

BI-RADS and Interpretation of Mammograms: What the Provider Needs to Know

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BI-RADS Background and Overview

The Breast Imaging and Reporting Data System (BI-RADS) was developed by the American College of Radiology (ACR), in collaboration with multiple other organizations, (including CDC) in 1991 to answer concerns about ambiguous mammography reports with indecisive conclusions from radiologists. BI-RADS classification grew out of the need to help the provider reduce morbidity and mortality of patients with breast cancer by appropriate use of breast imaging reporting, tracking, and follow-up.

Mammography Quality Standards Act (MQSA) passed in 1992 to improve overall quality of mammography in the United States, with final rules going into effect in April 1999. The MQSA includes the following requirements:

- 1. Report of results of mammogram must be provided to referring provider within 30 days of the examination.**
- 2. A letter in lay language of results of the mammogram must be provided to the patient by the radiologist.**
- 3. Every mammogram report must include an assessment category based on the BI-RADS system.**

The CDC requires all facilities participating in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) to report their results using the BI-RADS assessment categories.

The six BI-RADS reporting categories represent gradations of the likelihood that a cancer exists, from lowest to highest probability.

Category 0: Assessment Incomplete - additional imaging needed.

Category 1: Negative

Category 2: Benign Findings - negative

Category 3: Probably Benign - short interval follow-up suggested.

Category 4: Suspicious Abnormality - biopsy should be considered.

Category 5: Highly suggestive of malignancy - appropriate action should be taken.

BI-RADS Categories - Provider action and Responsibilities

Category 0:

Formal Definition: “Findings for which additional imaging evaluation is needed. This is almost always used in a SCREENING situation. Recommendation of additional imaging includes the use of spot compression, magnification, special mammographic views, ultrasound, etc.”

Provider Responsibilities must include working in concert with the radiologist to assure that the patient returns for additional imaging, usually on a different day. It is **IMPERATIVE** that the patient return, as no final assessment has been assigned, and the evaluation of the mammographic abnormality is by definition incomplete.

Category 1:

Formal Definition: “Negative Examination — nothing to comment on. Recommendation is to continue with routine screening in one year, if the patient is 40 or older.”

Provider Responsibility: Assure as much as possible that the patient returns for the next screening in one year.

Exception: Patient with a palpable lump. Here, decision to biopsy should be based on clinical assessment.

Category 2:

Formal Definition: “There is a finding on the mammogram, but it is a benign or negative finding. Recommendation is again for routine screening in one year, if the patient is 40 years of age or older.”

Includes: Typically benign masses (fat containing), typically benign calcifications, and typically benign skin lesions, some of which may initially may have been placed in Category 0 and not found to be typically benign until **AFTER** additional evaluation is completed.

Provider Responsibility: Assure as much as possible that the patient returns for the next screening in one year.

Category 3:

Formal Definition: “Probably benign findings - short interval follow-up suggested. A finding placed in this category should have a very high probability of being benign (greater than 98%). It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability.”

Applies ONLY to:

- Non-palpable lesions
- Cases where comparison of prior films has been performed before interpretation, if available.
- Cases evaluated with supplemental work-up, including additional mammographic views and/or ultrasound **PRIOR** to being placed in Category 3.
- Cases in which proper use of interpretive criteria in evaluating breast lesions has been applied.

Includes certain clustered calcifications, non-calcified solitary solid masses, focal asymmetric densities with concave borders, single dilated ducts without discharge, architectural distortion at a surgical site, multiple benign appearing masses, multiple clusters of round or oval calcifications, and scattered round or oval calcifications.

Lesions should be placed in Category 3 only AFTER a complete imaging evaluation. No case should be placed in this category directly from screening.

Occasionally, a patient may desire core needle biopsy or excisional biopsy for a Category 3 lesion if she does not wish to wait six months for a follow-up mammogram or if she has an inordinate fear of breast cancer. In these situations, the provider should work with the radiologist to help the patient obtain the appropriate follow-up for her individual situation.

If the lesion is stable, then evaluation usually includes a bilateral mammogram six months following the initial six-month follow-up, to return the patient to routine screening. The patient should then be placed on yearly mammography thereafter.

Provider Responsibility: Help the radiologist in getting the patient to return for short interval follow-up (usually six months), in a timely fashion.

Category 4

Formal Definition: “Lesions that do not have the characteristic morphologies of breast cancer, but have a definite probability (between 10% and 90%) of being malignant. The radiologist has sufficient concern to urge a biopsy. Tissue diagnosis of these lesions is MANDATORY.”

Includes benign-appearing solid lesions that grow over time, atypical solid masses without spiculation or distinct margins, focal architectural distortion, amorphous or indistinct calcifications (low grade DCIS).

Provider Responsibility: Assure that tissue diagnosis is obtained in a timely fashion, either by needle biopsy or excisional biopsy.

Category 5:

Formal Definition: “Highly suggestive of malignancy (greater than 90% probability). Again, tissue diagnosis is MANDATORY.”

Includes spiculated mass, pleomorphic or heterogeneous calcifications, branching or linear calcifications (high grade DCIS).

Provider Responsibility: Assure that tissue diagnosis is obtained in a timely fashion, either by needle biopsy or excisional biopsy.

BI-RADS - Significance for the provider and assuring proper follow-up for the patient

The provider's recommendation is the single most powerful influence in the patient's screening adherence and return for follow-up. Providers therefore **MUST** believe in their ability to affect patients' behavior.

Those patients most likely to have incomplete follow-up include those who:

1. Have never had a mammogram
2. Are age 65 or older
3. Have had fewer mammograms in the last five years
4. Have lower household income, or lower socio-economic status
5. Lack insurance coverage
6. Have less education
7. Self report their own health as "fair" or "poor"
8. Feel they are "too old" for treatment or desire "not to know if something is wrong"
9. Receive services from a provider other than the primary care provider.
10. Have a test result of BI-RADS Category 3 (probably benign). These patients often mistakenly equate early follow-up with definite benign diagnosis. They must be made to understand that a lesion is benign **ONLY** if it is stable over time.
11. Report difficulty in getting an appointment.
12. Have transportation problems.

Providers can take steps to increase adherence to follow-up and offer the patient help by:

1. Scheduling appointments, providing reminders, and shortening the waiting time of this interval. The uncertainty of diagnosis often is more stressful than receiving a diagnosis of cancer.
2. Identifying potential barriers and helping the patient find solutions to problems.
3. Writing a prescription for follow-up procedures, which both reinforces the patient's ability to adhere to advice and is now required **BY LAW** for virtually all patients in New Mexico.

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