

**American College of Radiology
ACR Appropriateness Criteria®
Breast Cancer Screening**

Variant 1: Breast cancer screening. Average-risk women: women with <15% lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☼☼
Digital breast tomosynthesis screening	Usually Appropriate	☼☼
US breast	May Be Appropriate	○
MRI breast without and with IV contrast	Usually Not Appropriate	○
MRI breast without IV contrast	Usually Not Appropriate	○
FDG-PET breast dedicated	Usually Not Appropriate	☼☼☼☼
Sestamibi MBI	Usually Not Appropriate	☼☼☼

Variant 2: Breast cancer screening. Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15% to 20% lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☼☼
Digital breast tomosynthesis screening	Usually Appropriate	☼☼
MRI breast without and with IV contrast	May Be Appropriate	○
US breast	May Be Appropriate	○
FDG-PET breast dedicated	Usually Not Appropriate	☼☼☼☼
Sestamibi MBI	Usually Not Appropriate	☼☼☼
MRI breast without IV contrast	Usually Not Appropriate	○

Variant 3: Breast cancer screening. High-risk women: women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between 10 to 30 years of age, women with 20% or greater lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☼☼
Digital breast tomosynthesis screening	Usually Appropriate	☼☼
MRI breast without and with IV contrast	Usually Appropriate	○
US breast	May Be Appropriate	○
FDG-PET breast dedicated	Usually Not Appropriate	☼☼☼☼
Sestamibi MBI	Usually Not Appropriate	☼☼☼
MRI breast without IV contrast	Usually Not Appropriate	○

BREAST CANCER SCREENING

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Summary of Literature Review

Introduction/Background

Other than skin cancer, breast cancer is the most common cancer diagnosis and the second leading cause of cancer death in women. Since the advent of screening mammography in the United States, breast cancer mortality has decreased 36% between 1989 and 2012, after slowly increasing before that time [1]. Long-term follow-up analysis of populations before and after the institution of screening mammography attributes the decrease in mortality to screening of the general population [2]. In addition to mortality reduction, early detection allows for a wider range of less invasive treatment options.

The sensitivity of mammography is dependent upon breast density, where sensitivity decreases with the increase of breast density. Breast density is reported on mammography as: A = “almost entirely fatty,” B = “scattered areas of fibroglandular density,” C = “heterogeneously dense,” or D = “extremely dense,” where “heterogeneously dense” and “extremely dense” (C and D categories) are considered dense [3].

Discussion of Procedures by Variant

Variant 1: Breast cancer screening. Average-risk women: women with <15% lifetime risk of breast cancer.

Mammography and DBT

In follow-up of randomized controlled trials of screening mammography in women 40 to 74 years of age, there continues to be a highly significant decrease in mortality in those randomized to invitation to screening mammography [4]. Because breast cancer incidence increases with age, more women among the younger age group (40-50) will need to be screened for each life saved than for women 50 years of age or older. However, because younger women have a longer life expectancy, life years gained for the women diagnosed with breast cancer by screening in their 40s is higher than in the 50- to 70-year-old population [5]. The age at which various organizations recommend beginning screening mammography and the frequency at which mammography is recommended in different age groups varies based upon the weight given to the perceived risks (false-positive examinations and the possibility of over-diagnosis) and benefits of screening (mortality reduction and less invasive treatment options). Some groups recommend screening for all women starting at age 50, with screening recommended between 40 to 50 years of age dependent upon patient preference [6] or risk [7]. However, personalized screening in the 40 to 49 year age group would cause the majority of screen-detected cancers to be excluded from detection [8,9]. Groups also vary on whether screening mammography is recommended as an annual or biennial examination. Based on a review of the randomized trials and subsequent meta-analyses, the ACR recommends annual screening beginning at 40 years of age [10]. There is no upper age limit established for screening mammography, but as the benefits of screening mammography may take years to be fully realized, screening recommendations should take into account life expectancy and comorbid conditions, with screening mammography remaining appropriate when a woman’s life expectancy exceeds 5 to 7 years [10,11].

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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.

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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, the cancer detection rate is increased with use of DBT compared with 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 dataset) may replace the need for a 2-D correlative view; current data suggest that these synthetic images perform as well as standard full-field digital images [35,36]. DBT is almost always performed as part of an examination that also includes digital mammography. The digital mammography part of the examination may be in the form of traditional projection mammography or synthesized image from the DBT data.

US

The presence of dense breast tissue lowers the sensitivity of mammography and increases breast cancer risk when compared with patients with fatty breasts [37]. Adding hand-held or automated breast ultrasound (US) to mammography in women with dense breasts increases the cancer detection rate but also substantially increases the false-positive rate [38-40]. In the initial clinical experience with screening breast US after a dense breast notification law was enacted on a state-wide level, the cancer detection rate increased but the number of short interval follow-up recommendations increased substantially and the positive predictive value of a biopsy recommendation was much lower [41,42]. For women with dense breasts tissue but no additional risk factors, US may be useful as an adjunct to mammography for incremental cancer detection [10], but the balance between increased cancer detection and the increased risk of a false-positive examination should be considered in the decision. There are no data to support the use of US for average-risk women with nondense breasts [43].

MBI and FDG-PET Breast Dedicated

Supplementing mammography with molecular breast imaging (MBI) in women with dense breasts increases the cancer detection rate [44,45]. However, there have been no large population studies of MBI for screening, and the whole-body radiation dose with this technique is concerning [46]. Positron emission tomography with fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG-PET) breast is similarly limited by radiation dose and lack of evidence in large screening populations.

MRI

There is insufficient evidence to support the use of magnetic resonance imaging (MRI) for screening women of average risk.

Variant 2: Breast cancer screening. Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15% to 20% lifetime risk of breast cancer.

Some women with an intermediate risk of breast cancer may benefit by beginning screening mammography earlier than 40 years of age and may also benefit from supplemental screening. The recommendations for supplemental screening for women at intermediate risk of breast cancer, including those with a personal history of breast cancer, a history of lobular carcinoma in situ or ADH, those with an intermediate family history and a lifetime risk of 15% to 20%, or women with dense breasts continues to be an area of debate [47].

Mammography and DBT

Annual screening mammography is recommended for women with biopsy-proven lobular neoplasia or atypical ductal hyperplasia beginning at diagnosis, but not when <30 years of age [11]. Women who have a prior history of breast cancer are recommended to have mammography every 12 months (and 6 to 12 months post-radiation if the breast is conserved) [11].

The sensitivity of mammography is dependent upon breast density, with sensitivity decreasing with increasing breast density. 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 can 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 the 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 dataset) may replace the need for a 2-D correlative view; current data suggest that these synthetic images perform as well as standard full-field digital images [35,36]. DBT is almost always performed as part of an examination that also includes digital mammography. The digital mammography part of the examination may be in the form of traditional projection mammography or synthesized from the DBT data.

US

In women with dense breasts and increased risk of breast cancer, mammography sensitivity can be as low as 50%; supplementing mammography screening with US will significantly increase cancer detection, although false-positive rates are also substantially increased [48,49]. In intermediate-risk women with dense breasts, supplemental US screening is an option [48,49].

MRI

The American Cancer Society considers there to be insufficient evidence for or against MRI as an adjunct to mammography in women at intermediate risk of breast cancer [47]. However, recent studies support the use of screening MRI in certain subsets of this population, including women with a history of lobular carcinoma in situ [50,51] or a personal history of breast cancer [52,53].

MBI and FDG-PET Breast Dedicated

Supplementing mammography with MBI in women with dense breasts increases the cancer detection rate [44,45]. However, there have been no large population studies of MBI for screening and whole body radiation dose with this technique is concerning [46]. FDG-PET breast is similarly limited by radiation dose and lack of evidence in large screening populations.

Variant 3: Breast cancer screening. High-risk women: women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between 10 to 30 years of age, women with 20% or greater lifetime risk of breast cancer.

Women at high risk for breast cancer include those with BRCA or other known genetic predispositions, women with a very strong family history placing them at more than a 20% lifetime risk of breast cancer, and those with prior mantle radiation therapy between 10 to 30 years of age [47]. In addition to beginning screening mammography earlier than the general population, women in this high-risk group benefit from supplemental screening.

Mammography and DBT

Annual mammography is recommended starting 8 years after radiation therapy but not before age 25 for women who received mantle radiation between 10 to 30 years of age [10,11]. As there is some concern about young women with an inherited cancer predisposition having increased sensitivity to radiation, women with a genetic predisposition are recommended for annual screening beginning 10 years earlier than the affected relative at the time of diagnosis but not before age 30 [11].

The sensitivity of mammography is dependent upon breast density, with sensitivity decreasing with increasing breast density. 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, the 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 those 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 dataset) may replace the need for a 2-D correlative view; and current data suggest that these synthetic images perform as well as standard full-field digital images [35,36]. DBT is almost always

performed as part of an examination that also includes digital mammography. The digital mammography part of the examination may be in the form of traditional projection mammography or synthesized image from the DBT data.

MRI

Breast MRI in high-risk women has a higher sensitivity than mammography, and the combination of mammography and MRI in this population has the highest sensitivity [54-61]. In a high-risk population, MRI and mammography combined have a higher sensitivity (92.7%) than US and mammography combined (52%) [49,62]. Therefore, in high-risk women for whom supplemental screening is indicated, MRI is recommended when possible. 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 10 to 30 years of age as well as women with other genetic syndromes that increase the risk of breast cancer.

Screening high-risk women with breast MRI is cost-effective, and the cost-effectiveness of screening MRI increases with increasing breast cancer risk [63,64]. The American Cancer Society recommends breast-screening MRI in high-risk women [47], and the ACR and the Society of Breast Imaging endorse those recommendations [10].

US

Screening US is indicated in high-risk patients who cannot tolerate MRI. Mammography alone does not perform as well as mammography plus supplemental screening in high-risk women, especially those with a genetic predisposition, and supplemental screening US is indicated in high-risk patients who cannot tolerate MRI [49,62].

MBI and FDG-PET Breast Dedicated

Supplementing mammography with MBI in women with dense breasts increases the cancer detection rate [44,45]. However, there have been no large population studies of MBI for screening and the whole-body radiation dose with this technique is concerning [46]. FDG-PET breast is similarly limited by radiation dose and lack of evidence in large screening populations.

Summary of Recommendations

- For average-risk women, annual screening mammography or DBT (with accompanying planar or synthesized 2-D images) is recommended beginning at age 40. For women with dense breasts, US may also be considered, but the balance between increased cancer detection and the increased risk of a false-positive examination should be considered in the decision.
- For intermediate-risk women, breast mammography or DBT (with accompanying planar or synthesized 2-D images) is recommended. MRI may be considered as an adjunct to mammography or DBT (with accompanying planar or synthesized 2-D images) depending upon risk factors. For women with dense breasts, US may be an option, but the balance between increased cancer detection and the increased risk of a false-positive examination should be considered in the decision.
- For high-risk women, mammography or DBT (with accompanying planar or synthesized 2-D images) is recommended. MRI is recommended as an adjunct to screening mammography or DBT (with accompanying planar or synthesized 2-D images). US is recommended when the patient cannot tolerate MRI.

Summary of Evidence

Of the 65 references cited in the *ACR Appropriateness Criteria® Breast Cancer Screening* document, all of them are categorized as diagnostic references including 12 well-designed studies, 12 good-quality studies, and 22 quality studies that may have design limitations. There are 18 references that may not be useful as primary evidence. There is one reference that is a meta-analysis study.

The 65 references cited in the *ACR Appropriateness Criteria® Breast Cancer Screening* document were published from 2005 to 2017.

While there are references that report on studies with design limitations, 24 well-designed or good-quality studies provide good evidence.

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

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 [65].

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
○	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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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.