

American College of Radiology ACR Appropriateness Criteria®

Clinical Condition:**Breast Cancer Screening****Variant 1:**

High-risk women: women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between the ages of 10-30, women with 20% or greater lifetime risk of breast cancer.

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography screening	9	Beginning at age 25-30 or 10 years before age of first-degree relative with breast cancer or 8 years after radiation therapy, but not before age of 25. Mammography and MRI are complementary examinations, both should be performed.	☢ ☢
MRI breast without and with contrast	9	Mammography and MRI are complementary examinations, both should be performed. See statement regarding contrast in text under “Anticipated Exceptions.”	○
US breast	6	If patient cannot have MRI.	○
FDG-PEM	2		☢ ☢ ☢ ☢
Tc-99m sestamibi BSGI	2		☢ ☢ ☢ ☢
MRI breast without contrast	1		○
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 2:

Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15%-20% lifetime risk of breast cancer.

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography screening	9		☢ ☢
MRI breast without and with contrast	7	See statement regarding contrast in text under “Anticipated Exceptions.”	○
US breast	5		○
FDG-PEM	2		☢ ☢ ☢ ☢
Tc-99m sestamibi BSGI	2		☢ ☢ ☢ ☢
MRI breast without contrast	1		○
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition:**Breast Cancer Screening****Variant 3:****Average-risk women: women with <15% lifetime risk of breast cancer, breasts not dense.**

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
Mammography screening	9		☢ ☢
MRI breast without and with contrast	3		○
US breast	2		○
MRI breast without contrast	1		○
FDG-PEM	1		☢ ☢ ☢ ☢
Tc-99m sestamibi BSGI	1		☢ ☢ ☢ ☢
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

BREAST CANCER SCREENING

Expert Panel on Breast Imaging: Martha B. Mainiero, MD¹; Ana Lourenco, MD²; Mary C. Mahoney, MD³; Mary S. Newell, MD⁴; Lisa Bailey, MD⁵; Lora D. Barke, DO⁶; Carl D'Orsi, MD⁷; Jennifer A. Harvey, MD⁸; Mary K. Hayes, MD⁹; Phan Tuong Huynh, MD¹⁰; Peter M. Jokich, MD¹¹; Su-Ju Lee, MD¹²; Constance D. Lehman, MD, PhD¹³; David A. Mankoff, MD, PhD¹⁴; Joshua A. Nepute, MD¹⁵; Samir B. Patel, MD¹⁶; Handel E. Reynolds, MD¹⁷; M. Linda Sutherland, MD¹⁸; Bruce G. Haffty, MD.¹⁹

Summary of Literature Review

Mammography

Mammography is the only method of screening for breast cancer shown to decrease mortality [1-4]. Annual screening mammography is recommended starting at: 1) age 40 for general population; 2) age 25-30 for BRCA (BRCA 1) carriers and untested relatives of BRCA carriers; 3) age 25-30 or 10 years earlier than the age of the affected relative at diagnosis (whichever is later) for women with a first-degree relative with premenopausal breast cancer or for women with a lifetime risk of breast cancer $\geq 20\%$ on the basis of family history; 4) 8 years after radiation therapy but not before age 25 for women who received mantle radiation between the ages of 10-30; and 5) any age for women with biopsy-proven lobular neoplasia, atypical ductal hyperplasia (ADH), ductal carcinoma in situ (DCIS), or invasive breast cancer [5]. However, mammography alone does not perform as well as mammography plus supplemental screening in certain subsets of women, particularly those with a genetic predisposition to the disease and those with dense breasts [6-11]. Therefore, supplemental screening is recommended in selected high-risk populations.

Magnetic Resonance Imaging

Breast magnetic resonance imaging (MRI) in high-risk women has been shown to have a higher sensitivity than mammography, and the combination of mammography and MRI in this population has the highest sensitivity [12-19]. In a high-risk population, MRI and mammography combined have a higher sensitivity (92.7%) than ultrasound (US) and mammography combined (52%) [6]. Therefore, in high-risk women for whom supplemental screening is indicated, MRI is recommended when possible.

Screening high-risk women with breast MRI is cost-effective [20,21] and the cost-effectiveness of screening MRI increases with increasing breast cancer risk. The American Cancer Society recommends screening breast MRI in certain high-risk women [22], and the ACR and Society of Breast Imaging endorse those recommendations [5]. Screening MRI is recommended in women with BRCA gene mutations and their untested first-degree relatives as well as women with a lifetime risk of breast cancer of $\sim 20\%$ or greater. Also included in this high-risk group are women who have received radiation therapy to the chest between the ages of 10-30 as well as women with other genetic syndromes that increase the risk of breast cancer (eg, Li Fraumeni syndrome). For other women with an intermediate risk of breast cancer, such as those with a lifetime risk of 15%-20%, a personal history of breast cancer, or a history of lobular neoplasia or ADH, the use of screening MRI is an area of ongoing investigation [5,22]. However, recent literature supports the use of screening MRI in addition to mammography in patients with a personal history of breast cancer [23] and lobular neoplasia [24].

Ultrasound

Screening US is indicated in high-risk patients who cannot tolerate MRI. Supplemental screening with US for women with intermediate risk and dense breasts is an option to increase cancer detection. However, hand-held US screening by the radiologist has a high false-positive rate and is time-consuming [25]. Therefore, this may not be a cost-effective practice. The balance between cancer detection and the risk of a false positive result should be considered by women and their health care providers when considering the use of screening US or other ancillary screening examinations.

Other Imaging Modalities

There is insufficient evidence to support the use of other imaging modalities such as thermography, breast specific gamma imaging (BSGI), positron emission mammography (PEM), or optical imaging for breast cancer screening [5]. Radiation dose from BSGI and PEM are 15-30 times higher than the dose of a digital mammogram [26,27], and they are not indicated for screening in their present form.

¹Principal Author, Rhode Island Hospital, Providence, Rhode Island.

²Research Author, Rhode Island Hospital, Providence, Rhode Island.

³Panel Chair, University of Cincinnati, Cincinnati, Ohio.

⁴Panel Vice-chair, Emory University Hospital, Atlanta, Georgia.

⁵Imagimed, LLC, Rockville, Maryland, American College of Surgeons.

⁶Invision Sally Jobe, Englewood, Colorado.

⁷Emory University Hospital, Atlanta, Georgia.

⁸University of Virginia Medical Center, Charlottesville, Virginia.

⁹Memorial Regional Hospital, Hollywood, Florida.

¹⁰St. Luke's Episcopal Hospital, Houston, Texas.

¹¹Rush Breast Imaging Center, Chicago, Illinois.

¹²University of Cincinnati, Cincinnati, Ohio.

¹³University of Washington, Seattle, Washington.

¹⁴University of Washington, Seattle, Washington, Society of Nuclear Medicine.

¹⁵University of Cincinnati Medical Center, Cincinnati, Ohio.

¹⁶Radiology Inc., Mishawaka, Indiana.

¹⁷Radiology Association of Atlanta, Atlanta, Georgia.

¹⁸Newport Diagnostic Center, Newport Beach, California.

¹⁹UMDNJ-Robert Wood Johnson Medical School, New Brunswick, New Jersey.

The American College of Radiology seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply individual or society endorsement of the final document.

Reprint requests to: Department of Quality & Safety, American College of Radiology, 1891 Preston White Drive, Reston, VA 20191-4397.

Summary

- For high-risk women, annual screening mammography and contrast-enhanced MRI are both indicated. US can be used for patients with contraindications to MRI.
- For intermediate-risk women, annual screening mammography is indicated. Contrast-enhanced MRI may be indicated in some patients.
- For average-risk women, annual screening mammography is indicated.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (ie, <30 mL/min/1.73m²), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73m². For more information, please see the [ACR Manual on Contrast Media](#) [28].

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document.

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
⊕	<0.1 mSv	<0.03 mSv
⊕ ⊕	0.1-1 mSv	0.03-0.3 mSv
⊕ ⊕ ⊕	1-10 mSv	0.3-3 mSv
⊕ ⊕ ⊕ ⊕	10-30 mSv	3-10 mSv
⊕ ⊕ ⊕ ⊕ ⊕	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".		

Supporting Document(s)

- [ACR Appropriateness Criteria® Overview](#)
- [Procedure Information](#)
- [Evidence Table](#)

References

1. Reduction in breast cancer mortality from organized service screening with mammography: 1. Further confirmation with extended data. *Cancer Epidemiol Biomarkers Prev* 2006; 15(1):45-51.
2. Duffy SW, Tabar L, Chen HH, et al. The impact of organized mammography service screening on breast carcinoma mortality in seven Swedish counties. *Cancer* 2002; 95(3):458-469.
3. Hendrick RE, Smith RA, Rutledge JH, 3rd, Smart CR. Benefit of screening mammography in women aged 40-49: a new meta-analysis of randomized controlled trials. *J Natl Cancer Inst Monogr* 1997; (22):87-92.
4. Tabar L, Vitak B, Chen HH, Yen MF, Duffy SW, Smith RA. Beyond randomized controlled trials: organized mammographic screening substantially reduces breast carcinoma mortality. *Cancer* 2001; 91(9):1724-1731.
5. Lee CH, Dershaw DD, Kopans D, et al. Breast cancer screening with imaging: recommendations from the Society of Breast Imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. *J Am Coll Radiol* 2010; 7(1):18-27.
6. Berg WA. Tailored supplemental screening for breast cancer: what now and what next? *AJR Am J Roentgenol* 2009; 192(2):390-399.
7. Brekelmans CT, Seynaeve C, Bartels CC, et al. Effectiveness of breast cancer surveillance in BRCA1/2 gene mutation carriers and women with high familial risk. *J Clin Oncol* 2001; 19(4):924-930.
8. Chart PL, Franssen E. Management of women at increased risk for breast cancer: preliminary results from a new program. *CMAJ* 1997; 157(9):1235-1242.
9. Macmillan RD. Screening women with a family history of breast cancer--results from the British Familial Breast Cancer Group. *Eur J Surg Oncol* 2000; 26(2):149-152.
10. Scheuer L, Kauff N, Robson M, et al. Outcome of preventive surgery and screening for breast and ovarian cancer in BRCA mutation carriers. *J Clin Oncol* 2002; 20(5):1260-1268.
11. Warner E, Plewes DB, Shumak RS, et al. Comparison of breast magnetic resonance imaging, mammography, and ultrasound for surveillance of women at high risk for hereditary breast cancer. *J Clin Oncol* 2001; 19(15):3524-3531.
12. Hagen AI, Kvistad KA, Maehle L, et al. Sensitivity of MRI versus conventional screening in the diagnosis of BRCA-associated breast

- cancer in a national prospective series. *Breast* 2007; 16(4):367-374.
13. Hartman AR, Daniel BL, Kurian AW, et al. Breast magnetic resonance image screening and ductal lavage in women at high genetic risk for breast carcinoma. *Cancer* 2004; 100(3):479-489.
 14. Kriege M, Brekelmans CT, Boetes C, et al. Differences between first and subsequent rounds of the MRISC breast cancer screening program for women with a familial or genetic predisposition. *Cancer* 2006; 106(11):2318-2326.
 15. Kuhl CK, Schrading S, Leutner CC, et al. Mammography, breast ultrasound, and magnetic resonance imaging for surveillance of women at high familial risk for breast cancer. *J Clin Oncol* 2005; 23(33):8469-8476.
 16. Leach MO, Boggis CR, Dixon AK, et al. Screening with magnetic resonance imaging and mammography of a UK population at high familial risk of breast cancer: a prospective multicentre cohort study (MARIBS). *Lancet* 2005; 365(9473):1769-1778.
 17. Lehman CD, Isaacs C, Schnall MD, et al. Cancer yield of mammography, MR, and US in high-risk women: prospective multi-institution breast cancer screening study. *Radiology* 2007; 244(2):381-388.
 18. Sardanelli F, Podo F, D'Agnolo G, et al. Multicenter comparative multimodality surveillance of women at genetic-familial high risk for breast cancer (HIBCRIT study): interim results. *Radiology* 2007; 242(3):698-715.
 19. Warner E, Plewes DB, Hill KA, et al. Surveillance of BRCA1 and BRCA2 mutation carriers with magnetic resonance imaging, ultrasound, mammography, and clinical breast examination. *JAMA* 2004; 292(11):1317-1325.
 20. Plevritis SK, Kurian AW, Sigal BM, et al. Cost-effectiveness of screening BRCA1/2 mutation carriers with breast magnetic resonance imaging. *JAMA* 2006; 295(20):2374-2384.
 21. Taneja C, Edelsberg J, Weycker D, Guo A, Oster G, Weinreb J. Cost effectiveness of breast cancer screening with contrast-enhanced MRI in high-risk women. *J Am Coll Radiol* 2009; 6(3):171-179.
 22. 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(2):75-89.
 23. Brennan S, Liberman L, Dershaw DD, Morris E. Breast MRI screening of women with a personal history of breast cancer. *AJR Am J Roentgenol* 2010; 195(2):510-516.
 24. Sung JS, Malak SF, Bajaj P, Alis R, Dershaw DD, Morris EA. Screening breast MR imaging in women with a history of lobular carcinoma in situ. *Radiology* 2011; 261(2):414-420.
 25. 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):2151-2163.
 26. Hendrick RE. Radiation doses and cancer risks from breast imaging studies. *Radiology* 2010; 257(1):246-253.
 27. O'Connor MK, Li H, Rhodes DJ, Hruska CB, Clancy CB, Vetter RJ. Comparison of radiation exposure and associated radiation-induced cancer risks from mammography and molecular imaging of the breast. *Med Phys* 2010; 37(12):6187-6198.
 28. American College of Radiology. *Manual on Contrast Media*. Available at: http://www.acr.org/~link.aspx?_id=29C40D1FE0EC4E5EAB6861BD213793E5&_z=z.

The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.