

D. FREQUENTLY ASKED QUESTIONS

1. ***Do the FDA mammography regulations require that BI-RADS® categories be assigned to MR examinations?***

No, the FDA mammography regulations do not apply to MRI; however, the ACR does recommend using BI-RADS® final assessment codes for MR examinations.

2. ***A patient's breast MRI exam resulted in a BI-RADS® category 2 assessment (Benign); her mammography exam resulted in a BI-RADS® category 4 assessment (Suspicious). The patient has a previous history of malignancy following lumpectomy, and her physician believes that the area needs a biopsy. If the mammography report disagrees with the breast MRI exam, is it appropriate to recommend a biopsy in the impression of the breast MRI report based on the positive mammogram?***

Yes, you may include a recommendation for biopsy in your breast MRI report in a separate sentence after having rendered a benign assessment, explaining that a biopsy is recommended based on suspicious mammographic findings. If your reporting system has a combined module that includes all three breast imaging modalities (mammography, US, and MRI), appropriate letters will be sent to clinicians and patients based on the most serious BI-RADS® category (in this case category 4). Also, as a general rule, imaging studies should not be used to contradict a biopsy from another breast imaging study.

3. ***A screening mammography examination received an incomplete assessment (BI-RADS® category 0) due to an abnormal asymmetry. The subsequent diagnostic mammography examination is also BI-RADS® category 0. A US examination then is performed that is assessed as negative (BI-RADS® category 1). Even though the US is negative, I want to further evaluate this patient with MRI because the mammography examination was of concern. If I issue an overall final assessment for all of the procedures, how should I determine the appropriate assessment category to ensure proper care?***

This question involves two nonrecommended uses of BI-RADS® category 0. First, with few uncommon exceptions, category 0 should not be used for diagnostic mammography examinations. Therefore, if diagnostic mammography is performed in conjunction with US, an overall BI-RADS® assessment category should be given (rather than a category 0 assessment for the mammography followed by a category 1 assessment for the US). The overall assessment would depend on the mammographic and sonographic findings and whether benign findings are or are not described in the diagnostic breast imaging report. Refer to the following examples.

- If no findings are described in either the mammography or US portions of the report, the appropriate overall assessment is negative (BI-RADS® category 1).
- If one or more specific benign findings are described in either the mammography or US portions of the report, the appropriate overall assessment is benign (BI-RADS® category 2).
- If diagnostic mammography depicts a focal asymmetry with no associated mass, calcifications, or architectural distortion; if there is no sonographic or palpable correlate to the mammographic finding; and if there are no prior mammography examinations available for comparison, it may be appropriate to render a probably benign (BI-RADS® category 3) assessment.
- If diagnostic mammography indicates the presence of a suspicious abnormality despite absence of a sonographic correlate (or vice versa), the appropriate overall assessment is suspicious (BI-RADS® category 4).

Second, BI-RADS® category 0 should **not be used for diagnostic breast imaging findings that warrant further evaluation with MRI**. Rather, the radiologist should issue a final assessment for the combined diagnostic mammography and US examinations in a report that is made **before** the MRI is performed. If further evaluation with MRI is warranted, the radiologist should incorporate this recommendation into the patient management recommendations in the combined mammography/US report. This provides the following advantages:

- If the recommended MRI examination is not performed, the combined diagnostic breast imaging report will stand as issued.
- If MRI is performed as recommended, it would not be necessary to re-interpret the mammography and US examinations. A negative or benign MRI assessment would sustain a similar assessment made at diagnostic mammography and US. If the MRI examination shows more abnormal findings than those identified at mammography and US, the MRI assessment would supersede that made for mammography and US.

Also note that breast MRI is not appropriate follow-up in many situations, including:

- Instead of biopsy of a suspicious finding at mammography and/or US.
- As an alternative to short-interval follow-up of probably benign findings at mammography and/or US.
- To further evaluate findings that should be recognized as benign at mammography and/or US, such as gynecomastia or multiple bilateral partially circumscribed, partially obscured masses. Also most lymph nodes and fat necrosis may be characterized as benign at mammography and/or US.

MRI is rarely helpful in further evaluation of possible architectural distortion that is too vague to target for stereotactic or sonographic biopsy.

4. What happens if additional imaging following a BIRADS® 0 assessment does not show a benign finding?

Short-interval follow-up or biopsy would most likely be necessary. The MR interpretation should be detailed with descriptions of any and all abnormalities with the level of suspicion, so that the radiologist performing the additional imaging does not need to reinterpret the original MR examination.

5. Axillary adenopathy is seen at screening MRI with no suspicious findings in the breasts. What should the BI-RADS® final assessment be?

In the absence of a known infectious or inflammatory cause, isolated **unilateral** axillary adenopathy should receive a suspicious (BI-RADS® category 4) assessment. Unilateral axillary adenopathy suggests occult breast carcinoma or, much less commonly, lymphoma, metastatic melanoma, ovarian cancer, or other metastatic cancer. Consequently, a careful search of the ipsilateral breast images is warranted. Bilateral axillary US may be performed to confirm that the finding is asymmetric/unilateral. Clinical evaluation for infection or inflammation in the ipsilateral breast, axilla, arm, and hand is recommended at the time of US, as mastitis, breast abscess, an infected skin lesion, and cat scratch fever are all potential sources of benign unilateral axillary adenopathy. If a benign cause is elucidated, a benign (BI-RADS® category 2) assessment would be appropriate. In the absence of a known infectious or inflammatory source, a suspicious (BI-RADS® category 4) assessment would be appropriate, with the intent to biopsy after further evaluation and review of the clinical history. It is then appropriate to proceed with US-guided

fine-needle aspiration (FNA) or core biopsy, and it may be advisable to perform ipsilateral whole-breast US at that visit to search for an occult primary breast carcinoma.

Bilateral axillary adenopathy would be assessed as benign (BI-RADS® category 2) in some situations and as suspicious (BI-RADS® category 4) in others. Bilateral axillary adenopathy is frequently reactive/infectious in origin, such as with inflammatory conditions (sarcoidosis, systemic lupus erythematosus, psoriasis, etc.) and HIV. In such situations, the appropriate assessment is benign (BI-RADS® category 2). Patients with known lymphoma or leukemia may also have bilateral axillary adenopathy. In this situation, the BI-RADS® assessment should be based on findings in the breasts themselves, but the report also should indicate the presence of adenopathy and the known underlying disease. For example, a report might indicate a negative or benign assessment, followed by “with bilateral axillary adenopathy presumed due to known lymphoma.” It may be helpful to have an assistant contact the referring health care provider to clarify whether there is such a history before issuing a final report. If there is no known explanation for bilateral adenopathy, and particularly if it is new, then it may be a sign of lymphoma/leukemia, and a suspicious (BI-RADS® category 4) assessment is warranted, with a recommendation for US-guided FNA or core biopsy. Note that ideally, biopsy specimens should be kept in saline or RPMI 1640 if lymphoma is suspected, to facilitate fluorescence-activated cell sorting.

6. What assessment category should be used for a breast MRI exam for implant integrity (i.e., one that demonstrates intact or ruptured implants)? Should such exams be audited as TP, FP, TN, or FN?

Implant assessments should not be assigned a BI-RADS® assessment category. They do not include imaging of breast tissue.