American College of Radiology ACR Appropriateness Criteria® Imaging after Mastectomy and Breast Reconstruction

<u>Variant: 1</u> Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis screening	Usually Not Appropriate	⊗ ⊗
Mammography screening	Usually Not Appropriate	⊗ ⊗
MRI breast without and with IV contrast	Usually Not Appropriate	0
MRI breast without IV contrast	Usually Not Appropriate	0
FDG-PET breast dedicated	Usually Not Appropriate	**
Sestamibi MBI	Usually Not Appropriate	***

<u>Variant: 2</u> Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	May Be Appropriate	⊕ ⊕
Mammography screening	May Be 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
FDG-PET breast dedicated	Usually Not Appropriate	•••
Sestamibi MBI	Usually Not Appropriate	∵ ∵ ∵

<u>Variant: 3</u> Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis screening	Usually Not Appropriate	⊗ ⊗
Mammography screening	Usually Not Appropriate	⊗ ⊗
MRI breast without and with IV contrast	Usually Not Appropriate	0
MRI breast without IV contrast	Usually Not Appropriate	0
FDG-PET breast dedicated	Usually Not Appropriate	���
Sestamibi MBI	Usually Not Appropriate	∵ ∵ ∵

<u>Variant: 4</u> Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis screening	Usually Not Appropriate	⊗ ⊗
Mammography screening	Usually Not Appropriate	⊗ ⊗
MRI breast without and with IV contrast	Usually Not Appropriate	0

MRI breast without IV contrast	Usually Not Appropriate	0
FDG-PET breast dedicated	Usually Not Appropriate	€ €
Sestamibi MBI	Usually Not Appropriate	⊗ ⊗ ⊗

<u>Variant: 5</u> Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis screening	Usually Not Appropriate	⊗ ⊗
Mammography screening	Usually Not Appropriate	⊗ ⊗
MRI breast without and with IV contrast	Usually Not Appropriate	0
MRI breast without IV contrast	Usually Not Appropriate	0
FDG-PET breast dedicated	Usually Not Appropriate	**
Sestamibi MBI	Usually Not Appropriate	**

<u>Variant: 6</u> Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

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Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis screening	Usually Not Appropriate	⊗ ⊗
Mammography screening	Usually Not Appropriate	⊗ ⊗
MRI breast without and with IV contrast	Usually Not Appropriate	0
MRI breast without IV contrast	Usually Not Appropriate	0
FDG-PET breast dedicated	Usually Not Appropriate	⊗ ⊗
Sestamibi MBI	Usually Not Appropriate	∵

<u>Variant: 7</u> Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	0
Digital breast tomosynthesis diagnostic	May Be Appropriate	⊗ ⊗
Mammography diagnostic	May Be Appropriate	⊗ ⊗
MRI breast without and with IV contrast	Usually Not Appropriate	0
MRI breast without IV contrast	Usually Not Appropriate	0
FDG-PET breast dedicated	Usually Not Appropriate	∵ ∵
Sestamibi MBI	Usually Not Appropriate	∵ ∵

<u>Variant: 8</u> Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging.

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

FDG-PET breast dedicated	Usually Not Appropriate	∵ ∵
Sestamibi MBI	Usually Not Appropriate	∵ ∵

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Summary of Literature Review

Introduction/Background

Mastectomy may be performed to treat breast cancer [1] with some authors reporting increasing rates of mastectomy relative to breast conservation in the United States [2-4]. Mastectomy may also be performed as a prophylactic approach in women with a high lifetime risk of developing breast cancer. Mastectomy techniques have changed over time with radical mastectomy replaced by modified radical mastectomy and with options such as skin-sparing and nipple-sparing procedures now available [5]. In addition, mastectomies may be performed with or without reconstruction. Reconstruction approaches differ and may be autologous, involving a transfer of tissue (skin, subcutaneous fat, and muscle) from other parts of the body to the chest wall. Examples of autologous reconstruction include latissimus dorsi flaps, transverse rectus abdominis myocutaneous (TRAM) flaps, and variants such as deep inferior epigastric perforator flaps [1]. Reconstruction may also involve implants. Implant reconstruction may occur as a single procedure or as multistep procedures with initial use of an adjustable tissue expander allowing the mastectomy tissues to be stretched without compromising blood supply. Ultimately, a full-volume implant, which may be saline, silicone, or both, will be placed. Implant reconstruction often involves the placement of acellular matrix, which can increase risk of seroma formation and occasionally is visible on imaging.

Reconstructions with a combination of autologous and implant reconstruction may also be performed. Other techniques such as autologous fat grafting may be used to refine both implant and flap-based reconstruction [6].

Although most of the breast tissue is removed after mastectomy, recurrence may occur in residual tissue. The majority of recurrences in the reconstructed breast will be found in the skin and the subcutaneous tissues followed by recurrences deep to the pectoralis muscle [7]. Recurrence rates are reported to be approximately 1% to 2% annually for both mastectomy and mastectomy with reconstruction, and overall recurrence has been reported at between 2% to 15% and has been noted to vary based on the initial cancer type and stage as well as follow-up period of the study [5,7-13]. Clinical evaluation has been a mainstay of evaluation of the postmastectomy breast [4], and the appropriate surveillance imaging strategy for patients with a history of mastectomy with or without reconstruction is an evolving topic, with evidence predominantly drawn from small retrospective studies. Finally, women who have undergone mastectomy with or without reconstruction may present with symptomatic concerns, both in the immediate postoperative period and later. Sequalae of the surgery, such as hematomas, infections, and most commonly in

the early postoperative period, fat necrosis [7], may present as palpable findings. Recurrent disease may also present as a palpable lump [7,14].

Initial Imaging Definition

Imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

• There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

OR

• There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously in which each procedure provides unique clinical information to effectively manage the patient's care).

Discussion of Procedures by Variant

Variant 1: Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

Please note that this clinical scenario is focused on the appropriateness of imaging modalities for screening the side of the mastectomy. For screening of the contralateral native breast in the setting of a unilateral mastectomy, see the ACR Appropriateness Criteria topic on "Breast Cancer Screening" [15].

Variant 1: Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

A. FDG-PET Breast Dedicated

There is no relevant literature to support the use of fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG)-PET breast for screening in this clinical setting.

Variant 1: Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

B. Digital Breast Tomosynthesis Screening

There is no relevant literature to support the use of digital breast tomosynthesis (DBT) for screening the postmastectomy side. However, annual screening with 2-D mammography or DBT is recommended for the contralateral native breast. DBT addresses some of the limitations encountered with standard 2-D 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. See the ACR Appropriateness Criteria [®] topic on "Breast Cancer Screening" [15] for further quidance.

Variant 1: Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

C. Mammography Screening

Annual screening with 2-D mammography or DBT is recommended for the contralateral native

breast. There is insufficient evidence to support screening with 2-D mammography of the postmastectomy side. Although one small retrospective study has shown a small increase in cancer detection with mammography in postmastectomy patients [16], another study has demonstrated no benefit [8].

Variant 1: Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

D. MRI Breast Without IV Contrast

There is no relevant literature to support the use of MRI breast without intravenous (IV) contrast for screening in this clinical setting.

Variant 1: Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

E. MRI Breast Without and With IV Contrast

There is no relevant literature to support the use of MRI without and with IV contrast, specifically for screening the postmastectomy nonreconstructed breast. However, based on breast cancer risk, including factors such as age at cancer diagnosis, breast density, and family history, women with a personal history of cancer may undergo MRI for the contralateral native breast [17]. In this setting, the postmastectomy breast may be imaged and evaluated on MRI with potential for malignancy detection and characterization [18].

Variant 1: Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

F. Sestamibi MBI

There is no relevant literature to support the use of Tc-99m sestamibi molecular breast imaging (MBI) for screening in this clinical setting.

Variant 1: Female. Breast cancer screening. History of cancer, mastectomy side(s), no reconstruction.

G. US Breast

There is insufficient evidence to support the use of ultrasound (US) for screening in this setting. There is a paucity of evidence-based literature [16,18-20], with only a few small retrospective studies finding utility in screening with US in this setting. A subset of a retrospective study evaluated 67 women postmastectomy who had suspected recurrence and underwent US imaging; although some of these women were symptomatic, 7 recurrent impalpable cancers were detected only on US in the cohort [16]. This study also found 3/61 cancers detected only on mammography and not on US. A study of 1,796 US examinations in 874 asymptomatic patients (median follow-up of 37 months) found 15 clinically occult recurrences detected with US in 15 patients (cancer detection rate of 1.7% per patient and 0.8% per examination) [19]. Lee et al [20] evaluated 1,180 consecutive screening USs of the mastectomy site and the ipsilateral axillary fossa in 468 asymptomatic women and found 10 malignancies with a similar cancer detection rate of 2.1% per patient and 0.8% per screening examination.

Variant 2: Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

Please note that this clinical scenario is focused on the appropriateness of imaging modalities for screening the side of the mastectomy following reconstruction. For screening of the contralateral native breast in the setting of a unilateral mastectomy, see the ACR Appropriateness Criteria [®] topic on "Breast Cancer Screening" [15].

Variant 2: Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

A. FDG-PET Breast Dedicated

There is no relevant literature to support the use of FDG-PET breast for screening in this clinical setting.

Variant 2: Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

B. Digital Breast Tomosynthesis Screening

Although insufficient studies have been performed to assess the utility of DBT in this setting, multiple investigations have demonstrated that DBT is helpful in the screening setting of the native breast, thus decreasing recall rates and increasing cancer detection rates compared to a conventional mammographic workup [21-26].

Variant 2: Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

C. Mammography Screening

Evidence is limited, but a few retrospective studies suggest a benefit to screening women with autologous reconstruction after mastectomy for cancer in the reconstruction side. Helvie et al [27] looked at 214 consecutive screening mammograms in 113 women with TRAM flap reconstructions, 106 (94%) of which were performed after mastectomy for cancer. The cancer detection rate was 0.9% per screen and 1.9% per patient (2/106, 95% confidence interval [CI]: 0.33%, 7.32%) and positive predictive value (PPV) of biopsy was 33% (95% CI: 6%, 76%). Noroozian et al [10] in a larger study of 515 women and 618 mastectomies with reconstruction, 485 of which were performed for cancer, found the cancer detection rate of screening mammography to be 1.5/1,000 screening mammograms, comparable to that for one native breast of age-matched women. However, Freyvogel et al [28] retrospectively evaluated 541 postmastectomy and autologous reconstruction patients. Of these, 397 patients had screening mammography and 537 patients underwent routine clinical examination. Of the patients in the cohort, 26 of 27 (96.3%) had a clinically detectable recurrence, and the two cancers detected on screening were also palpable on follow-up clinical examination. Lee et al [29] evaluated 554 mammograms (265 TRAM flap reconstructions); no cancers were detected through screening and no interval nonpalpable recurrent breast cancers missed at mammography were identified, yielding a 0% rate of detection (exact 95% CI: 0.0%, 1.4%). The authors concluded that screening this population is less effective than screening average-risk women in their 40s, although it should be noted that the upper end of the CI is in line with the rates reported by the other studies mentioned above. Of note, there are no studies specifically evaluating decrease in mortality from screening women in this setting.

Variant 2: Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

D. MRI Breast Without IV Contrast

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

Variant 2: Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

E. MRI Breast Without and With IV Contrast

There is insufficient evidence to support the use of MRI without and with IV contrast for screening

in this setting. Based on breast cancer risk, including factors such as age at cancer diagnosis, breast density, and family history, women with a personal history of cancer may undergo MRI for the contralateral native breast [17]. In this setting, MRI will also allow for evaluation of the reconstructed breast and may be able to demonstrate recurrent malignancy, although the literature is scant with only several small studies and case reports [30,31]. Reiber et al [31], for example, used MRI to evaluate 41 patients with flap reconstructions, finding one mammographically and sonographically occult cancer in a patient with a latissimus dorsi flap. However, MRI also generated three false-positive biopsies.

Variant 2: Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

F. Sestamibi MBI

There is no relevant literature to support the use of Tc-99m sestamibi MBI for screening in this clinical setting.

Variant 2: Female. Breast cancer screening. History of cancer, autologous reconstruction side(s) with or without implant.

G. US Breast

There is no relevant literature to support the use of US for screening in this clinical setting.

Variant 3: Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

Please note that this clinical scenario is focused on the appropriateness of imaging modalities for screening the side of the mastectomy following reconstruction. For screening of the native breast in the setting of unilateral mastectomy, see the ACR Appropriateness Criteria topic on "Breast Cancer Screening" [15]. For evaluation of the implant itself, discussion of the evidence regarding screening for implant rupture, and evaluation for breast implant associated anaplastic large cell lymphoma, please see the ACR Appropriateness Criteria topic on "Breast Implant Evaluation" [32].

Variant 3: Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

A. Digital Breast Tomosynthesis Screening

There is no relevant literature to support the use of DBT for screening in this clinical setting.

Variant 3: Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

B. Mammography Screening

There is no relevant literature to support the use of mammography for screening in this clinical setting.

Variant 3: Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

C. FDG-PET Breast Dedicated

There is no relevant literature to support the use of FDG-PET breast for screening in this clinical setting.

Variant 3: Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

D. MRI Breast Without IV Contrast

There is no relevant literature to support the use of MRI without IV contrast for screening in this clinical setting.

Variant 3: Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

E. MRI Breast Without and With IV Contrast

There is insufficient evidence to support screening women specifically to evaluate the postmastectomy breast with implant reconstruction. A small retrospective study of 45 breast MRI surveillance examinations performed in women who underwent mastectomy for either cancer or prophylaxis and had either implant, flap, or mixed reconstruction found no locoregional recurrences that were not also clinically suspected [33]. Golan et al [34] evaluated 159 women status post bilateral mastectomy and reconstruction who underwent 415 surveillance MRI examinations. In this study, the majority of the women (90%) had implant reconstruction. Of these, 405 (98%; 95% CI: 96%–99%) of the studies were negative, and one breast recurrence was found on MRI (cancer detection rate 2.4 per 1,000 MRI examinations, 95% CI: 0.4–13) in a woman who was also found to have metastatic disease. In addition, the false-positive rate was 90% (95% CI: 54%–99%). The interval cancer rate in this group was 5/1000 (95% CI: 1.3–17), and 4 women were diagnosed with metastatic disease. However, based on breast cancer risk, including factors such as age at cancer diagnosis, breast density, and family history, women with a personal history of cancer may undergo MRI for the contralateral native breast [17].

Variant 3: Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

F. Sestamibi MBI

There is no relevant literature to support the use of Tc-99m sestamibi MBI for screening in this clinical setting.

Variant 3: Female. Breast cancer screening. History of cancer, nonautologous (implant) reconstruction sides(s).

G. US Breast

There is no relevant literature to support the use of US for screening in this clinical setting.

Variant 4: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

See the ACR Appropriateness Criteria[®] topic on "Breast Cancer Screening" [15].

Variant 4: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

A. FDG-PET Breast Dedicated

There is no relevant literature to support the use of FDG-PET breast for screening in this clinical setting.

Variant 4: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

B. Digital Breast Tomosynthesis Screening

There is no relevant literature to support the use of DBT for screening in this clinical setting.

Variant 4: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

C. Mammography Screening

There is no relevant literature to support the use of mammography for screening in this clinical setting.

Variant 4: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

D. MRI Breast Without IV Contrast

There is no relevant literature to support the use of MRI without IV contrast for screening in this clinical setting.

Variant 4: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

E. MRI Breast Without and With IV Contrast

There is insufficient evidence to support the use of MRI without and with IV contrast for breast cancer screening in this setting.

Variant 4: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

F. Sestamibi MBI

There is no relevant literature to support the use of Tc-99m sestamibi MBI for screening in this clinical setting.

Variant 4: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy, no reconstruction.

G. US Breast

There is no relevant literature to support the use of US for screening in this clinical setting.

Variant 5: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

See the ACR Appropriateness Criteria[®] topic on "Breast Cancer Screening" [15].

Variant 5: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

A. Digital Breast Tomosynthesis Screening

There is no relevant literature to support the use of DBT for screening in this clinical setting.

Variant 5: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

B. Mammography Screening

There is insufficient evidence to support the use of mammography for breast cancer screening in this population. A recent study by Noroozian et al [10] found no evidence to support the use of screening mammography in women who had undergone bilateral prophylactic mastectomy with autologous reconstruction. Of 133 prophylactic mastectomies with autologous reconstruction (805 mammograms), the cancer detection rate with mammography was 0%.

Variant 5: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

C. FDG-PET Breast Dedicated

There is no relevant literature to support the use of FDG-PET breast for screening in this clinical setting.

Variant 5: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

D. MRI Breast Without IV Contrast

There is no relevant literature to support the use of MRI without IV contrast for screening in this clinical setting.

Variant 5: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

E. MRI Breast Without and With IV Contrast

Although there may be residual breast glandular tissue after mastectomy and MRI may be useful in delineating the amount of this residual tissue in women after prophylactic mastectomy [35], there is insufficient evidence to support the use of MRI breast without and with IV contrast for breast cancer screening in this population. A small retrospective study of breast MRI surveillance examinations performed in a subset of women who underwent bilateral mastectomy for either cancer or prophylaxis and had either implant, flap, or mixed reconstructions found no cancers that were not also evident on clinical examinations [33].

Variant 5: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

F. Sestamibi MBI

There is no relevant literature to support the use of Tc-99m sestamibi MBI for screening in this clinical setting.

Variant 5: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with autologous reconstructions.

G. US Breast

There is no relevant literature to support the use of US for screening in this clinical setting.

Variant 6: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

Please note that this clinical scenario focuses on breast cancer screening for malignancy, see the ACR Appropriateness Criteria [®] topic on "Breast Cancer Screening" [15]. For evaluation of the implant itself and for discussion of the evidence regarding evaluation of saline or silicone implants in asymptomatic patients, please see the ACR Appropriateness Criteria [®] topic on "Breast Implant Evaluation" [32].

Variant 6: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

A. Digital Breast Tomosynthesis Screening

There is no relevant literature to support the use of DBT for screening in this clinical setting.

Variant 6: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

B. Mammography Screening

There is no relevant literature to support the use of mammography for screening in this clinical setting.

Variant 6: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

C. FDG-PET Breast Dedicated

There is no relevant literature to support the use of FDG-PET breast for screening in this clinical setting.

Variant 6: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

D. MRI Breast Without IV Contrast

There is no relevant literature to support the use of MRI without IV contrast for screening in this clinical setting.

Variant 6: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

E. MRI Breast Without and With IV Contrast

There is insufficient evidence to support screening for women with prophylactic mastectomy and implant reconstruction. It has been suggested that the yield of screening in this setting is especially low in the setting of retropectoral implant placement, in which recurrences are most likely to be clinically palpable [33,34]. A small retrospective study of breast MRI in 48 women status post bilateral mastectomy with and without reconstruction, some of whom underwent surveillance MRI, found no malignancy that was not also evident on clinical examination [33]. A retrospective study of 159 women status post bilateral mastectomy and reconstruction and undergoing MRI surveillance found no cancers in the subset of 31 women who had mastectomy performed for risk reduction [34].

Variant 6: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

F. Sestamibi MBI

There is no relevant literature to support the use of Tc-99m sestamibi MBI for screening in this clinical setting.

Variant 6: Female. Breast cancer screening. High-risk, bilateral prophylactic mastectomy with nonautologous (implant) reconstructions.

G. US Breast

There is no relevant literature to support the use of US for screening in this clinical setting.

Variant 7: Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

Variant 7: Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

A. Digital Breast Tomosynthesis Diagnostic

There is insufficient evidence to support the use of DBT as the initial imaging modality in women with palpable lumps or clinically significant pain on the side of the mastectomy. However, DBT can be useful in the diagnostic setting. It is known to improve lesion characterization in noncalcified lesions and to improve cancer detection when compared to conventional mammographic workup [36-38].

Variant 7: Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

B. Mammography Diagnostic

There is limited evidence to support the use of diagnostic mammography as the initial imaging

modality in this clinical setting. A study of 67 women who underwent mastectomy and were suspected of recurrence found 3/61 cancers detected only on mammography and not on US [16]. Another study evaluating palpable lumps in 101 patients who had undergone mastectomy, the majority of whom (69%) had reconstruction with implants, demonstrated that mammography could be useful to confirm benign findings such as fat necrosis and benign calcifications identified on US [39]. However, diagnostic mammography yielded no additional cancers beyond those depicted on US.

Variant 7: Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

C. FDG-PET Breast Dedicated

There is no relevant literature to support the use of FDG-PET breast in this clinical setting.

Variant 7: Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

D. MRI Breast Without IV Contrast

There is no relevant literature to support the use of MRI without IV contrast in this clinical setting.

Variant 7: Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

E. MRI Breast Without and With IV Contrast

There is no evidence to support the use of MRI breast without and with IV contrast as the initial imaging modality in women with palpable lump or clinically significant pain on the mastectomy side. However, MRI may help characterize malignancy once identified and has been found to be more accurate than US in delineating extent of disease, although there is a paucity of evidence-based literature [18].

Variant 7: Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

F. Sestamibi MBI

There are a few small retrospective studies evaluating the use of Tc-99m sestamibi MBI in the context of a clinically suspicious lump. For example, Usmani et al [40] looked at 41 consecutive postmastectomy patients and found a sensitivity of 89%, specificity of 92%, PPV of 96%, negative predictive value (NPV) of 80%, and accuracy of 90% with Tc-99m sestamibi MBI. This was compared to US, which had a lower sensitivity of 86%, specificity of 77%, PPV of 89%, NPV of 71%, and accuracy of 83% (P = .001). The authors found that the combined sensitivity was 100%, specificity 77%, PPV 90%, NPV 100%, and accuracy 93%. However, there is insufficient evidence to support the use of Tc-99m sestamibi MBI as the initial imaging modality in this setting.

Variant 7: Female. Palpable lump or clinically significant pain on the side of the mastectomy without reconstruction. Initial imaging.

G. US Breast

A retrospective evaluation of 118 palpable lumps in 101 patients, 9% of whom were status postmastectomy found 13 cancers in the mastectomy bed in women with a history of cancer. US had a high NPV of 97% and a PPV of 27% [39]. Gweon et al [41] evaluated both palpable and nonpalpable US BI-RADS categorization of lesions 4a and above at the mastectomy site and found 9/20 (45%) malignancies among palpable lesions; they also found that 100% of all BI-RADS 4c and BI-RADS 5 lesions proved to be malignant. In the event of an indeterminate US finding or an US finding suggestive of fat necrosis, diagnostic mammography or DBT may be helpful for lesion

characterization and may preclude the need for biopsy if a clearly benign finding such as an oil cyst is identified.

Variant 8: Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging.

Please note that this clinical scenario focuses on evaluation of the reconstruction, which may be an implant reconstruction. For imaging evaluation of the implant itself and for discussion of the evidence regarding evaluation of implant integrity, please see the ACR Appropriateness Criteria [®] topic on "Breast Implant Evaluation" [32].

Variant 8: Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging.

A. Digital Breast Tomosynthesis Diagnostic

There is insufficient evidence to support the use of DBT as the initial imaging modality for women with palpable lumps or clinically significant pain on the side of the mastectomy with reconstruction. However, DBT can be useful in the diagnostic setting. It is known to improve lesion characterization in noncalcified lesions and to improve cancer detection when compared to conventional mammographic workup [36-38].

Variant 8: Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging.

B. Mammography Diagnostic

There is limited evidence to support the use of diagnostic mammography as the initial imaging modality in this clinical setting. Mammography may be helpful in identifying a benign postsurgical etiology of a palpable concern such as fat necrosis or oil cyst. For example, a study evaluating palpable lumps in 101 patients who had undergone mastectomy, the majority of whom (69%) had reconstruction with implants, demonstrated that mammography could be useful to confirm benign findings such as fat necrosis and benign calcifications identified on US [39]. However, the study also showed that diagnostic mammography yielded no additional cancers beyond those depicted on US. In another small study, Edeiken et al [42] found that mammography depicted only 14 of 25 (56%) of the recurrences visualized on US in women who had undergone autogenous myocutaneous flaps after mastectomy.

Variant 8: Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging.

C. FDG-PET Breast Dedicated

There is no relevant literature to support the use of FDG-PET breast as the initial imaging modality in this clinical setting.

Variant 8: Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging.

D. MRI Breast Without IV Contrast

There is no role for MRI without IV contrast as the initial imaging modality in this clinical setting. For evaluation of implant integrity, please see the ACR Appropriateness Criteria topic on "Breast Implant Evaluation" [32].

Variant 8: Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging.

E. MRI Breast Without and With IV Contrast

There is insufficient evidence for MRI without and with IV contrast as the initial imaging modality in this setting. There are a few small studies evaluating MRI in women with symptomatic concerns and breast reconstruction. Devon et al [43] evaluated 24 TRAM reconstructions in 22 women with the majority of cases (64%) presenting with palpable abnormality or pain. Sixteen women in the study had MRI without mammography or US. In 4 of 24 cases (17%), MRI detected recurrent breast cancer, including axillary nodal recurrence. Of note, tissue expanders may be a contraindication to breast MRI [44].

Variant 8: Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging. F. Sestamibi MBI

There is no relevant literature to support the use of Tc-99m sestamibi MBI as the initial imaging modality in this clinical setting.

Variant 8: Female. Palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous). Initial imaging. G. US Breast

There are a few small studies to support the use of US this setting. Dashevsky et al [39] looked at 118 palpable lumps in 101 patients postmastectomy (85% of whom were also postreconstruction). In total, 14 palpable lumps in 12 patients were malignant, and 104 palpable lumps in 89 patients were nonmalignant. Thirteen cancers were identified on US with only two false-positives (NPV 97%, PPV 27%). Edeiken et al [42] evaluated 20 women with autologous flap reconstruction after mastectomy who presented with palpable lumps; US ultimately identified 39 of 39 (100%) of cancers, 18 of which were palpable and 21 of which were occult. In the event of an indeterminate US finding, or an US finding suggestive of fat necrosis, diagnostic mammography or DBT may be helpful for lesion characterization and may preclude the need for biopsy if a clearly benign finding such as an oil cyst is identified.

Summary of Recommendations

- **Variant 1:** Imaging for breast cancer screening is usually not appropriate for a female with history of cancer and no reconstruction on breast(s) that underwent mastectomy.
- **Variant 2:** Mammography or DBT for breast cancer screening may be appropriate for a female with history of cancer and autologous reconstruction on breast(s) with or without implant(s).
- **Variant 3:** Imaging for breast cancer screening is usually not appropriate for a female with history of cancer and nonautologous (implant) reconstruction on breast(s).
- **Variant 4:** Imaging for breast cancer screening is usually not appropriate for a high-risk female with no reconstruction on breasts that underwent bilateral prophylactic mastectomy.
- **Variant 5:** Imaging for breast cancer screening is usually not appropriate for a high-risk female with autologous reconstructions on breasts that underwent bilateral prophylactic mastectomy.
- **Variant 6:** Imaging for breast cancer screening is usually not appropriate for a high-risk female with nonautologous (implant) reconstructions on breasts that underwent a bilateral prophylactic mastectomy.
- **Variant 7:** US breast as initial imaging is usually appropriate for a female with a palpable lump or clinically significant pain on the side of the mastectomy without reconstruction.

• **Variant 8:** US breast as initial imaging is usually appropriate for a female with a palpable lump or clinically significant pain on the side of the mastectomy with reconstruction (autologous or nonautologous).

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at https://acsearch.acr.org/list. 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, please go to the ACR website at https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria.

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 riskbenefit 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 [45].

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
0	0 mSv	0 mSv
②	<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."

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Disclaimer

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.

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