GUIDELINES FOR ORDERING

BREAST IMAGING EXAMINATIONS[1]

One of the challenges of medical practice in the twenty-first century is ordering imaging studies in a manner that provides your patients and you with prompt, efficient and appropriate imaging, while meeting a large and often intimidating body of regulatory requirements. These guidelines are offered as a compendium of recommendations for ordering breast imaging examinations and have been prepared from regulations promulgated by the Centers for Medicare and Medicaid Services (CMS), appropriateness criteria published by the American College of Radiology (ACR) and the American Cancer Society (ACS) and, where appropriate, current medical evidence as published in peer reviewed publications.

As with any information that is based on both regulations and medical evidence, the guidelines presented below can only represent the information available at the time they are being written. While they are believed to be an accurate portrayal of the subject, the reader is encouraged to investigate the resources cited to form his or her own impressions of the strength and accuracy of the guidelines.

Patient History and Diagnosis Documentation

Medicare documentation rules require that any imaging test or procedure billed to Medicare must be:

1. Ordered by the patient's treating physician or other approved health care provider;
2. Medically necessary for the treatment of the patient; and,
3. Properly documented with sufficient patient history or diagnoses to establish medical necessity as defined by Medicare.

The recent CMS Program Memorandum Transmittal B-01-61, "ICD-9-CM Coding for Diagnostic Tests," sets out certain important ground rules. First, CMS requires "referring physicians . . . to provide diagnostic information to the testing entity at the time the test is ordered." Second, the interpreting physician (in this case, radiologist) "should code the ICD-9-CM code that provides the highest degree of accuracy and completeness for the diagnosis resulting from the test, or for the sign(s)/symptom(s) that prompted the ordering of the test." Third, an order may include "a written document signed by the treating physician/practitioner," "a telephone call [or] an electronic mail by the treating physician/practitioner or his/her office to the testing facility." CMS goes on to state: "If the order is communicated via telephone, both the treating physician/practitioner or his/her office and the testing facility must document the telephone call in their respective copies of the beneficiary's medical record." Fourth, " . . . when the interpreting physician does not have diagnostic information as to the reason for the test, and the referring physician is unavailable to provide such information, it is appropriate to obtain the information directly from the patient. However, an attempt should be made to confirm . . . by contacting the referring physician."

As a radiology practice we are required by law to retain the treating physician's order for any examination that we perform, and to produce this order in case of an audit. Our staff may from time to time find it necessary to telephone or otherwise contact your office for additional supporting historical or diagnostic information during the scheduling or registration of your patients. We apologize in advance for any inconvenience that this may cause you and your office staff, but

we are obliged to follow the law. In order to head off most of these potential calls, please:

1. Provide a finding at the highest level of specificity that has been attained for the patient's condition. For example, "palpable lesion 4cm from nipple in upper outer quadrant of right breast" is preferable to "palpable" when requesting a diagnostic ultrasound.
2. List symptoms or signs as the reason for a test, if that is your highest level of certainty. It is helpful to then state a "rule out" or "possible" diagnosis to guide us as to your thinking.
3. Avoid using diagnostic terms like "tumor", "cancer", or "mass" prior to definitive diagnosis.
4. Feel free to specify conditions by using actual ICD-9 codes, if they are available and appropriate.

Determination of Medical Necessity

Medicare publishes its standards of medical necessity as Local Medical Review Policies, or LMRP's. These policies cover a variety of services of interest to CMS, and list the approved range of ICD-9-CM codes for substantiating the medical necessity of each service, grouped under each CPT code.

Our staff will consult the LMRP appropriate for the examination you have ordered, if one has been published. If the patient's stated history or diagnosis does not support medical necessity, as defined by Medicare, we will make every attempt to contact your office for additional historical information which might further clarify your diagnostic concerns. Please do not give us, or allow your staff to give us, incorrect or inaccurate information intended solely to establish medical necessity. We prohibit our staff from coaching or directing any provider to supply inaccurate diagnosis or historical data for the purpose of inappropriately justifying medical necessity. Once again, we have adopted this policy to remain in compliance with the law.

Advance Beneficiary Notices

Medicare and other payers do not prohibit us from performing services they deems "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. ABNs 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, Medicare in the usual fashion. Some patients have secondary, or MediGap; insurance that may pay most or all of our charges. Finally, Medicare regulations now permit retrospective coding, meaning that ICD-9 coding may reflect diagnoses made as a result of the test itself.

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. Ques-

tioning your clinical judgment is not our intent, and we will do everything possible to explain the situation to your patient.

Most physicians do not wish to subject their patients to anxiety by giving them prescriptions that have “R/O cancer” or other potentially serious diagnoses. Once again, listing the symptoms leading up to your decision to order the test will usually suffice. Alternatively, please send a confidential FAX requisition with the appropriate history directly to us.

Frequently Linked Examinations

Please remember to list all desired imaging examinations on the patient’s written order form. Medicare rules specifically prohibit us from adding additional imaging studies beyond those requested by the treating physician/practitioner, except in cases of true medical emergency. Sequential diagnostic examinations are probably the most frequently encountered linked examinations. For example, if only a diagnostic mammogram is ordered for “palpable lesion in the right breast,” we are technically not allowed to add a breast ultrasound without obtaining a new written order. We are not allowed to substantially change or add to your written order unilaterally, even if we feel we know exactly what you meant to say.

Conditional Contingent Orders

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, any policy of ***always*** adding on additional examinations is frowned upon by the federal government. We follow carefully defined, evidence-based, protocols (see *Breast Imaging Protocols* attached) and add procedures ***only*** when they are clinically indicated. 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. A discussion of our breast imaging protocol follows in the appendix to this document.

The Breast Imaging Continuum

Screening Mammography

With rare exceptions (e.g., screening mammography, bone density) Medicare does not cover preventive or screening services. If ordered incorrectly, a fully justified procedure or test could easily seem to fall into the “screening” category to a Medicare auditor. It is important, therefore, to support an order with information regarding the medical reason for the examination.

Naturally, a screening mammogram does not require detailed reasons for the order, but it does require that the patient be asymptomatic, meet the age requirements of the third party administrator (TPA) (e.g., age 40 or over for Medicare), and that the appropriate interval have passed since the previous mammogram (e.g., be delivered in the 12th month following the prior screening mammogram (Medicare) or greater than 365 days in the case of most commercial payers).

Documentation of the reason for the exam is critically important because some examinations, like mammography, may in different applications be considered as screening in one instance,

and diagnostic in another. Proper categorization is required both to assure the proper focus for the exam, and because under the Affordable Care Act, specific screening or preventative services, including the screening mammogram, provide for a waiver of deductible and copayment provisions that would apply to the diagnostic application of the same procedure.

The ACR defines the indications for a screening mammogram as:

1. Annually for asymptomatic women age 40 and older who are at average risk for breast cancer.
2. Asymptomatic women under age 40 who are at increased risk for breast cancer.
    a. Woman with known mutation or genetic syndrome with increased breast cancer risk: yearly starting by age 30, but not before age 25.
    b. Untested woman with a first-degree relative with known BRCA mutation: yearly starting by age 30, but not before age 25.
    c. Woman with a 20% or greater lifetime risk for breast cancer based on breast cancer risk models: yearly starting by age 30, but not before age 25, or 10 years earlier than the age at which the youngest first-degree relative was diagnosed, whichever is later.
    d. Woman with a history of chest (mantle) radiation received between the ages of 10 and 30: yearly starting 8 years after the radiation therapy, but not before age 25.
    e. Women with biopsy-proven lobular neoplasia, atypical ductal hyperplasia (ADH), ductal carcinoma in-situ (DCIS), invasive breast cancer, or ovarian cancer; yearly from time of diagnosis, regardless of age.[1]

It is important to note that screening mammograms can be scheduled for times when a physician is not present, but that diagnostic mammograms specifically require "direct supervision" of the physician. "If a woman arriving for a screening examination indicates she has a clinical problem . . . [the exam must be] converted into a diagnostic case . . .[1] and this will often result in a requirement that the patient be rescheduled or wait for a diagnostic appointment time to open up. Careful ordering will eliminate this delay and inconvenience.

Women with implants may undergo screening mammography[1], but the procedure requires a special technique and is usually scheduled as a diagnostic appointment in order to assure that the additional time required is allocated. Please make certain that we know if a woman has implants at the time her mammogram is ordered.

Under MQSA we are required to provide a report of the mammography examination to the ordering physician and to the patient within 30-days of the examination. Our policy is to provide these results within a much shorter period – generally within a few days. Because evaluation of prior mammograms is a part of screening interpretation, the lack of availability of prior images may impact our efforts to deliver a speedy report for new patients. If prior images are not available, we may need to recall the patient for additional imaging that would be unnecessary if the prior images could be utilized for comparison.

If the patient's mammogram is not interpreted as normal or benign, we will recall her for additional imaging. The patient recall does **not** mean that the patient has cancer. In most women who are recalled for additional imaging, the additional imaging is required simply to allow the radiologist to resolve an ambiguity in the screening images. When additional imaging is required we notify the patient directly and schedule her appointment as soon as possible to avoid unnecessary anxiety.

We assess the patient's breast density at the time of her screening mammogram and, if she has dense breast tissue, we offer her screening breast ultrasound.

Screening Breast Ultrasound

Mortality from breast cancer has been clearly linked to tumor size.[2] It has long been recognized that the sensitivity of the mammogram (e.g., ability of the radiologist to identify characteristics that might indicate a breast cancer decreases with increasing fibroglandular density), and that the particular impact of reduced sensitivity is on the detection of smaller, more treatable cancers.

Over the past fifteen years, and particularly within the last five years, the evidence has been mounting that screening ultrasound, used adjunctively with screening mammography, can improve the detection of small cancers in women with dense breast tissue.[3,4,5,6] The results of these studies, performed with handheld ultrasound, have been also been validated for automated breast ultrasound.[7,8,9]

The evidence has been persuasive, and has sparked the grassroots efforts in many states to legislate reporting of breast density directly to women as a part of their screening mammography reports. While this practice does not believe that legislation has a place in medicine, we do believe that breast density impacts early detection and in the importance that screening breast ultrasound can play in early detection. In fact, the experience in Connecticut, the first state to adopt such legislation, found an approximate doubling of detected cancers in women when whole breast ultrasound was added for women with dense breast tissue who had normal mammograms.[10,11]

We offer screening breast ultrasound for all women with dense breast tissue on the day of their screening mammogram. [Supplemental information on breast density and screening ultrasound has been furnished for your review.] Not all insurance companies or other payers reimburse for screening ultrasound. There is a procedure code for ultrasound (CPT™ 76645) and a diagnosis code that distinguishes the screening procedure from a diagnostic ultrasound (ICD-9 793.82), but ultrasound has only been recognized in the screening armamentarium for a few years. Screening breast ultrasound also takes substantially longer than a focused ultrasound exam. To offer this service we have found it necessary to charge a modest amount in excess of the standard ultrasound charge for those patients who elect to receive screening breast ultrasound. All women offered the additional procedure will be required to sign an ABN (see above).

Screening Breast MRI

Breast MRI is indicated as an adjuvant screening procedure for those women who meet the recommendations for high risk screening of the American Cancer Society (e.g., the conditions of 2 a-d in the screening mammography section above).[12] It should be noted that for these women the recommendation provides for screening mammography and breast MRI ***from age 30*** for women who meet the criteria. We normally assess risk for our screening patients, but generally do not come into contact with asymptomatic women under the age of 40, and we ask your cooperation in determining if your patients in the age range of 30-40 meet one or more of these conditions. If so, we will be happy to assess their risk without charge, and make screening recommendations according to that individual risk.

Breast MRI is also indicated for women who have been diagnosed with a breast cancer.[13] For these women the use of MRI will disclose otherwise occult cancers both the ipsilateral and contralateral breast that should be considered in treatment planning. There is also apparent specific value in reducing the incidence of re-excision following primary surgery because of improved visualization of cancer margins on MRI.[14,15]

Diagnostic Breast Imaging

For symptomatic women the initial imaging is typically diagnostic mammography. Indications for ordering diagnostic mammography are:[1]

1. To assess certain clinical findings that may include a palpable abnormality, persistent focal area of pain or tenderness, bloody or clear nipple discharge, or skin changes.
2. A finding detected on screening mammography that requires further imaging evaluation. This could either be a callback examination following an abnormal screening mammogram, or conversion of a screening mammogram to a diagnostic mammogram when an abnormality is detected at the time of the screening visit.
3. Short-interval follow-up for probably benign radiographic findings as defined by the ACR Breast Imaging Reporting and Data System (BI-RADS®).
4. Asymptomatic patients previously treated for breast cancer may undergo screening or diagnostic mammography at the discretion of the facility.

Mammography is not always successful in resolving the radiologist's concerns from a screening finding, or for the resolution of a symptomatic complaint. In these instances breast ultrasound may be appropriate (e.g., palpable lesions, axillary pain, etc.), specialized techniques like galectography may be utilized, or even MRI with the proper indications.

If imaging procedures are unable to resolve to a benign finding to al level that gives the radiologist or the patient confidence, a biopsy will be recommended. We utilize minimally invasive techniques, choosing the most appropriate for the lesion and patient. In very rare circumstances we will recommend a surgical biopsy. In all instances in which we recommend biopsy we expedite our processes so that we can provide patients with needed services and eliminate patient anxiety and uncertainty.

It should be clear from the foregoing that the ***continuum*** of breast screening and diagnosis is far from simple. While it is possible to individually order each procedure in the continuum of breast imaging, such a course can lead to delays in the delivery of care and increased patient frustration and anxiety. To simplify this process and allow patients to receive a definitive diagnosis in the minimum practicable time, we have developed two Conditional Contingent Orders; one to cover screening, and the other covering diagnosis. Please note that each of these orders incorporates protocols that are evidence-based and represent what we believe to be the most effective pathway to early detection and diagnosis of breast cancer. The protocols have been attached to this guidance document.

Conditional Contingent Order for Breast Screening

Under the Conditional Contingent Order for Breast Screening, screening will be individualized as follows:

High-Risk Patients. Women who are at high risk per the ACS Recommendations[12] will receive annual screening mammography and annual screening breast MRI. Women in this high-risk group generally are defined by having one or more of the following characteristics:

1. Women with known mutation or genetic syndrome;
2. Women with two first-degree relatives with known BRCA mutation and/or premenopausal breast cancer;
3. Women with a 20% or greater lifetime risk for breast cancer based on breast cancer risk models;
4. Women with a history of chest (mantle) radiation received between the ages of 10 and 30; or
5. Women with a history of Li-Fraumeni, Cowden, or Bannayan-Riley-Ruvalcaba syndromes.

Women with Reduced Mammographic Sensitivity Due to Dense Breast Tissue. Women with objectively determined breast density categorized in the highest two BI-RADS density categories will receive both screening mammography and screening breast ultrasound on an annual basis from age 40.

Women at Low Risk Without Dense Breast Tissue. Women without either the risk factors that would identify them as being at high risk for breast cancer, or having dense breast tissue, will receive an annual screening mammogram.

[See *Breast Imaging Protocols* Attached]

Conditional Contingent Order for Diagnostic Studies

This conditional contingent order directs us to perform a diagnostic work-up of the patient directed by the protocol attached to this document. Note that the protocol generally follows the outline presented above under Diagnostic Breast Imaging, but is more detailed. We have annotated each of the protocols to the medical literature and to appropriateness criteria published by professional organizations.

Again, we neither encourage nor discourage the use of Conditional Contingent Orders. They are presented for the convenience of you and your patients.

[See *Breast Imaging Protocols* Attached]

Confirmation of Additional History

At any time that it becomes necessary to modify or substantially add to the original diagnosis or clinical history given to us, we will record this new information and FAX it to you for your review. Please review this form for accuracy and let us know if there are any errors. Since the law requires that both you and we enter this information into the patient's clinical record, we encourage you to incorporate our FAX (or at least the information that it conveys) into your office chart. We will also utilize this form to record information received directly from the patient. We are not seeking to conduct our own separate history-taking, but will ask the patient to relate his or her impression of what led you to request this particular imaging evaluation.

Alternatives

In short, there are no alternatives. As providers of services under Medicare, both the referring physician and the radiologist have a legal obligation to furnish accurate diagnostic information in connection with any Medicare claim. The Social Security Act and subsequent legislation allows for imposition of stiff civil penalties, including fines and possible exclusion from Medicare and Medicaid, for violations of regulations. Even criminal penalties may apply in egregious cases of willful misconduct. Our practice takes these legal responsibilities seriously. We encourage you to do the same, both for your own protection and your peace of mind. Please view with skepticism any representations that may be made to you by others indicating that these Federal regulations are in any way optional, overly restrictive, or unlikely to be enforced. The fact remains that we all have to live with these laws and regulations.

Please Contact Us

If you have any questions, complaints, or suggestions, please feel free to call us at any time.

Once again, we thank you for your continued support of our mission to better serve your patients.

References

1 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.

2 Duffy SW, Tabar L, Vitak B, et al. Tumor size and breast cancer detection: what might be the effect of a less sensitive screening tool than mammography. *Breast J,* 2006;12 Suppl 1:S91-5.

3 Berg WA, Blume JD, Cormack JB, et al. Combined screening with ultrasound and mammography vs mammography alone in women at elevated risk of breast cancer. *JAMA* 2008; 299(18):2151-63.

4 Leconte I, Feger C, Galant C, Berliere M, Berg B, D'Hoore W, Maldague B. Mammography and subsequent whole-breast sonography of nonpalpable breast cancers: the importance of radiologic breast density. *AJR Am J Roentgenol*. 2003;180:1675–1679.

5 Crystal P, Strano SD, Shcharynski S, et al. Using sonography to screen women with mammographically dense breasts. *AJR Am J Roentgenol*, 2003; 181:177-82.

6 Kolb TM, Lichy J, Newhouse JH. Comparison of the performance of screening mammography, physical examination, and breast US and evaluation of factors that influence them: an analysis of 27,825 patient evaluations. *Radiology*, 2002; 225:165-75.

7 Drucker K, Horsch Kj, Pesce LL, et al. Interreader scoring variability in and observer study using dual-modality imaging for breast cancer detection in women with dense breasts. *Acad Radiol*, 2013; 20:847-53.

8 Kelly KW, Dean J, Lee SJ, et al. Breast cancer detection: radiologists' performance using mammography with and without automated whole breast ultrasound. *Eur. Radiol*, 2010; 20(11):2557-64.

9 Wankel E, Heckmann M, Henrich M, et al. Automated breast ultrasound: lesion detection and BI-RADS classification – a pilot study. *Rofo*, 2008; 180(9):804-808.

10 Hooley RJ, Greenberg KL, Stackhouse RM, et al. Screening US in patients with mammographically dense breasts: initial experience with Connecticut Public Act 09-41. *Radiology*, 2012; 265(1):59-69.

11 Weigert J, Steenbergen S. The Connecticut experiment: the role of ultrasound in the screening of women with dense breasts. *Breast J*, 18(6):517-22.

12 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.

13 Lehman CD, Gatsonis C, Kuhl CK, et al. MRI evaluation of the contralateral breast in women with recently diagnosed breast cacner. *New Engl J Med*, 2007; 556(13):1295-303.

14 Grobmyer SR, Mortellaro VE, Marshall J, et al. Is there a role for routine use of MRI in selection of patients for breast conserving cancer therapy? *J Am Coll Surg*, 2008; 206(5):1045=50.

15 Obdeijn IM, Tilanus-Linthorst MM, Spronk S, et al. Preoperative breast MRI can reduce the rate of tumor-positive resection margins and reoperations in patients undergoing breast-conserving surgery. *AJR Am J Roentgenol*., 2013;200(2):304-10.