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	RRL*
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.	☢ ☢
Digital breast tomosynthesis 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 IV contrast	9	Mammography and MRI are complementary examinations, both should be performed.	O
US breast	6	If patient cannot have MRI.	O
FDG-PEM	2		☢ ☢ ☢ ☢
Tc-99m sestamibi BSGI	2		☢ ☢ ☢ ☢
MRI breast without IV contrast	1		O
Rating Scale: 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	RRL*
Mammography screening	9	Mammography and MRI are complementary examinations. MRI should not replace mammography.	☢ ☢
Digital breast tomosynthesis screening	9	Mammography and MRI are complementary examinations. MRI should not replace mammography.	☢ ☢
MRI breast without and with IV contrast	7	Mammography and MRI are complementary examinations. MRI should not replace mammography.	O
US breast	5		O
FDG-PEM	2		☢ ☢ ☢ ☢
Tc-99m sestamibi BSGI	2		☢ ☢ ☢ ☢
MRI breast without IV contrast	1		O
Rating Scale: 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	RRL*
Mammography screening	9		☢☢
Digital breast tomosynthesis screening	9		☢☢
MRI breast without and with IV contrast	3		O
US breast	2		O
MRI breast without IV contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Expert Panel on Breast Imaging: Martha B. Mainiero, MD[1]; Lisa Bailey, MD[2]; Carl D'Orsi, MD[3]; Edward D. Green, MD[4]; Anna I. Holbrook, MD[5]; Su-Ju Lee, MD[6]; Ana P. Lourenco, MD[7]; Linda Moy, MD[8]; Karla A. Sepulveda, MD[9]; Priscilla J. Slanetz, MD, MPH[10]; Sunita Trikha, MD[11]; Monica M. Yepes, MD[12]; Mary S. Newell, MD.[13]

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 (BReast CAncer 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 ≥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.

Digital Breast Tomosynthesis

Digital breast tomosynthesis (DBT) can address some of the limitations encountered with standard mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that may decrease the lesion-masking effect of overlapping normal tissue, and reveal the true nature of potential false positive findings without the need for recall. Several studies confirm that in a screening setting, cancer detection rate is increased with use of DBT compared to 2-D mammography alone [12-27]. Additionally, the rate of recall for benign findings (false positives) can be decreased [12,14-17,20-25,27-30]. Some authors found these advantages to be especially pronounced in women under age 50 [20,31], in those with dense breasts [31,32], and with lesion types including spiculated masses [33] and asymmetries [28]. Interpretation time for DBT images is greater than for standard mammography [14,34]. Additionally, dose is increased if standard 2-D images are obtained in addition to DBT images. However, synthesized reconstructed images (a virtual planar image created from the tomographic data set) may replace the need for a 2-D correlative view; and current data suggests that these synthetic images perform as well as standard full-field digital images [35,36].

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 [37-44]. 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 [45,46] 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 [47], 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 ~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

[1]Principal Author, Rhode Island Hospital, Providence, Rhode Island. [2]Bay Area Breast Surgeons, Emeryville, California, American College of Surgeons. [3]Emory University Hospital, Atlanta, Georgia. [4]The University of Mississippi Medical Center, Jackson, Mississippi. [5]Emory University Hospital, Atlanta, Georgia. [6]University of Cincinnati, Cincinnati, Ohio. [7]Rhode Island Hospital, Providence, Rhode Island. [8]NYU Clinical Cancer Center, New York, New York. [9]Baylor College of Medicine, Houston, Texas. [10]Beth Israel Deaconess Medical Center, Boston, Massachusetts. [11]North Shore University Hospital, Manhasset, New York. [12]University of Miami, Miami, Florida. [13]Panel Chair, Emory University Hospital, Atlanta, Georgia.

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 [5,47]. However, recent literature supports the use of screening MRI in addition to mammography in patients with a personal history of breast cancer [48] and lobular neoplasia [49].

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 [50]. 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 [51,52], and they are not indicated for screening in their present form.

Summary of Recommendations

- 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.

Summary of Evidence

Of the 52 references cited in the *ACR Appropriateness Criteria® Breast Cancer Screening* document, all of them are categorized as diagnostic references including 9 well designed studies, 7 good quality studies, and 21 quality studies that may have design limitations. There are 13 references that may not be useful as primary evidence. There are 2 references that are meta-analysis studies.

The 52 references cited in the *ACR Appropriateness Criteria® Breast Cancer Screening* document were published from 1997-2015.

While there are references that report on studies with design limitations, 16 well designed or good quality studies provide good evidence.

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 Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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