American College of Radiology ACR Appropriateness Criteria[®] Imaging after Breast Surgery

Variant 1:

Female. Age 40 years or older. Postsurgical excision with nonmalignant pathology. Asymptomatic. Initial imaging.

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

Variant 2:

Female. Age 30 to 39 years. Postsurgical excision with nonmalignant pathology. Asymptomatic. Initial imaging.

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

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Variant 3:

Adult female younger than 30 years of age. Postsurgical excision with nonmalignant pathology. Asymptomatic. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis diagnostic	Usually Not Appropriate	��
Digital breast tomosynthesis screening	Usually Not Appropriate	��
Mammography diagnostic	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
Sestamibi MBI	Usually Not Appropriate	���
FDG-PET breast dedicated	Usually Not Appropriate	∞∞∞

<u>Variant 4:</u> Adult female. Postsurgical excision for breast cancer. Positive margins. Asymptomatic. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis diagnostic	May Be Appropriate (Disagreement)	�€
Mammography diagnostic	May Be Appropriate	*
MRI breast without and with IV contrast	May Be Appropriate	0
US breast	Usually Not Appropriate	0
Digital breast tomosynthesis screening	Usually Not Appropriate	*
Mammography screening	Usually Not Appropriate	*
MRI breast without IV contrast	Usually Not Appropriate	0
Sestamibi MBI	Usually Not Appropriate	���
FDG-PET breast dedicated	Usually Not Appropriate	

Variant 5:

Adult female. Surveillance following completion of breast conservation therapy for breast cancer. Negative margins. With or without radiation. Asymptomatic.

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

IMAGING AFTER BREAST SURGERY

Expert Panel on Breast Imaging: Tejas S. Mehta, MD, MPH^a; Ana P. Lourenco, MD^b; Bethany L. Niell, MD, PhD^c; Debbie L. Bennett, MD^d; Ann Brown, MD^e; Alison Chetlen, DO^f; Phoebe Freer, MD^g; Lillian K. Ivansco, MD, MPH^h; Maxine S. Jochelson, MDⁱ; Katherine A. Klein, MD^j; Sharp F. Malak, MD, MPH^k; Marion McCrary, MD^l; David Mullins, MD^m; Colleen H. Neal, MDⁿ; Mary S. Newell, MD^o; Gary A. Ulaner, MD, PhD^p; Linda Moy, MD.^q

Summary of Literature Review

Introduction/Background

The ACR recommends annual screening mammography starting at age 40 in average-risk women [1]. Approximately 2% of patients undergoing screening have a recommendation for percutaneous biopsy. From these, 20% to 40% will go on to have surgical intervention [2]. Women with clinically suspicious findings without imaging correlate may also undergo surgical intervention. For women with pathologic diagnosis of breast cancer, surgical treatment can be in the form of mastectomy (see ACR Appropriateness Criteria[®] on "Imaging after Mastectomy and Breast Reconstruction" [3]) or breast conservation therapy, with concurrent or delayed cosmetic reconstruction. There is variability in management of different high-risk pathologies on percutaneous biopsy, with some lesions such as atypical ductal hyperplasia more commonly being excised and other lesions such as lobular neoplasia excised in some cases with others undergoing surveillance. Occasionally, benign pathology without atypia may undergo surgical excision due to large size resulting in breast deformity, other symptoms, or personal preference. Knowledge of how best to surveil women who have had breast surgery for cancer and for benign lesions, including high risk pathology, is important.

Initial Imaging Definition

Initial imaging is defined as 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 where each procedure provides unique clinical information to effectively manage the patient's care).

Discussion of Procedures by Variant

Variant 1: Female. Age 40 years or older. Postsurgical excision with nonmalignant pathology. Asymptomatic. Initial imaging.

Benign breast disease can be classified into 3 broad categories: nonproliferative lesions, proliferative lesions without atypia, and proliferative lesions with atypia. Nonproliferative lesions include benign calcifications, fibrocystic changes, fibroadenomas, lipomas, fat necrosis, and nonsclerosing adenosis. Proliferative lesions without atypia include usual ductal hyperplasia, sclerosing adenosis, complex fibroadenomas, radial scars/complex sclerosing lesions, papillomas, and papillomatosis. Proliferative lesions with atypia include atypical ductal hyperplasia, atypical lobular hyperplasia, lobular carcinoma in situ (LCIS), and flat epithelial atypia [4,5]. Benign breast disease and breast tissue density are independent risk factors for developing breast cancer [5,6]. One study of women from the Breast Cancer Surveillance Consortium (BCSC) reported breast cancer in 25% of women with excision for

^aUMass Memorial Medical Center, Worchester, Massachusetts. ^bPanel Chair, Alpert Medical School of Brown University, Providence, Rhode Island. ^cPanel Vice-Chair, H. Lee Moffitt Cancer Center and Research Institute, Tampa, Florida. ^dWashington University School of Medicine, Saint Louis, Missouri. ^eUniversity of Cincinnati, Cincinnati, Ohio. ^fPenn State Health Hershey Medical Center, Hershey, Pennsylvania. ^gUniversity of Utah, Salt Lake City, Utah. ^hKaiser Permanente, Atlanta, Georgia. ⁱMemorial Sloan Kettering Cancer Center, New York, New York. ^jUniversity of Michigan, Ann Arbor, Michigan. ^kSt. Bernards Healthcare, Jonesboro, Arkansas. ^bDuke Signature Care, Durham, North Carolina; American College of Physicians. ^mPrinceton Community Hospital, Princeton, West Virginia; American College of Surgeons. ^mProMedica Breast Care, Toledo, Ohio. ^oEmory University Hospital, Atlanta, Georgia; RADS Committee. ^pHoag Family Cancer Institute, Newport Beach, California and University of Southern California, Los Angeles, California; Commission on Nuclear Medicine and Molecular Imaging. ^qSpecialty Chair, NYU Clinical Cancer Center, New York, New York.

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proliferative lesions with atypia [7]. Almost 30% of women with breast cancer have a history of benign breast disease [4].

Please note that this clinical scenario is focused on the appropriateness of initial imaging modalities based on a history of surgical excision with nonmalignant pathology. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Digital Breast Tomosynthesis Diagnostic

There is no relevant literature to support the routine use of diagnostic digital breast tomosynthesis (DBT) in this clinical scenario. Women in this clinical scenario are asymptomatic and should undergo screening mammography or tomosynthesis [8]. Some benign breast diseases, with or without other factors, can increase a woman's risk to higher-than-average risk. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "Breast Cancer Screening" [8] and "Supplemental Breast Cancer Screening Based on Breast Density" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Although there are no relevant studies examining mammographic follow-up intervals of benign breast disease following surgical biopsy, there are some studies examining imaging intervals following benign core biopsy. In populations with nonproliferative lesions or proliferative lesions without atypia, imaging intervals of 6 months compared to routine annual screening did not improve cancer detection rates or change invasive cancer rates, stage, tumor size, or nodal status [11,12]. The studies on proliferative lesions with atypia, examining the need for excision and, if not excised, need for short interval follow-up, are varied [13-16] and are outside the scope of this document. Atypical ductal hyperplasia on core biopsy typically warrants surgical consultation and/or multidisciplinary discussion regarding the benefits and risks of subsequent excision. There is more varied practice in management of atypical lobular hyperplasia, LCIS, and flat epithelial atypia found on core biopsy.

Digital Breast Tomosynthesis Screening

The ACR and Society of Breast Imaging (SBI) recommend all asymptomatic women \geq 40 years of age undergo annual screening mammography, even if they are average risk [1,8,17]. Please refer to the ACR Appropriateness Criteria[®] topic on "<u>Breast Cancer Screening</u>" [8]. Women in this clinical scenario should undergo annual screening mammography.

One study of more than 2 million screening mammograms in nearly 800,000 women, with 15% having a self-reported history of prior benign percutaneous or excisional breast biopsy, showed no difference in mammographic sensitivity; however, there was decreased specificity and mammographic performance, which was attributed to tissue characteristics rather than the biopsy itself [18]. Another study comparing patients with history of proliferative lesions with atypia with matched screenings based on age, density, and breast cancer family history also found no differences in mammographic sensitivity or proportion of interval cancers; however, they also reported lower specificity in the atypical proliferative lesions group [19].

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 imaging in this clinical scenario.

Mammography Diagnostic

There is no relevant literature to support the routine use of diagnostic mammography in this clinical scenario. Women in this clinical scenario are asymptomatic and should undergo screening mammography or tomosynthesis [8]. Some benign breast diseases, with or without other factors, can increase a woman's risk to higher-than-average risk. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "Breast Cancer Screening" [8] and "Supplemental Breast Cancer Screening Based on Breast Density" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Although there are no relevant studies examining mammographic follow-up intervals of benign breast disease following surgical biopsy, there are some studies examining imaging intervals following benign core biopsy. In populations with nonproliferative lesions or proliferative lesions without atypia, imaging intervals of 6 months compared with routine annual screening did not improve cancer detection rates or change invasive cancer rates, stage, tumor size, or nodal status [11,12]. The studies on proliferative lesions with atypia, examining the need for

excision and, if not excised, the need for short interval follow-up, are varied [13-16,20] and are outside the scope of this document. A majority agree that there is a need for surgical excision when atypical ductal hyperplasia is found on core biopsy. There is more varied practice in management of atypical lobular hyperplasia, LCIS, and flat epithelial atypia found on core biopsy.

Mammography Screening

The ACR and SBI recommend all asymptomatic women \geq 40 years of age undergo annual screening mammography, even if they are average risk [1,8,17]. Please refer to the ACR Appropriateness Criteria[®] topic on "<u>Breast Cancer</u> <u>Screening</u>" [8]. Women in this clinical scenario should undergo annual screening mammography.

One study of more than 2 million screening mammograms in nearly 800,000 women, with 15% having a self-reported history of prior benign percutaneous or excisional breast biopsy, showed no difference in mammographic sensitivity; however, there was decreased in specificity and mammographic performance, which was attributed to tissue characteristics rather than the biopsy itself [18]. Another study comparing patients with history of proliferative lesions with atypia with matched screenings based on age, density, and breast cancer family history also found no differences in mammographic sensitivity or proportion of interval cancers; however, they also reported lower specificity in the atypical proliferative lesions group [19].

MRI Breast Without and With IV Contrast

There is no relevant literature to support the routine use of MRI breast without and with intravenous (IV) contrast in an average-risk patient. Some benign breast diseases, especially atypical ductal hyperplasia and lobular neoplasia can increase a woman's overall risk for developing breast cancer. In these situations, the use of MRI breast without and with IV contrast may be warranted. Please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer</u> <u>Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

MRI Breast Without IV Contrast

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

Sestamibi MBI

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

US Breast

There is no relevant literature to support the routine use of breast ultrasound (US) in this clinical scenario. Some benign breast disease, especially atypical ductal hyperplasia and lobular neoplasia can increase a woman's overall risk for developing breast cancer. Please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer</u> <u>Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Variant 2: Female. Age 30 to 39 years. Postsurgical excision with nonmalignant pathology. Asymptomatic. Initial imaging.

Benign breast disease can be classified into 3 broad categories: nonproliferative lesions, proliferative lesions without atypia, and proliferative lesions with atypia. Nonproliferative lesions include benign calcifications, fibrocystic changes, fibroadenomas, lipomas, fat necrosis, and nonsclerosing adenosis. Proliferative lesions without atypia include usual ductal hyperplasia, sclerosing adenosis, complex fibroadenomas, radial scars/complex sclerosing lesions, papillomas, and papillomatosis. Proliferative lesions with atypia include atypical ductal hyperplasia, atypical lobular hyperplasia, LCIS, and flat epithelial atypia [4,5]. Benign breast disease and breast tissue density are independent risk factors for developing breast cancer [5,6]. One study of women from the BCSC reported breast cancer in 25% of women with excision for proliferative lesions with atypia [7]. Almost 30% of women with breast cancer have a history of benign breast disease [4].

Please note that this clinical scenario is focused on the appropriateness of initial imaging modalities based on a history of surgical excision with nonmalignant pathology. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Digital Breast Tomosynthesis Diagnostic

There is no relevant literature to support the routine use of diagnostic DBT in this clinical scenario. Diagnostic imaging is not typically used for asymptomatic women. Women in this clinical scenario should undergo age- and risk-appropriate screening. Some benign breast diseases, with or without other risk factors, can increase a woman's risk to higher-than-average risk. In these patients, mammography may be warranted at an earlier age before 40. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "Breast Cancer Screening" [8] and "Supplemental Breast Cancer Screening Based on Breast Density" [9] and the ACR recommendations on screening in women at higher-than-average [10].

Digital Breast Tomosynthesis Screening

There is no relevant literature to support the routine use of screening DBT in an average-risk patient. The ACR and SBI recommend asymptomatic average-risk women undergo annual screening mammography starting at age 40 [1,8,17]. Women in this clinical scenario should undergo age and risk appropriate screening. Some benign breast diseases, with or without other risk factors, can increase a woman's risk to higher-than-average risk. In these patients, mammography may be warranted at an earlier age before 40. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "Breast Cancer Screening" [8] and "Supplemental Breast Cancer Screening Based on Breast Density" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

FDG-PET Breast Dedicated

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

Mammography Diagnostic

There is no relevant literature to support the routine use of diagnostic mammography in this clinical scenario. Diagnostic imaging is not typically used for asymptomatic women. Women in this clinical scenario should undergo age- and risk-appropriate screening. Some benign breast diseases, with or without other risk factors, can increase a woman's risk to higher-than-average risk. In these patients, mammography may be warranted at an earlier age before 40. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "Breast Cancer Screening" [8] and "Supplemental Breast Cancer Screening Based on Breast Density" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Mammography Screening

There is no relevant literature to support the routine use of screening mammography in an average-risk patient. The ACR and SBI recommend asymptomatic average-risk women undergo annual screening mammography starting at age 40 [1,8,17]. Women in this clinical scenario should undergo age and risk appropriate screening. Some benign breast diseases, with or without other risk factors, can increase a woman's risk to higher-than-average risk. In these patients, mammography may be warranted at an earlier age before 40. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "Breast Cancer Screening" [8] and "Supplemental Breast Cancer Screening Based on Breast Density" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

MRI Breast Without and With IV Contrast

There is no relevant literature to support the routine use of MRI breast without and with IV contrast in an averagerisk patient. Some benign breast disease, especially atypical ductal hyperplasia and lobular neoplasia can increase a woman's overall risk for developing breast cancer. In these situations, the use of MRI breast without and with IV contrast may be warranted. Please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

MRI Breast Without IV Contrast

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

Sestamibi MBI

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

US Breast

There is no relevant literature to support the routine use of breast US for surveillance in this clinical scenario. Some benign breast disease, especially atypical ductal hyperplasia and lobular neoplasia can increase a woman's overall

risk for developing breast cancer. Please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer</u> <u>Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Variant 3: Adult female younger than 30 years of age. Postsurgical excision with nonmalignant pathology. Asymptomatic. Initial imaging.

Benign breast disease can be classified into 3 broad categories: nonproliferative lesions, proliferative lesions without atypia, and proliferative lesions with atypia. Nonproliferative lesions include benign calcifications, fibrocystic changes, fibroadenomas, lipomas, fat necrosis, and nonsclerosing adenosis. Proliferative lesions without atypia include usual ductal hyperplasia, sclerosing adenosis, complex fibroadenomas, radial scars/complex sclerosing lesions, papillomas, and papillomatosis. Proliferative lesions with atypia include atypical ductal hyperplasia, atypical lobular hyperplasia, LCIS, and flat epithelial atypia [4,5]. Benign breast disease and breast tissue density are independent risk factors for developing breast cancer [5,6]. One study of women from the BCSC reported breast cancer in 25% of women with excision for proliferative lesions with atypia [7]. Almost 30% of women with breast cancer have a history of benign breast disease [4].

Please note that this clinical scenario is focused on the appropriateness of initial imaging modalities based on a history of surgical excision with nonmalignant pathology. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Digital Breast Tomosynthesis Diagnostic

There is no relevant literature to support the routine use of diagnostic DBT in this clinical scenario. Diagnostic imaging is not typically used for asymptomatic women. Women in this clinical scenario should undergo age- and risk-appropriate screening. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "Breast Cancer Screening" [8] and "Supplemental Breast Cancer Screening Based on Breast Density" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Digital Breast Tomosynthesis Screening

There is no relevant literature to support the routine use of screening DBT in an average-risk patient. The ACR and SBI recommend asymptomatic average-risk women undergo annual screening mammography starting at age 40 [1,8,17]. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "Breast Cancer Screening" [8] and "Supplemental Breast Cancer Screening Based on Breast Density" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

FDG-PET Breast Dedicated

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

Mammography Diagnostic

There is no relevant literature to support the routine use of diagnostic mammography in this clinical scenario. Diagnostic imaging is not typically used for asymptomatic women. Women in this clinical scenario should undergo age- and risk-appropriate screening. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer</u> <u>Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Mammography Screening

There is no relevant literature to support the routine use of screening mammography in an average-risk patient. The ACR and SBI recommend asymptomatic average-risk women undergo annual screening mammography starting at age 40 [1,8,17]. For screening guidelines based on overall risk for breast cancer, please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening</u> <u>Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

MRI Breast Without and With IV Contrast

There is no relevant literature to support the routine use of MRI breast without and with IV contrast in an averagerisk patient. Some benign breast disease, especially atypical ductal hyperplasia and lobular neoplasia can increase a woman's overall risk for developing breast cancer. In these situations, the use of MRI breast without and with IV contrast may be warranted. Please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

MRI Breast Without IV Contrast

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

Sestamibi MBI

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

US Breast

There is no relevant literature to support the routine use of breast US for surveillance in this clinical scenario. Some benign breast disease, especially atypical hyperplasia and lobular neoplasia can increase a woman's overall risk for developing breast cancer. Please refer to the ACR Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Variant 4: Adult female. Postsurgical excision for breast cancer. Positive margins. Asymptomatic. Initial imaging.

Margin status is an important predictor of local recurrence of invasive or in situ cancer after breast conservation surgery. For invasive breast cancer (with or without DCIS), a negative margin is defined as no tumor on ink by histology. In contrast, guidelines recommend that margins for pure DCIS (with or without microinvasion) be at least 2 mm [21].

In one study, patients with ductal carcinoma in situ treated with breast conservation and radiation therapy had varied 10-year rates of local failure, ranging from 8% if margins were negative to 15% with positive margins [22]. Age was also a risk factor in this cohort, with local failure at 10 years of 5% in patients \geq 60 years of age and as high as 18% in patients <40 years of age [22]. The addition of radiation treatment after lumpectomy reduced the risk of local recurrence by approximately 50%. Some patients also received endocrine therapy; however, this is a not a substitute for radiation therapy [22].

Frequencies of positive margins after initial surgery vary based on multiple factors including type of breast cancer, appearance on imaging, breast density, and surgical technique. Positive margins at first surgery and at final breast surgery are predictors of breast cancer recurrence [23]. The goal of surgery is to remove the tumor and obtain negative margins. Re-excision is usually performed in the setting of positive margins, often without additional imaging evaluation. Imaging is sometimes used to help delineate residual disease before re-excision. Sometimes despite re-excision, margins remain close or positive.

Digital Breast Tomosynthesis Diagnostic

There is no relevant literature to support the routine use of diagnostic DBT in this clinical scenario. When diagnostic mammography is performed in this scenario, it is typically for evaluation of residual calcifications, which are better visualized on magnification mammograms rather than DBT. One small retrospective study evaluated postexcision mammography and MRI to assess for residual disease. Of 51 patients with malignant calcifications (32 with and 19 without residual disease), mammography sensitivity, specificity, and accuracy were 78.1%, 42.1%, and 62.7%, respectively. MRI was better than mammography, especially in the setting of low background parenchymal enhancement, in which sensitivity, specificity, and accuracy were 88.8%, 57.1%, and 76.5%, respectively [24]. Another small single institution study of 281 patients with ductal carcinoma in situ, of which 144 underwent postexcision preirradiation mammography, found postexcision preirradiation mammography resulted in a change in surgical management in 7% (10/144) and removal of residual ductal carcinoma in situ in 4% (6/144) of patients. More importantly there was no significant change in 10-year local recurrence-free survival (95% versus 92%, with and without postexcision preirradiation mammography) [25].

Digital Breast Tomosynthesis Screening

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

FDG-PET Breast Dedicated

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

Mammography Diagnostic

There is insufficient evidence to support the routine use of diagnostic mammography in this clinical scenario. However, it can be helpful in a subset of patients in which there is concern for residual microcalcifications, which are better visualized on magnification mammograms rather than DBT. One small retrospective study evaluated postexcision mammography and MRI to assess for residual disease. Of 51 patients with malignant calcifications (32 with and 19 without residual disease), mammography sensitivity, specificity, and accuracy were 78.1%, 42.1%, and 62.7%, respectively. MRI was better than mammography, especially in the setting of low background parenchymal enhancement, in which sensitivity, specificity, and accuracy were 88.8%, 57.1%, and 76.5%, respectively [24]. Another small single institution study of 281 patients with ductal carcinoma in situ, of which 144 underwent postexcision preirradiation mammography, found postexcision preirradiation mammography resulted in a change in surgical management in 7% (10/144) and removal of residual ductal carcinoma in situ in 4% (6/144) of patients. More importantly there was no significant change in 10-year local recurrence-free survival (95% versus 92%, with and without postexcision preirradiation mammography) [25].

Mammography Screening

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

MRI Breast Without and With IV Contrast

There is insufficient evidence to support the routine use of MRI breast without and with IV contrast in this clinical scenario. MRI, when performed, is generally done before initial surgery. However, it may be performed following initial surgery in the setting of unsuspected positive margins. Evaluating residual disease in the surgical cavity is limited with MRI because of associated benign enhancement of the borders of the resection cavity obscuring residual disease. MRI may be helpful in identification of more widespread disease or remote disease [26,27]. This information can guide surgical planning for re-excision or need for mastectomy. One small retrospective study evaluated postexcision mammography and MRI to assess for residual disease in 51 patients with malignant calcifications (32 with and 19 without residual disease). MRI was better than mammography, especially in the setting of low background parenchymal enhancement, where sensitivity, specificity, and accuracy were 88.8%, 57.1%, and 76.5%, respectively. However higher background parenchymal enhancement did reduce sensitivity and accuracy [24].

MRI Breast Without IV Contrast

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

Sestamibi MBI

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

US Breast

There is no relevant literature to support the use of breast US in this clinical scenario.

Variant 5: Adult female. Surveillance following completion of breast conservation therapy for breast cancer. Negative margins. With or without radiation. Asymptomatic.

Margin status is an important predictor of local recurrence of invasive or in situ cancer after breast conservation surgery. For invasive breast cancer (with or without DCIS), a negative margin is defined as no tumor on ink by histology.

The aim of surveillance in patients after primary breast cancer treatment is to detect local recurrence and/or second breast cancers before symptoms develop. Women with a personal history of breast cancer develop a second breast cancer at a rate of 5% to 10% within 5 to 10 years after initial diagnosis [28-30]. Factors predicting risk of locoregional recurrence include age, tumor grade and size, multifocality, nodal involvement, receptor status, and whether the patient received radiotherapy, chemotherapy, or hormonal therapy [31-33].

Interval breast cancers have been reported in 24% to 30% with mammographic surveillance [34-36], and 7% with the use of multimodality imaging with mammography, US, and MRI [37]. Interval cancers are more likely to occur in women <40 to 50 years of age, in those with primary cancers that are negative estrogen receptor/progesterone receptor (ER/PR) or triple negative (negative ER/PR and negative HER2), in those with primary cancers being interval cancers, in patients with history of breast conservation therapy without radiation, and in women with dense breast tissue [35,36,38,39]. These patients may benefit from supplemental screening. Please refer to the ACR

Appropriateness Criteria[®] topic on "<u>Supplemental Breast Cancer Screening Based on Breast Density</u>" [9] and the ACR recommendations on screening in women at higher-than-average risk [10].

Digital Breast Tomosynthesis Diagnostic

Annual mammography is the best imaging test for surveillance in this clinical scenario, with reduction of mortality compared with women with history of breast cancer who do not get annual mammography [40,41]. The most common presentation of a recurrent or second breast cancer in patients with a personal history of breast cancer is an abnormal mammogram in an otherwise asymptomatic patient [22,34,36]. This ACR practice parameter allows asymptomatic women with a personal history of breast cancer to undergo diagnostic mammography [42].

A survey of radiologists showed variability in recommendation of diagnostic versus screening mammography for women treated with breast conservation therapy. Most (79%) recommended at least 1 diagnostic mammogram, with 49% recommending diagnostic mammography up to 2 years and 33% recommending diagnostic mammography from 2 to 5 years [43]. This is supported by the fact that most locoregional recurrences occur within 5 years after diagnosis [34,35,44], with recurrence risk greatest 2 to 3 years after initial therapy [23,28,33,37].

There is suboptimal compliance of annual mammography in select patients with a history of breast cancer. Groups most impacted are younger women <45 to 50 years of age, older women >65 years of age, African Americans and other underrepresented minorities, and women who did not have a recent physician visit [34,45-50].

The American Society of Radiology Oncology (ASTRO) and National Comprehensive Cancer Network (NCCN) both recommend annual mammographic surveillance for women who have completed radiation therapy as part of breast conservation therapy, with the first imaging performed at 6 to 12 months [51,52]. Other studies have found imaging before 12 months is not beneficial and/or leads to unnecessary additional imaging because of acute breast changes, supporting the first mammogram to be at 12 months after the last mammogram [30,53-56].

More frequent imaging of the ipsilateral affected breast beyond annual surveillance mammography, at 6-month intervals for the first 2 to 5 years, has also been studied. Two groups showed no benefits to this more frequent imaging [30,56]. One study found lower stage of recurrence in women undergoing 6-month surveillance compared with annual surveillance; however, this may be secondary to decreased compliance with imaging recommendations in the annual surveillance group and follow-up was insufficient to assess for any mortality differences [57].

The addition of DBT to 2-D digital mammography or 2-D synthetic images in the surveillance of patients with prior breast cancer history has been shown to reduce recall rates and indeterminate findings [58-61], without significant change in cancer detection rate [60,61].

Digital Breast Tomosynthesis Screening

Annual mammography is the best imaging test for surveillance in this clinical scenario, with reduction of mortality compared with women with history of breast cancer who do not get annual mammography [40,41]. The most common presentation of a recurrent or second breast cancer in patients with a personal history of breast cancer is an abnormal mammogram in an otherwise asymptomatic patient [22,34,36].

The ACR practice parameters state asymptomatic women previously treated for breast cancer may undergo annual screening or diagnostic mammography, as determined by the imaging facility [42]. The most common factor influencing this decision is the number of years since cancer diagnosis and treatment. A survey of radiologists showed variability in recommendation of diagnostic versus screening mammography for women treated with breast conservation therapy. Most (79%) recommended at least 1 diagnostic mammogram, with 49% recommending diagnostic mammography up to 2 years and 33% recommending diagnostic mammography from 2 to 5 years [43]. This is supported by the fact that most locoregional recurrences occur within 5 years after diagnosis [34,35,44], with recurrence risk greatest 2 to 3 years after initial therapy [23,28,33,37].

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The ASTRO and NCCN guidelines both recommend annual mammographic surveillance for women who have completed radiation therapy as part of breast conservation therapy, with the first imaging performed at 6 to 12 months [51,52]. Other studies have found imaging before 12 months is not beneficial and/or leads to unnecessary additional imaging due to acute breast changes, supporting the first mammogram to be at 12 months after the last mammogram [30,53-56].

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The addition of DBT to 2-D digital mammography or 2-D synthetic images in the surveillance of patients with prior breast cancer history has been shown to reduce recall rates and indeterminate findings [58-61], without significant change in cancer detection rate [60,61].

FDG-PET Breast Dedicated

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

Mammography Diagnostic

Annual mammography is the best imaging test for surveillance in this clinical scenario, with reduction of mortality compared to women with history of breast cancer who do not get annual mammography [40,41]. The most common presentation of a recurrent or second breast cancer in patients with a personal history of breast cancer is an abnormal mammogram in an otherwise asymptomatic patient [22,34,36]. The ACR practice parameters allows asymptomatic women with a personal history of breast cancer to undergo diagnostic mammography [42].

A survey of radiologists showed variability in recommendation of diagnostic versus screening mammography for women treated with breast conservation therapy. Most (79%) recommended at least 1 diagnostic mammogram, with 49% recommending diagnostic mammography up to 2 years and 33% recommending diagnostic mammography from 2 to 5 years [43]. This is supported by the fact that most locoregional recurrences occur within 5 years after diagnosis [34,35,44], with recurrence risk greatest 2 to 3 years after initial therapy [23,28,33,37].

There is suboptimal compliance of annual mammography in select patients with a history of breast cancer. Groups most impacted are younger women <45 to 50 years of age, older women >65 years of age, African Americans and other underrepresented minorities, and women who did not have a recent physician visit [34,45-50].

The ASTRO and NCCN guidelines both recommend annual mammographic surveillance for women who have completed radiation therapy as part of breast conservation therapy, with the first imaging performed at 6 to 12 months [51,52]. Other studies have found imaging before 12 months is not beneficial and/or leads to unnecessary additional imaging due to acute breast changes, supporting the first mammogram to be at 12 months after the last mammogram [30,53-56].

More frequent imaging of the ipsilateral affected breast beyond annual surveillance mammography, at 6-month intervals for the first 2 to 5 years, has also been studied. Two groups showed no benefits to this more frequent imaging [30,56]. One study found a lower stage of recurrence in women undergoing 6-month surveillance compared with annual surveillance; however, this may be secondary to decreased compliance with imaging recommendations in the annual surveillance group, and follow-up was insufficient to assess for any mortality differences [57].

The addition of DBT to 2-D digital mammography or 2-D synthetic images in the surveillance of patients with prior breast cancer history has been shown to reduce recall rates and indeterminate findings [58-61], without significant change in cancer detection rate [60,61].

Mammography Screening

Annual mammography is the best imaging test for surveillance in this clinical scenario, with reduction of mortality compared with women with history of breast cancer who do not get annual mammography [40,41]. The most common presentation of a recurrent or second breast cancer in patients with a personal history of breast cancer is an abnormal mammogram in an otherwise asymptomatic patient [22,34,36].

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The ASTRO and NCCN guidelines both recommend annual mammographic surveillance for women who have completed radiation therapy as part of breast conservation therapy, with the first imaging performed at 6 to 12 months [51,52]. Other studies have found imaging before 12 months is not beneficial and/or leads to unnecessary additional imaging due to acute breast changes, supporting the first mammogram to be at 12 months after the last mammogram [30,53-56].

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The addition of DBT to 2-D digital mammography or 2-D synthetic images in the surveillance of patients with prior breast cancer history, has been shown to reduce recall rates and indeterminate findings [58-61], without significant change in cancer detection rate [60,61].

MRI Breast Without and With IV Contrast

There is insufficient literature to support the routine use of MRI breast without and with IV contrast in this clinical scenario. The utility for breast MRI surveillance in patients with a personal history of breast cancer depends upon associated risk factors of the studied populations, as well as institutional protocols.

The ACR recommends annual breast MRI surveillance for any woman with a lifetime risk of breast cancer of ~20% or greater [8,10]. Annual breast MRI is recommended for women with a personal history of breast cancer and dense breasts as well as women diagnosed with breast cancer before 50 years of age [10], because these risk factor combinations likely result in a ~20% or greater estimated lifetime risk of developing breast cancer [10,62,63]. Annual breast MRI is also recommended for women with a mammographically occult primary breast cancer [62,63].

A large observational study from BCSC data of 812,164 women compared mammographic and MRI performance in women with and without a personal history of breast cancer. They found MRI was more likely to be performed in patients with a family history of breast cancer and personal history of breast cancer and in women with dense breast tissue. There were higher biopsy rates with MRI (6.3%) compared with mammography (2.2%), with lower cancer yield (19.5% versus 34.7%, respectively) [64]. The findings of higher cancer detection rates with MRI compared with mammography, with lower specificity and positive predictive value were confirmed [65,66].

Another large community-based study from BCSC data of 13,266 women with a personal history of breast cancer compared surveillance with MRI and mammography to mammography alone. The group with breast MRI had higher biopsy rates (odds ratio, 2.2) and cancer detection rates (odds ratio, 1.7), with no significant difference in sensitivity or interval cancers. This study did not control for confounders and suggested subgroup analysis was warranted to better delineate risks and benefits of breast MRI in this patient population [67].

Other single institution studies of patients with personal history of breast cancer assessed time of cancer detection with MRI. These studies found the use of MRI yielded lower new cancer detection rates in the first 3 years following breast cancer surgery, with greater MRI cancer detection rates beyond 3 years following breast cancer therapy [67-71].

MRI Breast Without IV Contrast

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

Sestamibi MBI

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

US Breast

There is insufficient evidence to support the routine use of breast US for routine surveillance in this clinical scenario.

Whole-breast US, using handheld or automated technique, may be used as a supplemental screening examination for women who are at high risk for developing primary or secondary breast cancer. Please refer to the ACR

Appropriateness Criteria[®] topics on "<u>Breast Cancer Screening</u>" [8] and "<u>Supplemental Breast Cancer Screening</u> <u>Based on Breast Density</u>" [9].

Studies of women with a prior history of breast cancer who underwent US evaluation in addition to mammography for surveillance imaging found increased cancer detection rate or slightly earlier recurrence detection [72-76]; however, those studies also had associated increases in overall biopsy rates and false positives [76,77]. None of these studies showed improved breast cancer mortality. In addition, in a large study of 6,584 USs in Asian women with personal history of breast cancer and negative mammogram, high interval cancer rates were seen in women <50 years of age and women with dense breasts, suggesting the need for additional supplemental imaging beyond US in select populations [73].

Summary of Recommendations

- Variant 1: DBT screening or mammography screening is usually appropriate for the initial imaging of postsurgical excision with nonmalignant pathology in asymptomatic female patients >40 years of age. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care). DBT screening and mammography screening are complementary to MRI breast without and with IV contrast (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).
- Variant 2: DBT screening or mammography screening may be appropriate for the initial imaging of postsurgical excision with nonmalignant pathology in asymptomatic female patients 30 to 39 years of age. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care). DBT screening and mammography screening are complementary to MRI breast without and with IV contrast (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).
- Variant 3: Imaging is usually not appropriate for the initial imaging of postsurgical excision with nonmalignant pathology in asymptomatic adult female patients <30 years of age.
- Variant 4: Mammography diagnostic or MRI breast without and with IV contrast may be appropriate for the initial imaging of postsurgical excision for breast cancer with positive margins in a female patient. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care). The panel did not agree on recommending DBT diagnostic for patients in this clinical scenario. There is insufficient medical literature to conclude whether or not these patients would benefit from this procedure. Imaging with this procedure is controversial but may be appropriate.
- Variant 5: DBT diagnostic or mammography diagnostic or DBT screening or mammography screening is usually appropriate for the surveillance following completion of breast conservation therapy for breast cancer with negative margins with or without radiation in asymptomatic adult female patients. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care). DBT diagnostic, mammography diagnostic, DBT screening, and mammography screening are complementary to MRI breast without and with IV contrast (ie, more than one procedure is ordered as a set or simultaneously in which each procedure provides unique clinical information to effectively mamography screening are complementary to US breast (ie, more than one procedure is ordered as a set or simultaneously in which each provides unique clinical information to effectively manage the patient's care).

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 go to www.acr.org/ac.

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 [78].

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
	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 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.