those who are at increased risk. The National Cancer Institute has developed a computerized risk-assessment tool based on the modified Gail model<sup>9</sup> that performs accurate risk projections for women based on a number of risk factors for breast cancer. The modified Gail model assesses the risk of invasive breast cancer as a function of age, menarche, age at first live birth or nulliparity, number of first-degree relatives with breast cancer, number of previous benign breast biopsies, atypical hyperplasia in a previous

breast biopsy, and race. The tool calculates and prints 5-year and lifetime projected probabilities of developing invasive breast cancer and can be used to identify women who are at increased risk. The Gail model, however, may not accurately assess breast cancer risk in non-Caucasian women.

Increased risk of developing breast cancer is defined as a 5-year risk of 1.7% or greater. This is the average risk of a 60-year-old woman, which is the median age of diagnosis of breast cancer in the U.S. The 5-year predicted risk of breast cancer required to enter the National Surgical Adjuvant Breast and Bowel Project (NSABP) prevention trial of tamoxifen versus placebo, as well as the Study of Tamoxifen and Raloxifene (STAR) trial, was 1.7% or greater.

National Cancer Institute (NCI) and the National Surgical Adjuvant Breast and Bowel Project (NSABP) Biostatistics Center have developed an interactive tool to measure a woman's risk of invasive breast cancer, which can be accessed at <http://bcra.nci.nih.gov/brc/>.

For women aged 35 years or older with a risk greater than or equal to 1.7%, clinical breast examinations every 6 to 12 months and annual mammography are recommended, and periodic BSE is encouraged. In addition, women in this group should be asked to consider risk reduction strategies in accordance with the [NCCN Breast Cancer Risk Reduction Guidelines](#).

*Women with a Strong Family History or Genetic Predisposition:* Genetic predisposition is defined by the family history one would use to refer a patient for genetic testing. Women in smaller families with an unusually early onset of breast cancer, particularly those families with male breast cancer should also be considered at genetic risk.

The criteria for genetic predisposition (BRCA 1 mutations) developed by the American Society of Clinical Oncology (ASCO)<sup>10</sup> are as follows:

- A family has more than two breast cancer cases and one or more cases of ovarian cancer diagnosed at any age
- A family has more than three breast cancer cases diagnosed before the age of 50
- A family has sister pair in which one of the following combinations was diagnosed before the age of 50: two breast cancers, two ovarian cancers, or a breast and an ovarian cancer.

ASCO endorsed the following indications for genetic testing in the 2003 updated statement on Genetic Testing for Cancer Susceptibility<sup>11</sup>: (i) personal or family history suggesting genetic cancer susceptibility (ii) the test can be adequately interpreted and (iii) the results will aid in the diagnosis or influence the medical or surgical management of the patient or family members at hereditary risk of cancer.

Women with a genetic predisposition for Hereditary Breast and Ovarian Cancer (HBOC) should have clinical breast exams every 6-12 months and annual mammograms beginning at age 25. Women 25 years or older with a strong family history or other genetic predisposition for breast cancer should have clinical breast exams every 6-12 months and annual mammograms starting 5-10 years prior to the youngest breast cancer case in the family. Periodic BSE is encouraged. Annual MRI (magnetic resonance imaging) is also recommended as an adjunct to mammogram and clinical breast exam. Women younger than age 25 with strong family history or genetic predisposition should have an annual clinical breast exam and be

encouraged to perform periodic BSE. Women in this group should be afforded the opportunity to consider risk reduction strategies in accordance with the [NCCN Breast Cancer Risk Reduction Guidelines](#).

The risk from radiation exposure due to mammography in young women with an inherited cancer predisposition is unknown, and there is concern about whether this genetic factor may increase sensitivity to irradiation. The cumulative risk of breast cancer, however, may be as high as 19% by the age of 40 in women with BRCA1 mutations.<sup>12</sup> Because the overall risk of breast cancer in BRCA1 or BRCA2 mutation carriers is estimated to be 20-fold greater than in the general population, the benefit of screening may justify the radiation exposure.

*Women with LCIS or Atypical Hyperplasia:* LCIS, although not in itself considered to be a site of origin for cancer, is associated with a eight- to ten-fold increase in the relative risk of subsequent development of cancer in either breast. A pathologic diagnosis of atypical hyperplasia confers a four- to five-fold increased relative risk of developing breast cancer. For women with LCIS or atypical hyperplasia, an annual mammogram and clinical breast examination every 6 to 12 months are recommended. Periodic breast self-exam is encouraged. These women should also be asked to consider risk reduction strategies as described in the [NCCN Breast Cancer Risk Reduction Guidelines](#).

Women with prior history of breast cancer should be treated according to the surveillance and follow-up section of the [NCCN Breast Cancer Treatment Guidelines](#).

### **Breast screening considerations**

There are limited data regarding screening of elderly women because most clinical trials for breast screening have used a cutoff

age of 65 or 70 years. With the high incidence of breast cancer in the elderly population, the same screening guidelines used for women who are age 40 or older are recommended. Clinicians should always use judgment when applying screening guidelines. If a patient has severe comorbid conditions limiting her life expectancy and no intervention would occur based on the screening findings, then the patient should not undergo screening.

A second consideration is the time interval of screening in women aged 40 to 49 years. Even though there is agreement between the American Cancer Society and the National Cancer Institute on the benefit of breast cancer screening, the interval of screening remains controversial as to whether or not mammograms should be performed every year or every 1 to 2 years. The NCCN Breast Cancer Screening and Diagnosis Guidelines Panel elected to follow the American Cancer Society guidelines of yearly mammography since mammograms can often detect a lesion 2 years before the lesion is discovered by clinical breast examination. To reduce mortality from breast cancer, yearly screening may be more beneficial.

As mentioned earlier, a survival benefit for BSE has not yet been demonstrated. BSE should be encouraged, however, because it may detect interval cancers between screenings. Women should be familiar with their breasts and promptly report any change to their health care provider. This does not need to be done in any specific formalized education program.<sup>4</sup> Current evidence does not support the use of breast scintigraphy (eg, sestamibi scan) or ductal lavage, MRI in average risk women as routine screening procedures. There are limited data available supporting the use of MRI and ultrasound for breast cancer screening as an adjunct to mammography for high risk women or those with dense breast tissue.

## Mammographic Evaluation

If the results of a screening mammography are normal, the follow-up is routine screening. When screening mammography reveals an abnormal finding, the radiologist should attempt to obtain any prior mammograms. This is most important for lesions that are of low suspicion mammographically. If, after a comparison of films, there is still a questionable area that is not clearly benign, then a diagnostic mammogram, with or without sonography, should be performed.

The decision tree is then based on the Breast Imaging Reporting and Data System (BI-RADS<sup>®</sup>) developed by the American College of Radiology.<sup>13</sup> The purpose of BI-RADS<sup>®</sup> now referred to as Assessment Category Definitions, is to create a uniform system of reporting mammography results with a recommendation associated with each category. The fourth edition of BI-RADS<sup>®</sup> is adopted in this guideline. In this edition, substantive changes have been incorporated and category 6 has been added.

BI-RADS<sup>®</sup> assessments are divided into incomplete (category 0) and assessment categories (category 1, 2, 3, 4, 5, and 6). An “incomplete assessment” refers to a finding for which additional evaluation is necessary. This category is almost always used in the context of a screening situation. Under certain circumstances this category may be used after a full mammographic workup. A recommendation for additional imaging evaluation may include, but is not limited to spot compression, magnification, special mammographic views and ultrasound. Whenever possible, if the study is not negative and does not contain a typical benign finding, the current examination should be compared to previous studies. The radiologist should use judgment on how vigorously to attempt obtaining previous studies.

After the mammographic assessment is completed, the abnormality is placed in one of the following six BI-RADS<sup>®</sup> categories:

1. *Negative*: This is a negative mammogram. The breasts are symmetric, and there are no masses, architectural distortion or suspicious calcification. For example, the screening mammogram shows a small area of questionable abnormality but, after the spot compression views are performed, the finding is considered completely normal and of no clinical concern.
2. *Benign Finding(s)*: This is also a negative mammogram, but there may be an actual finding that is benign. The typical case scenarios include benign-appearing calcifications, such as a calcifying fibroadenoma, an oil cyst, or a lipoma. The interpreter may also choose to describe intramammary lymph nodes, vascular calcification, implants or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy.
3. *Probably Benign Finding(s) - Short-Interval Follow-up Suggested*: This is a mammogram that is usually benign. Close monitoring of the finding is recommended to ensure its stability. The risk of malignancy is estimated to be less than 2%.
4. *Suspicious Abnormality Core needle Biopsy Should Be Considered*: These lesions fall into the category of having a wide range of probability of being malignant but are not obviously malignant mammographically. The risk of malignancy is widely variable and is greater than that for category 3 but less than that for category 5.
5. *Highly Suggestive of Malignancy*: These lesions have a high probability ( 95%) of being a cancer. They include spiculated mass or malignant-appearing pleomorphic calcifications, etc.

6. *Known Biopsy - Proven Malignancy*: This category has been added in this edition for breast lesions identified on the imaging study with biopsy proof of malignancy but prior to definitive therapies.

For categories 1 and 2, in which the mammogram is completely normal or the finding is benign mammographically, the recommendation is routine screening mammography in 1 year.

For category 3 (probably benign), diagnostic mammograms at 6 months, then every 6 to 12 months for 1 to 2 years are appropriate. At the first 6-month follow-up, a unilateral mammogram of the index breast is performed. The 12-month study would be bilateral in women aged 40 years and older so that the contralateral breast is imaged at the appropriate yearly interval. Depending on the level of concern, the patient is then followed, either annually with bilateral mammograms or every 6 months for the breast in question, for a total of 2 years.

If the lesion remains stable or resolves mammographically, the patient resumes routine screening intervals for mammography. If, in any of the interval mammograms, the lesion increases in size or changes its benign characteristics, a biopsy is then performed. The exception to this approach of short-term follow-up is when a return visit is uncertain or the patient is highly anxious or has a strong family history of breast cancer. In those cases, initial biopsy with histologic sampling may be a reasonable option.

For categories 4 and 5, tissue diagnosis using core needle biopsy (preferred) or needle localization excisional biopsy with specimen radiograph is necessary. When a needle biopsy is used (aspiration or core needle biopsy), concordance between the pathology report and the imaging finding must be obtained.<sup>14,15</sup> For example, a negative fine-needle aspiration associated with a spiculated category 5 mass is discordant and clearly would not be an acceptable diagnosis. When

the pathology and the imaging are discordant, the breast imaging should be repeated and additional tissue sampled or excised.

For category 6 (proven malignancy), the patient should be managed according to the [NCCN Breast Cancer Treatment Guidelines](#). If the pathology is benign and concordant with the mammogram risk of suspicion, the patient is followed mammographically and a new baseline mammogram is performed in 6 to 12 months, depending on institutional preferences, or the patient returns to routine screening. However, certain benign histologies diagnosed using core needle biopsy, such as atypical hyperplasia, LCIS, a radial scar or other pathological findings require excisional biopsy because these lesions may have an associated malignant process and the benign diagnosis may represent a sampling error.<sup>16-18</sup>

## Positive Findings on Physical Examination

### Dominant Mass in Breast

A dominant mass is a discrete lesion that can be readily identified during a clinical breast examination. The guidelines separate the evaluation of the dominant mass into two age groups: women aged 30 years or older and women under 30 years of age.

*Women aged 30 years or older*: The main difference in the guidelines for evaluating a dominant mass in women age 30 or older is the increased degree of suspicion of breast cancer. The initial evaluation begins with a bilateral diagnostic mammogram. Observation without further evaluation is not an option. After the mammographic assessment, the abnormality is placed in one of the six BI-RADS<sup>®</sup> categories.

For BI-RADS<sup>®</sup> categories 1, 2, and 3, the next step is to obtain an ultrasound and the findings are discussed below. For BI-RADS<sup>®</sup>

categories 4 and 5, assessment of the geographic correlation between clinical and imaging findings is indicated. If there is a lack of correlation, further evaluation is as for BI-RADS<sup>®</sup> categories 1, 2 or 3. If the imaging findings correlate with the palpable findings, workup of the imaging problem answers the palpable problem. Tissue diagnosis through core needle biopsy (preferred), or needle localization excisional biopsy with specimen radiograph is necessary. When a core needle biopsy is utilized, concordance between the pathology report and imaging finding must be obtained as described in the Mammographic Evaluation section of this manuscript.

### Ultrasound Findings

If ultrasound indicates a solid lesion that is suspicious or indeterminate, tissue biopsy should be obtained using core needle biopsy (preferred) or surgical excision. If the pathology is benign and image concordant with the ultrasound, physical examination with or without ultrasound or mammogram, is recommended every 6 to 12 months for 1 to 2 years to assess stability. Follow-up may be considered at earlier time intervals if clinically indicated. If the solid lesion increases in size, repeat tissue biopsy. Routine breast screening is followed for stable lesions. If the findings are indeterminate, atypical hyperplasia, or benign and image discordant, surgical excision should be performed. Routine breast screening is followed for the confirmed benign lesion. If the lesion is classified as atypical hyperplasia or LCIS, the physician should consider risk reduction therapy according to the [NCCN Breast Cancer Risk Reduction Guidelines](#) and the patient should be counseled to maintain regular breast screening. If the lesion is malignant, the patient is treated according to the [NCCN Breast Cancer Treatment Guidelines](#).

If the solid lesion is on ultrasound is probably benign, several options are available: surgical excision, core needle biopsy (preferred), or observation. If the lesion has been surgically excised and proven to be benign, the patient undergoes routine screening. If the lesion is classified as atypical hyperplasia or LCIS, the physician should consider risk reduction therapy according to the [NCCN Breast Cancer Risk Reduction Guidelines](#) and the patient should be counseled to maintain regular breast screening. Malignant lesions are treated according to the [NCCN Breast Cancer Treatment Guidelines](#). If the option of core needle biopsy is elected, and the result is benign and image concordant, a physical examination with or without ultrasound or mammogram, is recommended every 6 to 12 months for 1 to 2 years to ensure that the lesion is stable. Follow-up may be considered at earlier time intervals if clinically indicated. If the solid lesion increases in size, repeat tissue biopsy. Routine breast screening is followed for stable lesion. If the lesion is indeterminate or atypical hyperplasia, LCIS or benign and image discordant, surgical excision is recommended and the patient is followed as mentioned previously. Observation may be elected only if the lesion is less than 2 cm and there is low clinical suspicion, in which case a physical examination with or without ultrasound or mammogram is recommended every 6 months for 1-2 years to assess stability.

If the ultrasound evaluation reveals the mass to be consistent with an asymptomatic simple cyst, observation for 2-4 months for stability with patient reporting any changes would be appropriate, unless the patient is symptomatic or desires intervention because of anxiety. If a symptomatic or non-simple cyst is found, aspiration should be considered. With an irregular cyst wall or intracystic mass, surgical excision is preferred although ultrasound guided core biopsy and clip placement may assist in diagnosis. If blood-free fluid is obtained on

aspiration and the mass resolves, the patient should be reexamined in 2 to 4 months. If the physical examination remains negative, the patient returns to routine screening. If the mass recurs, further evaluation is required by ultrasound. Alternatively, surgical excision can be considered. If a bloody fluid is obtained on initial aspiration or if the mass persists after aspiration, then ultrasound with image-guided biopsy or surgical excision is warranted. If the ultrasound with image-guided biopsy findings are benign and image concordant, physical exam with or without ultrasound or mammogram every 6-12 months for 1-2 years is recommended. Follow-up may be considered at earlier time intervals if clinically indicated. If the mass increases in size, tissue sampling has to be repeated, where as routine breast screening is recommended if the mass remains stable. If the ultrasound and image guided biopsy findings turn out to be benign and image discordant or intermediate or atypical hyperplasia or LCIS, surgical excision is recommended. If the mass has been surgically excised and proven to be benign, the patient undergoes routine screening. If the mass is classified as atypical hyperplasia or LCIS, routine breast screening along with risk reduction therapy according to the [NCCN Breast Cancer Risk Reduction Guidelines](#) is recommended. For LCIS findings, in addition to the above two options, the patients should be treated according to [NCCN Breast Cancer Treatment Guidelines](#). Malignant findings either on ultrasound with image guided biopsy or surgical excision should be treated according to the [NCCN Breast Cancer Treatment Guidelines](#).

If the lesion cannot be visualized with ultrasound, tissue biopsy (core needle biopsy or excision) or observation at 3-6 months intervals with or without imaging should be considered for 1-2 years to assess stability. If the lesion increases in size, tissue sampling has to be repeated, where as routine breast screening is recommended if the lesion remains stable.

*Women under 30 years of age:* The preferred option for initial evaluation of a dominant mass is to proceed directly to ultrasound. From this point, the decision tree for women under 30 years of age is almost identical to the pathway for older women. The only difference is the need for a diagnostic mammogram, in some situations for the younger women. The other two options are needle sampling and observation. Because the degree of suspicion in women who are under the age of 30 is low, observation of the mass for one or two menstrual cycles is an option. If observation is elected and the mass resolves after one or two menstrual cycles, the patient may return to routine screening. If the mass persists, then needle sampling or ultrasound should be performed. The threshold for needle sampling will be lower for women at increased risk based on prior thoracic irradiation exposure, previous biopsy findings, or a family history of breast cancer, with or without genetic test results. The two outcomes of needle sampling are fluid or no fluid. If no fluid is obtained, ultrasound or fine needle aspiration (FNA) should be performed. The ultrasound findings are managed as previously discussed. If a FNA is performed, a pathologist should evaluate the cellular aspirate. If the cytology is consistent with fibroadenoma, the indications for surgical excision are the patient's level of anxiety, immediate plans for pregnancy, or a history of the mass increasing in size, with the possible differential diagnosis of a phyllodes tumor. If the fibroadenoma is less than 2 cm, observation for 1-2 years is also an option. The recommended observation interval is 3-6 months for 1-2 years. In addition, ultrasound may be considered to obtain size measurement each time and accurately monitor the mass stability. If there is increase in size, tissue sampling has to be repeated, where as routine breast screening is recommended if the lesion remains stable.

If the aspirate is nondiagnostic or indeterminate, ultrasound should be considered. If ultrasound indicates a solid lesion that is indeterminate or suspicious, a diagnostic mammogram should be obtained and further histologic tissue sampling should be performed by core needle or surgical biopsy. The evaluation then proceeds as described under ultrasound findings section for women aged 30 years or older. If cytology study reveals atypical hyperplasia, mammogram with ultrasound should be obtained prior to tissue biopsy. If the histologic evaluation reveals cancer, the patient should be treated according to the [NCCN Breast Cancer Treatment Guidelines](#).

If nontraumatic bloody fluid is obtained on initial aspiration or if the mass persists after aspiration, then ultrasound with image-guided biopsy or surgical excision is warranted. Further management is as for a woman 30 years or older. If blood-free fluid is obtained on aspiration and the mass resolves, the patient should be reexamined in 2 to 4 months. If the physical examination remains negative, the patient returns to routine screening. If the mass persists or recurs, further evaluation is required by ultrasound or surgical excision.

### **Nipple Discharge without a Palpable Mass**

In patients with a nipple discharge but no palpable mass, an evaluation of the character of the nipple discharge is the first step. If the nipple discharge is bilateral and milky, then pregnancy or an endocrine etiology must be considered. Milky secretions are commonly associated with the following medications: psychoactive drugs, antihypertensive medications, opiates, oral contraceptives and estrogen. The appropriate follow-up of a nonspontaneous, multiple-duct discharge in women under age 40 is observation, coupled with education of the patient to stop compression of the breast and to report any spontaneous discharge, if appropriate. In

women aged 40 years or older, screening mammography and a further workup based upon the BI-RADS<sup>®</sup> category along with education similar to that for younger women is recommended.

The most worrisome nipple discharge is one that is persistent, spontaneous, unilateral, serous, sanguinous, or serosanguinous. A guaiac test and cytology of the nipple discharge are optional, as a negative result should not stop further evaluation. Evaluation of this type of nipple discharge is based on the BI-RADS<sup>®</sup> category of the diagnostic mammogram. If the diagnostic mammogram is BI-RADS<sup>®</sup> category 1, 2, or 3, then a ductogram is optional to guide the surgical excision. Ductal excision is indicated for diagnosis of an abnormal nipple discharge, even if the ductogram is negative. However, the ductogram is useful to exclude multiple lesions and to localize the lesions prior to surgery. If the patient has a mammogram that is a BI-RADS<sup>®</sup> category 4 or 5, then the workup should proceed based on the diagnostic mammogram findings. If the findings are benign or intermediate, a ductogram is optional, but surgical duct excision would still be necessary. If the category 4 or 5 mammogram indicates malignancy, the patient should be treated according to the [NCCN Breast Cancer Treatment Guidelines](#).

### **Asymmetric Thickening or Nodularity**

Thickening, nodularity, or asymmetry is distinct from a dominant mass in that the finding is ill defined and often vague on physical breast examination. If the patient is under the age of 30 and has no high risk factors, ultrasound evaluation is appropriate. A mammogram would be performed only if the physical finding were clinically suspicious. Diagnostic mammograms for this age group are fairly low in yield because of the density of the breast and low risk of breast cancer.

In women over the age of 30, bilateral diagnostic mammograms, with or without an ultrasound evaluation should be obtained. If the breast imaging results are abnormal, assessment of the thickening, nodularity, or asymmetry should be performed as previously outlined for a mammographic abnormality.

If the mammogram and ultrasound findings are normal, the patient should be reexamined in 3 to 6 months. If the finding is stable, annual screening can be resumed. If a progressive or clinically suspicious change is noted, however, workup should proceed as for a dominant mass.

### Skin Changes

Any type of unusual skin changes around the breast may represent serious disease and needs evaluation. The initial evaluation begins with a bilateral diagnostic mammogram with or without ultrasound examination. If the mammogram is abnormal, the evaluation proceeds based on the mammogram findings. If the breast imaging results are normal, further workup is still needed.

Punch biopsy of skin or nipple biopsy should be performed for BI-RADS<sup>®</sup> category 1-3. Core needle biopsy (preferred) with or without punch biopsy should be performed of the mammographic lesion or BI-RADS<sup>®</sup> category 4-5. Surgical excision is another option. If the skin biopsy is malignant, the patient should be treated according to the [NCCN Breast Cancer Treatment Guidelines](#). However, if the skin biopsy is benign, a repeat biopsy or punch biopsy of the skin or nipple biopsy (if not previously done) should be performed. Consideration should be given to consultation with a breast specialist.

### Summary

The intent of these guidelines is to give health care providers a practical, consistent framework for screening and evaluating a spectrum of breast lesions. Clinical judgment should always be an important component of the optimal management of the patient.

If the physical breast examination, radiologic imaging, and pathologic findings are not concordant, the clinician should carefully reconsider the assessment of the patient's problem. Incorporating the patient into the health care team's decision-making empowers the patient to determine the level of breast cancer risk that is personally acceptable in the screening or follow-up recommendations.

These guidelines are a statement of consensus of its authors regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The National Comprehensive Cancer Network makes no representations nor warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

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