American College of Radiology ACR Appropriateness Criteria[®] Evaluation of the Symptomatic Male Breast

Variant 1:

Male patient of any age with symptoms of gynecomastia and physical examination consistent with gynecomastia or pseudogynecomastia. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|---------------------------------|
| Mammography diagnostic | Usually Not Appropriate | €€ |
| Digital breast tomosynthesis diagnostic | Usually Not Appropriate | \$ \$ |
| US breast | Usually Not Appropriate | 0 |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |

Variant 2:

Male younger than 25 years of age with indeterminate palpable breast mass. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|---------------------------------|
| US breast | Usually Appropriate | 0 |
| Mammography diagnostic | May Be Appropriate | \$ \$ |
| Digital breast tomosynthesis diagnostic | May Be Appropriate | \$\$ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |

Variant 3: Male 25 years of age or older with indeterminate palpable breast mass. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| Mammography diagnostic | Usually Appropriate | \$ \$ |
| Digital breast tomosynthesis diagnostic | Usually Appropriate | �� |
| US breast | May Be Appropriate | 0 |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |

<u>Variant 4:</u> Male 25 years of age or older with indeterminate palpable breast mass. Mammography or digital breast tomosynthesis indeterminate or suspicious.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|---------------------------------|
| US breast | Usually Appropriate | 0 |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |

<u>Variant 5:</u>

Male of any age with physical examination suspicious for breast cancer (suspicious palpable breast mass, axillary adenopathy, nipple discharge, or nipple retraction). Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|---------------------------------|
| Mammography diagnostic | Usually Appropriate | €€ |
| Digital breast tomosynthesis diagnostic | Usually Appropriate | \$ \$ |
| US breast | Usually Appropriate | 0 |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |

EVALUATION OF THE SYMPTOMATIC MALE BREAST

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Summary of Literature Review

Introduction/Background

Men with breast symptoms are typically concerned about the cause of their problem and whether or not it is due to breast cancer. The majority of male breast problems are benign, with gynecomastia as the most common cause of a palpable mass, breast enlargement, or pain [1-3]. Gynecomastia occurs physiologically in neonates and adolescents and with aging but can occur at any age as a side effect of many medications and recreational drugs, as a result of hormonal changes, and in the setting of chronic liver disease [4]. Although gynecomastia may present at any age, breast cancers usually occur in older men (median age of 63 years) [3,5]. Breast cancer in males accounts for <1% of all breast cancers. Although rare, breast cancer in men frequently presents with associated symptoms (eg, palpable lump, skin or nipple retraction, nipple discharge) and at an advanced stage (larger tumor size and a higher probability of nodal metastases) [6-8]. Because gynecomastia is a common entity, approximately 50% of men with breast cancer may have coexisting gynecomastia [9]. However, gynecomastia is not believed to be a risk factor for male breast cancer [10]. Although gynecomastia and breast cancer are the main considerations in most men with a palpable mass, other masses arising from the skin and subcutaneous tissues, such as lipomas, epidermal inclusion cysts, and oil cysts, are also commonly encountered. Pseudogynecomastia, which is due to excess fatty tissue deposition in the breasts, is also common, especially in patients with an elevated body mass index.

If the differentiation between benign disease and breast cancer cannot be made on the basis of clinical findings, or if the clinical presentation is suspicious, imaging is indicated [1,2].

Discussion of Procedures by Variant

Variant 1: Male patient of any age with symptoms of gynecomastia and physical examination consistent with gynecomastia or pseudogynecomastia. Initial imaging.

Most men with breast symptoms can be diagnosed on the basis of clinical findings without imaging [1,2]. Gynecomastia is the most common cause of a palpable mass, breast enlargement, or pain [1-3]. Gynecomastia is bilateral in approximately half of patients. On physical examination, gynecomastia often presents as a soft, rubbery, or firm mobile mass directly under the nipple [3,4]. In addition, gynecomastia is more likely to be painful than cancer [3], especially gynecomastia that has been present for <6 months [3,4].

Mammography

In men with clinical findings consistent with gynecomastia or pseudogynecomastia, mammography is not routinely indicated. When performed, 3 patterns of gynecomastia have been described on mammography: (1) nodular (subareolar nodule), (2) dendritic (subareolar flame-shaped tissue), and (3) diffuse glandular (much like a heterogeneously dense female breast) [11]. When pseudogynecomastia is identified as the sole imaging finding,

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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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mammography may obviate further unnecessary interventions for falsely presumed gynecomastia (eg, altering medications) [12].

Gynecomastia may be incidentally identified on chest CT [13]. Men with characteristic imaging findings of gynecomastia on CT do not benefit from further evaluation with mammography unless there is a suspicious clinical finding (eg, eccentric breast mass, nipple discharge, or axillary adenopathy) [13].

DBT

In men with clinical findings consistent with gynecomastia or pseudogynecomastia, digital breast tomosynthesis (DBT) is not routinely indicated. When performed, gynecomastia demonstrates similar imaging characteristics on DBT compared to mammography [14,15].

US Breast

In men with clinical findings consistent with gynecomastia or pseudogynecomastia, ultrasound (US) is not routinely indicated. When US is performed, gynecomastia may appear mass-like and demonstrate vascularity on color Doppler [16-18]. Comparison with the contralateral side may be helpful on real-time imaging, as synchronous bilateral breast carcinoma in males is rare. Chen et al [19] evaluated the incremental clinical value of US in 327 symptomatic male patients where mammography was negative or revealed only gynecomastia and found no additional malignancies. However, in that series, US did lead to additional unnecessary benign biopsies. Tangerud et al [20], in a study of 350 men with mammographic findings diagnostic of gynecomastia, did not identify any patients with male breast cancer when US, fine needle aspiration, or core biopsy was performed in conjunction with mammography.

When performed for suspected gynecomastia, US may demonstrate a lack of breast tissue in men with pseudogynecomastia and obviate further unnecessary interventions for falsely presumed gynecomastia (eg, altering medications) [12,21-23].

MRI Breast

In men with clinical findings consistent with gynecomastia or pseudogynecomastia, breast MRI is not indicated as the initial imaging study. There is no relevant literature regarding the use of breast MRI as the initial imaging evaluation of suspected gynecomastia.

Variant 2: Male younger than 25 years of age with indeterminate palpable breast mass. Initial imaging.

Only 6% of male breast cancers occur in men <40 years of age and 1% in men <30 years of age [24]. Given the relationship between breast cancer incidence and increasing age, age-based protocols in younger men have been developed [3,25]. If clinical breast examination is indeterminate, imaging is recommended prior to biopsy recommendation.

Mammography

The extremely low incidence of breast cancer in young men reduces the utility of mammography as the initial imaging study. However, if there are suspicious or indeterminate features on US, mammography or DBT should be performed before a biopsy recommendation is made because diagnostic mammography is useful in distinguishing malignancy from benign breast conditions in symptomatic males [1,2].

DBT

There is no relevant literature regarding the use of DBT in the evaluation of men <25 years of age with an indeterminate palpable breast mass. However, if there are suspicious or indeterminate features on US, mammography or DBT should be performed before a biopsy recommendation is made because mammography is useful in distinguishing malignancy from benign breast conditions in symptomatic males [1,2]. DBT can be performed in men and demonstrates similar imaging appearances for benign and malignant male breast disorders as mammography [14,15,26].

US Breast

Some authors suggest that using US is useful as the initial imaging modality in the young male who is unlikely to have breast cancer and who presents with an indeterminate physical symptom [3]. However, gynecomastia and oil cysts can have a suspicious appearance on US but can typically be diagnosed as benign on mammography or DBT. Therefore, if there are suspicious features on US, mammography or DBT should be performed before a biopsy recommendation is made.

MRI Breast

There is no relevant literature regarding the use of MRI as the initial imaging study in the evaluation of men <25 years of age with an indeterminate palpable breast mass.

Variant 3: Male 25 years of age or older with indeterminate palpable breast mass. Initial imaging.

Breast cancer is a disease of older men and typically presents at a later age than in women at a median age of 63 years [5]. If clinical breast examination is indeterminate, imaging is recommended prior to biopsy recommendation.

Mammography

For men with an equivocal physical examination and of an age at which breast cancer is more likely, mammography or DBT is recommended as the initial imaging modality. Diagnostic mammography is useful in distinguishing malignancy from benign breast conditions in symptomatic males [1,2]. A bilateral mammogram is routinely performed in symptomatic males [27], although there is no literature comparing the efficacy of bilateral versus unilateral imaging. A bilateral examination may be useful to assess for symmetry [28] and may detect asymptomatic contralateral gynecomastia or the rare nonpalpable contralateral carcinoma [3]. Although not routinely performed, pectoralis-displaced mammographic views can be acquired if the breast tissue is obscured by overlying well-developed pectoralis musculature [29].

Mammography is highly sensitive and specific in distinguishing benign from malignant disease and is likely more sensitive than US at detecting breast cancer because microcalcifications may be optimally visualized on this modality [3,6]. Studies demonstrate sensitivities ranging from 92% to 100%, specificities ranging from 90% to 96%, and negative predictive values (NPV) of 99% to 100% [3,9,12,28]. Thus, mammography is useful both in identifying breast cancer and for obviating the need for US or biopsy in patients for whom the benign mammographic appearance confirms the clinical impression.

DBT

For men with an equivocal physical examination finding, mammography or DBT is recommended as the initial imaging study because mammography has high sensitivity, specificity, and NPV [3,9,12,16]. Data on the incremental utility of DBT compared to mammography alone in the evaluation of the male breast are limited. However, DBT can be performed in men and demonstrates similar imaging appearances for benign and malignant male breast disorders as that of mammography [14,15,26].

US Breast

If the mammogram is indeterminate or suspicious, US can assist in clinical management and guide biopsy [3].

MRI Breast

There is no relevant literature regarding the use of MRI as the initial imaging study in the evaluation of men ≥ 25 years of age with an indeterminate palpable breast mass.

Variant 4: Male 25 years of age or older with indeterminate palpable breast mass. Mammography or digital breast tomosynthesis indeterminate or suspicious.

US Breast

If the mammogram is indeterminate or suspicious, US is usually appropriate as the next imaging modality because US can assist in lesion characterization and guide biopsy [3]. Performance of breast US in men may be more variable than mammography. Carrasco et al [3], in their series of 638 patients, reported a lower sensitivity of US for distinguishing benign from malignant disease (88.9% compared to 95% for mammography) but a similar, high specificity of 95%. However, Patterson et al [28], in a series of 166 patients, reported US to have the same sensitivity as mammography (100%) but lower specificity (74%).

MRI Breast

Breast MRI is generally not indicated for the evaluation of indeterminate palpable breast masses in men.

Variant 5: Male of any age with physical examination suspicious for breast cancer (suspicious palpable breast mass, axillary adenopathy, nipple discharge, or nipple retraction). Initial imaging.

Breast cancer is a disease of older men and typically presents at a later age (median age of 63 years) than in women [5]. Male breast cancer is rarely bilateral and typically presents with a painless, hard mass, which may be subareolar or, unlike gynecomastia, eccentric to the nipple. With breast cancer, there may be secondary signs of malignancy, such as nipple or skin retraction, nipple discharge, or axillary lymphadenopathy [6]. Breast cancers in

men often present at a more advanced stage than breast cancers in women, with up to 47% of men having axillary nodal involvement at the time of diagnosis [6]. In addition, nipple discharge is suspicious for breast cancer in men, with 2 studies showing carcinoma in 23% to 57% of men presenting with this symptom [7,8].

Mammography

For men with a suspicious physical examination finding, mammography or DBT is recommended as the initial imaging study because mammography has high sensitivity, specificity, and NPV [3,9,12,16]. Breast cancer in men typically presents with an irregular mass but may present as a focal asymmetry, asymmetry, or in association with calcifications [3,11,12,24]. Because lobular development does not typically occur in men and men do not have the same background of benign proliferative changes as do women, relatively benign imaging findings, such as a circumscribed mass or round calcifications, should be considered suspicious in male patients [3,6,27].

Mammography is highly sensitive and specific in distinguishing benign from malignant disease and is likely more sensitive than US at detecting breast cancer because microcalcifications may be optimally visualized on this modality [3,6]. Studies demonstrate sensitivities ranging from 92% to 100%, specificities ranging from 90% to 96%, and NPVs of 99% to 100% [3,9,12,28]. Thus, mammography is useful both in identifying breast cancer and for obviating the need for US or biopsy in patients for whom the benign mammographic appearance confirms the clinical impression.

DBT

For men with a suspicious physical examination finding, mammography or DBT is recommended as the initial imaging study because mammography has high sensitivity, specificity, and NPV [3,9,12,16]. Data on the incremental utility of DBT compared to mammography alone in the evaluation of male breast cancer are limited. However, DBT can be performed in men and demonstrates similar imaging appearances for benign and malignant male breast disorders as mammography [14,15,26]. No documented case of male breast cancer identified solely on DBT has been reported [15].

US Breast

Mammography is recommended as the initial imaging study because of its high sensitivity, specificity, and NPV, and the performance of breast US in men may be more variable than mammography [3,9,12,16]. Carrasco et al [3], in their series of 638 patients, reported a lower sensitivity of US for distinguishing benign from malignant disease (88.9% compared to 95% for mammography) but a similar, high specificity of 95.3%. However, Patterson et al [28] in a series of 166 patients reported US to have the same sensitivity as mammography (100%) but lower specificity (74%). In conjunction with mammography or DBT, US is often useful in assisting with management decisions and to facilitate US core biopsy [3].

Male breast cancers typically manifest as hypoechoic solid masses with irregular borders; however, cystic or circumscribed masses in men should also be viewed with suspicion unless definitely correlative benign findings (eg, oil cyst) are identified on mammography [3,11,24,30,31]. Lapid et al [32] in a series of 557 male patients demonstrated that mammography and/or US imaging in combination had an NPV of 99.8%, and a complex cystic and solid mass on US was the only false-negative examination.

MRI Breast

Breast MRI is generally not indicated for the evaluation of suspicious palpable lumps or axillary adenopathy prior to histologic diagnosis, especially as an initial imaging examination. Male breast cancer detected on MRI has been reported [33]. One study of 17 male patients who had undergone mammography and US investigated whether MRI descriptors of lesions' features and diagnostic criteria used in female patients may be used for male patients but did not assess the diagnostic accuracy or clinical usefulness of MRI in male patients [34].

Summary of Recommendations

- Variant 1: Imaging is not recommended for the initial imaging of a male patient of any age with symptoms of gynecomastia and physical examination consistent with gynecomastia or pseudogynecomastia.
- Variant 2: US breast is usually appropriate for the initial imaging of a male patient younger than 25 years of age with an indeterminate palpable breast mass.
- Variant 3: Diagnostic mammography or DBT is usually appropriate for the initial imaging of a male patient 25 years of age or older with an indeterminate palpable breast mass. These procedures are equivalent alternatives.

- Variant 4: US breast is usually appropriate for the imaging of a male patient 25 years of age or older with a breast mass deemed indeterminate or suspicious on diagnostic mammography or DBT.
- Variant 5: Diagnostic mammography or DBT and US breast are usually appropriate for the initial imaging of a male patient of any age with physical examination suspicious for breast cancer (suspicious palpable breast mass, axillary adenopathy, nipple discharge, or nipple retraction). Diagnostic mammography and DBT are equivalent alternatives as the initial imaging modality. US breast is usually appropriate as a complementary imaging modality.

Summary of Evidence

Of the 35 references cited in the *ACR Appropriateness Criteria*[®] *Evaluation of Symptomatic Male Breast* document, 2 are categorized as therapeutic references including 1 good-quality study. Additionally, 33 references are categorized as diagnostic references including 2 good-quality studies, and 14 quality studies that may have design limitations. There are 18 references that may not be useful as primary evidence.

The 35 references cited in the ACR Appropriateness Criteria[®] Evaluation of Symptomatic Male Breast document were published from 1977 to 2017.

Although there are references that report on studies with design limitations, 3 good-quality studies provide good evidence.

| 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. |

Appropriateness Category Names and Definitions

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 [35].

| Relative Radiation Level Designations | | |
|---------------------------------------|--|--|
| Relative Radiation Level* | Adult Effective Dose Estimate Range | Pediatric Effective Dose Estimate Range |
| 0 | 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 <u>www.acr.org/ac</u>.

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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.