

ST. ANYWHERE BREAST CENTER

BREAST IMAGING ORDERING INFORMATION¹

Mammography is one of the most highly regulated areas of medicine. In addition to the periodic review of a center's quality assurance program and statistics by the FDA (MQSA), most of the services provided are classified as Designated Health Services. Thus the accuracy of our data, and the integrity of our ordering system are very important.

Occasionally we encounter a patient who comes for her yearly screening mammogram who has developed signs or symptoms since her last doctor's visit or exam, or who has the mammogram appointment scheduled before her office visit so the referring physician is unaware of the patient's physical finding or complaint. In these situations your office will be notified and the appropriate examination will be performed.

With the exception of a screening mammogram, which does not require justification or a reason for the exam, the clinical information accompanying the imaging requisition must support the examination that is ordered. A screening exam does, however, require that sufficient time has passed since the woman's last screening mammogram. For Medicare the screening exam will be paid if performed not less than 11 months following the previous exam, but most third party payors require that 365 days have passed since the date of the last screening mammogram.

There are many challenges to the operation of a Women's Center and we realize that patients and physicians are tasked with complying with a seemingly never-ending series of rules and regulations. We also recognize that the patient with a high deductible or insurance coverage that may only cover screening exams and not diagnostic studies or vice versa may request that her study be ordered in such a manner as to assure insurance payment rather than out-of-pocket expense. This is a difficult dilemma. However, we are both required by Federal regulations to perform, document and bill for the procedure that is appropriate for the clinical situation and, if a patient shows up with an incorrect order, we will notify your office and the patient and a new order will be requested, which could delay her service.

Conditional Contingent Orders

The detection and diagnosis of breast cancer is complex, often involving an individualized sequence of diagnostic tests, each of which is dependent on the results

At times, the decision to proceed with further testing will depend on the results of a first-line imaging examination. For example, a physician treating a patient with a non-normal mammogram or who is symptomatic might order a diagnostic mammogram, but would be interested in a diagnostic ultrasound if the mammogram failed to resolve the diagnostic question. It is appropriate to order the ultrasound at the same time as the mammogram, but on a conditional basis, with the second procedure performed conditioned on and contingent upon the failure of the first exam to resolve the concerns that prompted the order.

Conditional or conditional contingent orders must not be routine, but should be used selectively on a case-by-case basis. Due to the clear potential for abuse, the federal government frowns upon any policy of always adding on additional examinations. We neither encourage nor discourage the use of conditional orders – they are simply a time and patient anxiety saver when used appropriately. We are, however, guided by evidence-based protocols, and these protocols form the basis for our conditional or contingent orders.

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Advance Beneficiary Notices

Medicare or other payers do not prohibit us from performing services they deem “not medically necessary.” However, in these instances, the patient is responsible for payment, either out-of-pocket or via a secondary insurer. In order to establish that the patient has been informed of his or her financial obligation prior to receiving the service, we are required to obtain the patient’s signature on an Advance Beneficiary Notice (ABN). This Medicare-approved form explains the process to the patient, and our staff is required to give the estimated cost up front and in writing. Advance Beneficiary Notices may not be obtained after the service is rendered.

The act of signing an ABN does not inevitably mean that your patient will have to pay for the examination. If, when we contact your office, you provide us in good faith with further historical information that allows the legitimate addition of an approved ICD-9 code, then the patient’s bill will be submitted to, and payable by, third party payers in the usual fashion.

If we have exhausted all reasonable possibilities to obtain insurance payment, we are required by law to make good faith efforts to collect our charges directly from the patient. We recognize that many seniors live on fixed incomes, and that they and others may simply be unable to pay our stated fee. We are happy to work with your patients to arrive at a fee adjustment in cases of genuine financial hardship.

By asking the patient to sign an ABN, our only goal is compliance with the law. We are sensitive to referring physicians’ concerns that patients might understandably draw the wrong conclusions from an implied doubt on our part about the necessity of the service you have ordered. Questioning your clinical judgment is not our intent, and we will do everything possible to explain the situation to your patient.

BREAST IMAGING

BI-RADS®

BI-RADS is the abbreviation for Breast Imaging Reporting and Database System. It is a quality assurance guide designed to standardize breast-imaging reporting and to facilitate outcome monitoring. It serves as a comprehensive guide providing standardized breast imaging terminology, report organization and assessment structure, as well as a classification system for mammography, ultrasound, and MRI of the breast. Each BI-RADS category has a follow-up recommendation associated with it to help radiologists and referring providers appropriately manage a patient's care.

You will find a BI-RADS assessment at the end of each breast imaging report with a recommendation for follow-up based on the BI-RADS assessment category. The following table summarizes the various BI-RADS categories, what an assessment means, and the follow-up recommendations.

BI-RADS			
Category	Definition	Cancer Risk	Follow-up Recommendations
Assessment is Incomplete			
0	Need additional imaging evaluation and /or prior mammogram for comparison	-----	Additional imaging and/or prior images are needed before a final assessment can be assigned
Assessment is Complete			
1	Negative	0%	
2	Benign	0%	
3	Probably Benign	≤2%	
4	Suspicious Abnormality – with the following subdivisions		
4a	Low suspicion	>2 and ≤10%	Biopsy recommended
4b	Intermediate suspicion	>10 and ≤50%	Biopsy recommended
4c	Moderate suspicion	>50 and ≤95%	Biopsy recommended
5	Highly suggestive of CA	≥95%	Requires biopsy or surgical treatment
6	Known biopsy proven CA	100%	Appropriate action should be taken

ST. ANYWHERE BREAST CENTER	CONDITIONAL CONTINGENT ORDERS
	PROTOCOLS

BREAST CANCER SCREENING

Policy: *Radiologist to perform screening appropriate to the relative risk of breast cancer for each individual woman, taking into account both the absolute risk of cancer, and also the risk of missing a cancer on mammography that is created by breast tissue density.*

For women categorized as being at high-risk by the American Cancer Society, breast MRI will be offered, adjuvant to screening mammography beginning at age 30, and continuing annually from then forward.

Women who are at low or intermediate risk will receive screening mammography annually beginning at age 40, pursuant to the recommendations of Medicare and the American College of Radiology. As a part of that exam, breast tissue density will be objectively assessed and, if individual density is found to be in the upper two quartiles (BI-RADS density c-d), she will be offered screening breast ultrasound to augment the mammogram.

Screening Mammography: An x-ray of the breast in an asymptomatic woman for the purpose of early detection of breast cancer.

- Routine or annual exam
- No symptoms or new clinical findings

BREAST CANCER DIAGNOSIS

Policy: *Radiologist to perform the appropriate procedures up to and including core biopsy for a suspicious abnormality identified on clinical exam, mammography, ultrasound or breast MRI. Work-up and evaluation will be based on the BI-RADS assessment.*

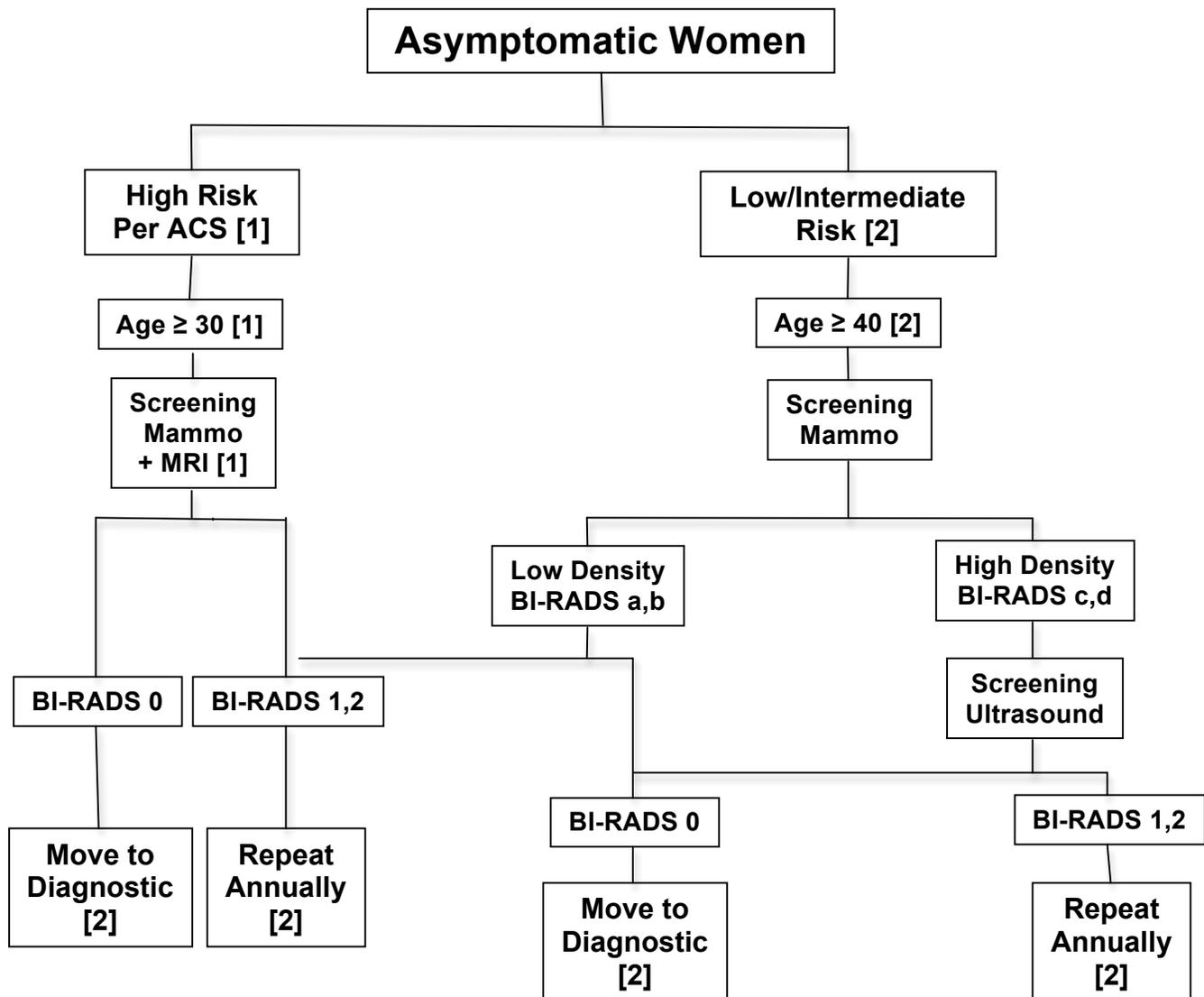
For patients recently diagnosed with breast cancer, a bilateral contrast enhanced breast MRI will be performed as a staging exam to determine the extent of disease prior to surgical or oncologic management (American Cancer Society Guidelines, 2007). MRI findings requiring further diagnostic imaging evaluation will be scheduled and performed up to and including additional biopsies.

Diagnostic Mammography: An x-ray of the breast in a woman or man referred for evaluation of:

- Breast symptoms
 - Focal pain
 - Nipple discharge
 - Patient implant problem
 - Breast Trauma
- New findings on breast exam
 - Palpable abnormality – lump, mass or thickening
 - Skin thickening or retraction
 - Nipple abnormality – inverted nipple
 - Large axillary lymph nodes
 - Change in breast size or shape – gynecomastia, shrinkage
- Follow-up exam
 - Additional evaluation following screening exam (BI-RADS 0)
 - Microcalcifications
 - Focal asymmetry/Asymmetric density
 - Architectural distortion
 - Short term follow-up exam (BI-RADS 3)
 - Patient with personal history of breast cancer
- Other
 - Adenocarcinoma metastasis, primary unknown

**ST. ANYWHERE
BREAST CENTER**

**CONDITIONAL CONTINGENT
ORDERS
PROTOCOLS - SCREENING**

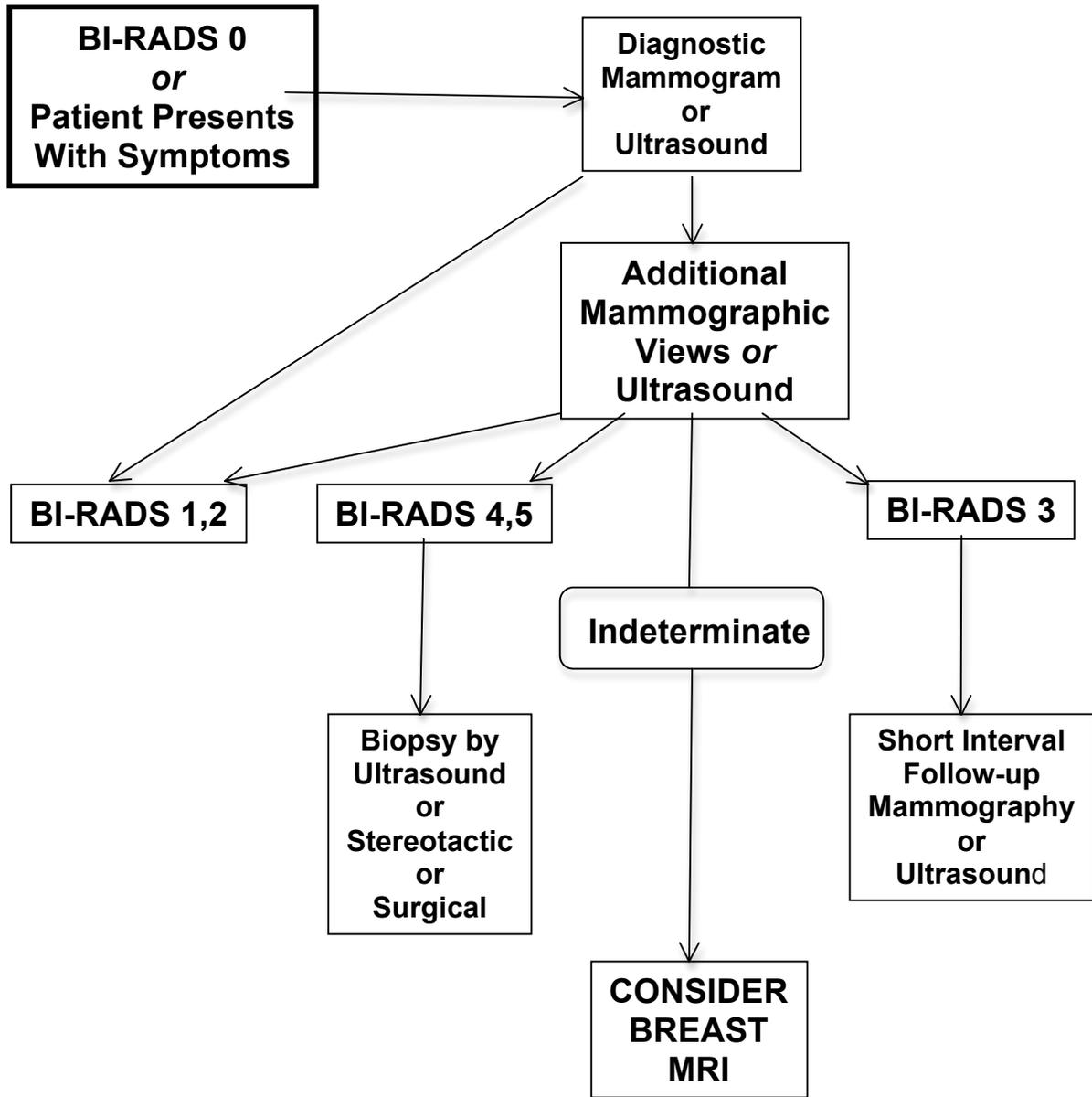


[1] Saslow D, Boetes C, Burke W, et al. American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. *CA Cancer J Clin.* 2007;57:75-89.

[2] Mahoney MC, Newell MS, Bailey L, et al. ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography. Reston, VA. American College of Radiology. Revised 2013 (Res. 11) http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Screening_Mammography.pdf, accessed September 28, 2013.

ST. ANYWHERE BREAST CENTER	CONDITIONAL CONTINGENT ORDERS
	PROTOCOLS – DIAGNOSTIC (1)

1 — NO MAMMOGRAPHIC FINDING OR PRE MRI



**ST. ANYWHERE
BREAST CENTER**

CONDITIONAL CONTINGENT
ORDERS
PROTOCOLS – DIAGNOSTIC (2)

2 – MRI

