American College of Radiology ACR Appropriateness Criteria[®] Male Breast Cancer Screening

Variant 1:	Adult male.	Breast cancer	screening.	Higher-than-av	verage risk.

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	*
Mammography screening	Usually Appropriate	*
US breast	Usually Not Appropriate	0
Mammography with IV contrast	Usually Not Appropriate	*
MRI breast without and with IV contrast	Usually Not Appropriate	0
MRI breast without and with IV contrast abbreviated	Usually Not Appropriate	0
MRI breast without IV contrast	Usually Not Appropriate	0
MRI breast without IV contrast abbreviated	Usually Not Appropriate	0
Sestamibi MBI	Usually Not Appropriate	���

Variant 2:

Adult male. Breast cancer screening. Average risk.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis screening	Usually Not Appropriate	۲
Mammography screening	Usually Not Appropriate	۲
Mammography with IV contrast	Usually Not Appropriate	�€
MRI breast without and with IV contrast	Usually Not Appropriate	0
MRI breast without and with IV contrast abbreviated	Usually Not Appropriate	0
MRI breast without IV contrast	Usually Not Appropriate	0
MRI breast without IV contrast abbreviated	Usually Not Appropriate	0
Sestamibi MBI	Usually Not Appropriate	���

1

Variant 3:

Adult male, younger than 25 years of age. Breast cancer screening. Any risk.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis screening	Usually Not Appropriate	\$
Mammography screening	Usually Not Appropriate	€€
Mammography with IV contrast	Usually Not Appropriate	�€
MRI breast without and with IV contrast	Usually Not Appropriate	0
MRI breast without and with IV contrast abbreviated	Usually Not Appropriate	0
MRI breast without IV contrast	Usually Not Appropriate	0
MRI breast without IV contrast abbreviated	Usually Not Appropriate	0
Sestamibi MBI	Usually Not Appropriate	���

MALE BREAST CANCER SCREENING

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Summary of Literature Review

Introduction/Background

Although breast cancer is the most common nonskin cancer in women, it is less prevalent in men, with only 1% of all breast cancer cases occurring in men [1,2]. The lifetime risk of breast cancer is approximately 1 in 726 for a man of average risk, whereas it is approximately 1 in 8 for a woman of average risk [3,4]. However, its incidence is increasing, with the American Cancer Society suggesting that 2,790 cases of male breast cancer would be diagnosed in 2023 compared with 900 in 1991. Most male breast cancers are diagnosed due to associated symptoms (eg. palpable lump, skin or nipple retraction, or nipple discharge) [5,6]. Although screening for breast cancer in women is well established, there has been less clarity around screening for male breast cancer. And yet, male breast cancer has a worse prognosis, with overall 20% mortality [1] and with the cumulative 20-year mortality risk of 12.4% for stage I, 26.2% for stage II, and 46.0% for stage III [1,7]. Furthermore, there is a worse 5- and 10-year overall survival and a 75% higher hazard ratio for early death for men relative to women with breast cancer [2], and these mortality rates for men have not shown the same reductions as for women over the past several decades, possibly secondary to later stage at diagnosis, with 40% of men presenting at stage III or IV [8]. Breast cancer is relatively more common in Black men than in White men [5]. In male breast cancers, 90% are ductal in origin, and 98% have associated or precursor ductal carcinoma in situ [9,10]. In the absence of exposure to estrogens, lobular pathology in the male breast is rare. Most male breast cancers are estrogen and progesterone receptor positive and are much less likely to be HER2 positive, and only 4% are triple negative [11].

Risk stratification is not well defined in men compared with women, in whom there are established guidelines for risk. Certain factors such as age, Black race [5], hormone level (higher estrogen and lower androgen levels), history of chest radiation therapy, first degree family history, genetic predispositions (eg, BRCA1, BRCA2, CHEK2, PALB2, Klinefelter syndrome), personal history of breast cancer, and Ashkenazi descent have all been shown to elevate risk [1,12]. Approximately 20% of male individuals with breast cancer have a family history of breast cancer, and men with BRCA2 mutation are 80 times more likely to develop breast cancer than the average-risk man, with a 1 in 10 chance over their lifetime [12,13]. In 1 study, 18.1% of men diagnosed with breast cancer were found to have a high-risk genetic mutation, most commonly BRCA2, CHEK2, or PALB2 [11]. Similarly, men with a prior personal history of breast cancer have a higher risk of developing a new ipsilateral or contralateral breast cancer, especially if the initial diagnosis occurred before 50 years of age, and therefore, these men may benefit from regular surveillance. Risk for subsequent cancers continues long term, even 15 years after initial treatment [14].

There are limited data on the benefit of screening with imaging for men at higher-than-average risk of breast cancer or men with a personal history of breast cancer and no reasonable data evaluating screening men of average risk or younger men for breast cancer. In men who have elevated risk and have undergone screening mammography, the data are inconsistent regarding screening intervals with some patients receiving annual mammography and others receiving more sporadic imaging [12]. As such, there are few established guidelines for breast cancer screening in

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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 representation of such organizations on expert panels. Participation on the expert panel does not necessarily imply endorsement of the final document by individual contributors or their respective organization.

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men, although National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) guidelines recommend screening mammography in men of elevated risks [15,16].

Although all patients are at risk for developing breast cancer, this document addresses breast cancer screening in cisgender men (assigned male at birth with a male gender identity). For breast cancer screening in transgender and gender diverse patients, please reference the ACR Appropriateness Criteria[®] topics on "<u>Transgender Breast Cancer</u> <u>Screening</u>" [17] and "<u>Female Breast Cancer Screening</u>" [18].

Discussion of Procedures by Variant

Variant 1: Adult male. Breast cancer screening. Higher-than-average risk.

The goal of imaging is early detection of a breast cancer prior to it being detected clinically to improve the mortality and morbidity from breast cancer. The expected outcome is improved longevity to the patient and decreased burden of disease. Male breast cancer accounts for <0.5% of all male cancers and only approximately 1% of all breast cancer cases [2]. However, some men carry a higher-than-average risk for breast cancer. Although there are no strict defined risk categories for men, men with a strong family history, a personal history of breast cancer, of Ashkenazi descent, Black race, or a known genetic mutation (eg, BRCA1, BRCA2, CHEK2, PALB2) are known to be of higher-than-average risk. Other high-risk predispositions include Klinefelter syndrome, which carries up to a 50 times increased risk for male breast cancer. Additionally, different processes that increase estrogen or lower androgens elevate a male individual's breast cancer risk (eg, gonadal dysfunction, end-stage cirrhosis/liver disease, obesity). Men who received chest radiation (ie, Hodgkin lymphoma) are also at higher risk for breast cancer. Due to a paucity of data and few guidelines, a finer classification of breast cancer risk in this patient population is not currently possible [2,11,12,14,15].

Digital Breast Tomosynthesis Screening

There are limited but emerging data supporting screening digital breast tomosynthesis (DBT) in high-risk men, with routine mammographic screening approaching similar cancer detection rates compared with women of average risk in standard population-based mammographic screening programs [19]. There are no randomized controlled trials evaluating screening mammography for men at elevated risk of breast cancer. In a retrospective study of 1,869 men with higher-than-average risk (ages 18-96 years; median 55 years) undergoing digital mammography or DBT to screen for breast cancer, the cancer detection rate was 18 per 1,000, with a sensitivity of 100%, a specificity 95%, and a positive predictive value of biopsy of 50%. The use of DBT was limited to only 46 examinations (2.2%). Mammography has been shown to be highly sensitive in men [12], likely secondary to most men having nondense breast tissue.

Many of the mammograms performed for men in this clinical scenario are ordered as diagnostic because screening mammography is commonly ordered only for cisgender women. Therefore, although most high-risk men undergo annual mammography as a "diagnostic" examination, for this discussion and for the purposes of this appropriateness criteria, the modality of "screening" is being used to describe "surveillance" mammography in asymptomatic patients. The imaging interval (annual versus biennial) or the age to start screening has not been well researched.

In one study comparing screening mammography in asymptomatic men at elevated risk relative to diagnostic mammography in symptomatic men, the average size of cancers detected at screening were significantly smaller and significantly more likely to be node negative (1.2 cm versus 2.1 cm average size and 0% versus 58% nodal involvement, respectively) [12]. These data suggest that screening or surveillance mammography in men of elevated risk may indeed prove useful. Because axillary nodal positivity is the strongest surrogate marker for systemic metastatic risk, the ability of screening mammography to detect breast malignancies with a markedly lower rate of nodal involvement is indicative of a probable benefit from screening mammography in men of elevated risk.

The first guidelines published in 2020 by ASCO recommend men with a known deleterious BRCA1 or BRCA2 mutation at least receive a baseline mammogram [20]. Men with a personal history of breast cancer should continue to receive annual ipsilateral mammography after treatment (formed as a strong recommendation with low evidence), and men with a personal history of breast cancer and a known deleterious genetic mutation should receive bilateral annual mammography (formed as a moderate recommendation with low evidence) [3]. The NCCN guidelines currently recommend that men with a BRCA1 or BRCA2 germline mutation consider getting annual screening mammograms starting at age 50 or 10 years before the earliest known male breast cancer diagnosis in the family (whichever comes first). NCCN guidelines acknowledge that there are "only minimal data" to support screening mammography in male breast cancer survivors [15].

Mammography Screening

There are limited but emerging data supporting screening in high-risk men, with routine mammographic screening approaching similar cancer detection rates compared with women of average risk in standard population-based mammographic screening programs [19]. There are no randomized controlled trials evaluating screening mammography for men at elevated risk of breast cancer. In a retrospective study of 1,869 men with higher-than-average risk (ages 18-96 years; median 55 years) undergoing digital mammography or DBT to screen for breast cancer, the cancer detection rate was 18 per 1,000, with a sensitivity of 100%, a specificity 95%, and a positive predictive value of biopsy of 50%. The use of DBT was limited to only 46 examinations (2.2%). Mammography has been shown to be highly sensitive in men [12], likely secondary to most men having nondense breast tissue.

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Mammography With IV Contrast

There is no relevant literature to support the use of mammography with intravenous (IV) contrast for breast cancer screening in this clinical setting.

MRI Breast Without and With IV Contrast

There is no relevant literature to support the use of MRI breast without and with IV contrast for breast cancer screening in this clinical setting. The ASCO guidelines state breast MRI is not routinely recommended in men with breast cancer (formed as a moderate recommendation with low evidence) [3].

MRI Breast Without and With IV Contrast Abbreviated

There is no relevant literature to support the use of MRI breast without and with IV contrast abbreviated for breast cancer screening in this clinical setting. The ASCO guidelines state breast MRI is not routinely recommended in men with breast cancer (formed as a moderate recommendation with low evidence) [3].

MRI Breast Without IV Contrast

There is no relevant literature to support the use of MRI breast without IV contrast for breast cancer screening in this clinical setting. The ASCO guidelines state breast MRI is not routinely recommended in men with breast cancer (formed as a moderate recommendation with low evidence) [3].

MRI Breast Without IV Contrast Abbreviated

There is no relevant literature to support the use of MRI breast without IV contrast abbreviated for breast cancer screening in this clinical setting. The ASCO guidelines state breast MRI is not routinely recommended in men with breast cancer (formed as a moderate recommendation with low evidence) [3].

Sestamibi MBI

There is no relevant literature to support the use of sestamibi molecular breast imaging (MBI) for breast cancer screening in this clinical setting.

US Breast

[12]The usefulness of US in a screening or surveillance mode for male individuals at elevated risk for breast cancer is not well studied and is currently unknown. There is no relevant literature to support the use of US for breast cancer screening in this clinical setting.

Variant 2: Adult male. Breast cancer screening. Average risk.

The goal of imaging is early detection of a breast cancer prior to it being detected clinically. This will likely improve the mortality and morbidity from breast cancer. The expected outcome is improved longevity to the patient and decreased burden of disease.

The average man in the United States has a lifetime risk of developing breast cancer of approximately 1 in 726 [4], whereas the lifetime risk is approximately 1 in 8 for a woman of average risk [3]. For this reason, no screening guidelines exist for men in the average risk population.

Digital Breast Tomosynthesis Screening

There is no relevant literature to support the DBT screening in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

Mammography Screening

There is no relevant literature to support mammographic screening in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

Mammography With IV Contrast

There is no relevant literature to support screening mammography with IV contrast in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

MRI Breast Without and With IV Contrast

There is no relevant literature to support breast MRI screening without and with IV contrast in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

MRI Breast Without and With IV Contrast Abbreviated

There is no relevant literature to support abbreviated breast MRI screening without and with IV contrast in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

MRI Breast Without IV Contrast

There is no relevant literature to support breast MRI screening without IV contrast in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

MRI Breast Without IV Contrast Abbreviated

There is no relevant literature to support abbreviated breast MRI screening without IV contrast in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

Sestamibi MBI

There is no relevant literature to support sestamibi MBI screening in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

US Breast

There is no relevant literature to support the breast US screening in this clinical setting. No standard screening regimen for breast cancer has been recommended in the average-risk man [21].

Variant 3: Adult male, younger than 25 years of age. Breast cancer screening. Any risk.

The goal of imaging is early detection of a breast cancer prior to it being detected clinically. This will likely improve the mortality and morbidity from breast cancer. The expected outcome is improved longevity to the patient and decreased burden of disease.

Breast cancer in men is a relatively rare disease, accounting for <0.5% of all male cancers. Male breast cancer is more common in older men. In men of elevated risk undergoing mammography and needing a biopsy, the age of

men with breast malignancy on biopsy was significantly higher than in men who had benign findings (64 versus 50 years of age) [12]. The average age of diagnosis of breast cancer in men is on average 5 years older than the average age in women, (67 versus 62 years), suggesting that screening men under the age of 25 is likely of no benefit [3].

Digital Breast Tomosynthesis Screening

There is no relevant literature to support DBT screening in this clinical setting.

Mammography Screening

There is no relevant literature to support mammographic screening in this clinical setting.

Mammography With IV Contrast

There is no relevant literature to support screening mammography with IV contrast in this clinical setting.

MRI Breast Without and With IV Contrast

There is no relevant literature to support screening breast MRI without and with IV contrast in this clinical setting.

MRI Breast Without and With IV Contrast Abbreviated

There is no relevant literature to support screening abbreviated breast MRI without and with IV contrast in this clinical setting.

MRI Breast Without IV Contrast

There is no relevant literature to support screening breast MRI without IV contrast in this clinical setting.

MRI Breast Without IV Contrast Abbreviated

There is no relevant literature to support abbreviated screening breast MRI without IV contrast in this clinical setting.

Sestamibi MBI

There is no relevant literature to support screening sestamibi MBI in this clinical setting.

US Breast

There is no relevant literature to support breast US screening in this clinical setting.

Summary of Highlights

This is a summary of the key recommendations from the variant tables. Refer to the complete narrative document for more information.

- Variant 1: For men of higher-than-average risk, screening mammography and/or tomosynthesis, which may often be ordered as surveillance diagnostic mammography, is usually appropriate. Other modalities including MRI and US are not usually appropriate.
- Variant 2 and 3: For men of average risk and for younger men, <25 years of age, screening with any imaging modality for breast cancer is usually not appropriate.

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at <u>https://acsearch.acr.org/list</u>. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents, click <u>here.</u>

Gender Equality and Inclusivity Clause

The ACR acknowledges the limitations in applying inclusive language when citing research studies that pre-dates the use of the current understanding of language inclusive of diversity in sex, intersex, gender and gender-diverse people. The data variables regarding sex and gender used in the cited literature will not be changed. However, this guideline will use the terminology and definitions as proposed by the National Institutes of Health [22].

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, because of both 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 with 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 [23].

Relative Radiation Level Designations			
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range	
0	0 mSv	0 mSv	
۲	<0.1 mSv	<0.03 mSv	
	0.1-1 mSv	0.03-0.3 mSv	
	1-10 mSv	0.3-3 mSv	
$\textcircled{\begin{tabular}{lllllllllllllllllllllllllllllllllll$	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."

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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.