American College of Radiology
ACR Appropriateness Criteria®
Breast Implant Evaluation

Variant: 1 Adult of any age. Female or transfeminine. Evaluation of saline breast implants. Asymptomatic. Initial imaging.

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

Variant: 2 Adult younger than 30 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	Usually Not Appropriate	☢☢
Mammography diagnostic	Usually Not Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O

Variant: 3 Adult 30 to 39 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.

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

Variant: 4 Adult age 40 years or older. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.

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

Variant: 5 Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Less than 5 years after implant placement. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Not Appropriate	O

Digital breast tomosynthesis diagnostic	Usually Not Appropriate	☢☢
Mammography diagnostic	Usually Not Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O

Variant: 6 Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Initial imaging at 5 to 6 years after implant placement and follow-up imaging every 2 to 3 years after initial negative imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
MRI breast without IV contrast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	Usually Not Appropriate	☢☢
Mammography diagnostic	Usually Not Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant: 7 Adult younger than 30 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.

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

Variant: 8 Adult 30 to 39 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.

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

Variant: 9 Adult age 40 years or older. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.

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

Variant: 10 Adult younger than 30 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level

US breast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	Usually Not Appropriate	☢☢
Mammography diagnostic	Usually Not Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O

Variant: 11 Adult 30 to 39 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
Mammography diagnostic	Usually Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O

Variant: 12 Adult age 40 years or older. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
Mammography diagnostic	Usually Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O

Variant: 13 Adult of any age. Female or transfeminine. Suspected breast implant-associated malignancy. Breast implant of any type. Initial imaging.

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

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Summary of Literature Review

Introduction/Background

Breast implants are routinely placed for augmentation and reconstruction and have been available for >50 years. A large variety of implants are commercially available, including saline, silicone (including form-stable varieties also known as gummy bear implants), double lumen varieties using both saline and silicone, and polyacrylamide gel. Saline-filled breast implants are inflated to the desired size with sterile isotonic saline, and silicone gel-filled breast implants contain a fixed volume of silicone gel, although silicone gel viscosity differs among implants and manufacturers [1]. For patients with uncertain implant type, the pathway for silicone implant should be followed. If an implant is determined to be saline from that imaging, then subsequent imaging should follow saline implant recommendations.

Of all patients with breast cancer, 20% to 40% will undergo breast reconstruction, the most frequent reconstruction techniques using autologous tissue or implants, or a combination of both. Several factors influence the type of reconstruction chosen, including the patient's desires, body habitus, medical comorbidities, prior radiotherapy, availability of donor sites, and the need for adjuvant therapy [2, 3]. Implant-based reconstruction may be a 1-step or a staged procedure [2]. In the United States, implant reconstructions are performed more often than autologous reconstruction for a variety of reasons, including patient choice, access, shorter operative time, and less-involved recovery. Breast augmentation is not without risk, and implant rupture is a well-known potential complication. The terms "intracapsular rupture" and "extracapsular rupture" are defined for silicone implants. Saline implants lose their volume when ruptured, because the saline is resorbed by the body, therefore implant rupture is usually clinical apparent [4]. The FDA implant "Patient Decision Checklist" suggests that for patients considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction, the initial statements discussing risks of implants should include statements discussing the risks, considerations for a successful breast implantation, risks of breast implant-associated (BIA) malignancies, risks of systemic symptoms, breast implant-specific risks, and recommended follow-up, including the recommendation to have an initial ultrasound (US) or MRI 5 to 6 years after initial implant surgery and then every 2 to 3 years thereafter be discussed with patients [1].

The FDA has issued several reports on BIA malignancy, first describing BIA anaplastic large cell lymphoma (BIA-ALCL) in 2011 [5], with subsequent reports and updates in 2022 and 2023 to include BIA squamous cell carcinoma (BIA-SCC) and various other lymphomas arising from the breast implant capsule [6, 7]. The General and Plastic Surgery Devices Advisory Panel convened in March 2019 recommended that the FDA require a boxed warning in breast implant labeling and a standardized checklist as part of the informed consent process, revise the MRI screening recommendations for asymptomatic ruptures of silicone gel-filled breast implants, and provide greater transparency regarding materials present in breast implants [1]. The 2022 and 2023 FDA updates recommend that discussions with patients considering breast implants be expanded to include information about BIA-SCC and various lymphomas in addition to BIA-ALCL.

Breast implants are manufactured with smooth and textured surfaces [1]. For breast implants with a textured shell surface, each breast implant manufacturer uses a proprietary manufacturing process to create the textured surface, which means that each manufacturer's textured shell is different [1]. Almost all reported cases of BIA-ALCL are associated with textured implants [8, 9]. BIA-ALCL can occur with both saline and silicone implants and in implants placed for both reconstruction and cosmetic indications [9]. BIA-ALCL arises around an implant and is a disease of the breast implant capsule (the scar tissue formed by the body around the implant) and not of the

breast tissue itself. A chronic inflammatory stimulus in the context of underlying host genetic factors and susceptibilities is thought to play a role in influencing the likelihood of malignant lymphoid transformation. This entity is a rare T-cell lymphoma and most often presents with delayed (>1 year after surgery) peri-implant effusion around a textured implant or surrounding scar capsule, with median time to presentation of 8 to 10 years following implantation (range 1-28 years) [10-12].

In contrast to BIA-ALCL, BIA-SCC has been reported in people with both smooth and textured implants [13]. The tumor arises from the epithelial cells of the breast implant capsule and not from the breast tissue itself. BIA-SCC occurs with both saline and silicone implants and in implants placed for both reconstruction and cosmetic indications. The number of cases of reported BIA-SCC in the literature is small (19 cases at the time of the 2023 FDA update). Similar to those with BIA-ALCL, patients with BIA-SCC typically present with unilateral swelling, pain, and/or erythema and have delayed peri-implant effusion. Patients present, on average, 22 years after implant placement. Based on published case reports, BIA-SCC may be aggressive, with higher mortality than BIA-ALCL.

Imaging options for implant evaluation include mammography, digital breast tomosynthesis (DBT), US, and MRI. However, saline implant rupture is usually clinically apparent, with diagnosis made by physical examination.

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses" [16].

Special Imaging Considerations

PET/CT: For confirmed cases of BIA malignancy, a PET/CT scan should be considered before surgical intervention [17]. Because postsurgical inflammation can persist for several months and mimic malignancy, preoperative PET/CT is useful [18]. PET/CT is often beneficial for demonstrating capsular masses and/or chest wall involvement and is the preferred test to evaluate for systemic spread to regional or distant lymph nodes and/or organ involvement once a diagnosis of BIA malignancy is established [19].

PET/CT is not useful as an initial imaging test for evaluation of peri-implant effusion without established diagnosis of BIA malignancy because there are both false-positives and false-negatives on PET in this setting. False-negatives can occur because the cell density within a malignant effusion may be too low for an effective positron signal to be detected; false-positives can occur due to normal inflammatory activity around the implant capsule and/or reactive changes in regional nodes [20].

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 wherein each procedure provides unique clinical information to effectively manage the patient's care).

Discussion of Procedures by Variant

Variant 1:Adult of any age. Female or transfeminine. Evaluation of saline breast implants. Asymptomatic. Initial imaging.

The goal of imaging is to detect saline breast implant rupture. There are no expected benefits from imaging saline breast implants when patients are asymptomatic.

Variant 1:Adult of any age. Female or transfeminine. Evaluation of saline breast implants. Asymptomatic. Initial imaging.
A. Digital breast tomosynthesis screening

There is no role for DBT screening for implant evaluation in asymptomatic patients with saline implants. However, female and transfeminine patients should follow breast cancer screening protocols as outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. A collapsed implant shell of a ruptured saline implant may be seen at DBT. The saline from the implant is resorbed by the body without significant sequelae or secondary findings in the breast.

Variant 1:Adult of any age. Female or transfeminine. Evaluation of saline breast implants. Asymptomatic. Initial imaging.
B. Mammography screening

There is no role for screening mammography for implant evaluation in asymptomatic patients with saline implants. However, female and transfeminine patients should follow breast cancer screening protocols as outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. A collapsed implant shell of a ruptured saline implant may be seen at mammography. The saline from the implant is resorbed by the body without significant sequelae or secondary findings in the breast.

Variant 1:Adult of any age. Female or transfeminine. Evaluation of saline breast implants. Asymptomatic. Initial imaging.
C. MRI breast without and with IV contrast

There is no role for MRI without and with intravenous (IV) contrast for implant evaluation in asymptomatic patients with saline implants [21]. The saline from the implant is resorbed by the body without significant sequelae or secondary findings in the breast.

Variant 1:Adult of any age. Female or transfeminine. Evaluation of saline breast implants. Asymptomatic. Initial imaging.
D. MRI breast without IV contrast

There is no role for MRI without IV contrast for implant evaluation in asymptomatic patients with

saline implants [21]. The saline from the implant is resorbed by the body without significant sequelae or secondary findings in the breast.

Variant 1:Adult of any age. Female or transfeminine. Evaluation of saline breast implants. Asymptomatic. Initial imaging.
E. US breast

There is no role for US for implant evaluation in asymptomatic patients with saline implants. The saline from the implant is resorbed by the body without significant sequelae or secondary findings in the breast.

Variant 2:Adult younger than 30 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.

The goal of imaging is to detect saline breast implant rupture in cases in which rupture is clinically suspected but with equivocal clinical findings. The information from imaging is expected to differentiate patients with saline implant rupture needing further management from those without saline implant rupture. The expected outcome is appropriate triage of patients with ruptured saline implant to further management while avoiding unnecessary procedures for patients without saline implant rupture.

Variant 2:Adult younger than 30 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
A. Digital breast tomosynthesis diagnostic

Rupture of saline implants is usually clinically evident because the saline is resorbed by the body over a period of days and the patient experiences a change in breast size and shape [21, 23]. Although DBT may be useful in patients with suspected saline implant rupture and equivocal clinical findings, DBT is typically not performed as the initial imaging study in patients <30 years of age.

Variant 2:Adult younger than 30 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
B. Mammography diagnostic

Rupture of saline implants is usually clinically evident because the saline is resorbed by the body over a period of days and the patient experiences a change in breast size and shape [21, 23]. Although diagnostic mammography may be useful in patients with suspected saline implant rupture and equivocal clinical findings, diagnostic mammography is typically not performed as the initial imaging study in patients <30 years of age.

Variant 2:Adult younger than 30 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
C. MRI breast without and with IV contrast

There is no role for MRI without and with IV contrast in the evaluation of saline implants [21].

Variant 2:Adult younger than 30 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
D. MRI breast without IV contrast

There is no role for MRI without IV contrast in the evaluation of saline implants [21].

Variant 2:Adult younger than 30 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
E. US breast

In cases of saline implant rupture, the collapsed implant shell is visible by US, and for patients <30 years of age, an US is helpful as the initial examination. If a patient is uncertain which type of implant is in place, the implant type can be determined at US by examining the implant at its margin and witnessing the effect the implant has on surrounding normal tissue [22]. Because the speed of sound through silicone (997 m/sec) is slower than that through soft tissues and saline (1,540 m/sec), it will take longer for sound waves to travel through a silicone implant compared with through a saline-filled implant, causing a step-off appearance at the edge of the silicone implant, which is not seen in saline implants [22].

Variant 3:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.

The goal of imaging is to detect saline breast implant rupture in cases in which rupture is clinically suspected. The information from imaging is expected to differentiate patients with saline implant rupture needing further management from those without saline implant rupture. The expected outcome is appropriate triage of patients with ruptured saline implant to further management while avoiding unnecessary procedures for patients without saline implant rupture.

Variant 3:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
A. Digital breast tomosynthesis diagnostic

For patients 30 to 39 years of age, DBT may be complementary to US. Rupture of saline implants is usually clinically evident because the saline is resorbed by the body over a period of days and the patient experiences a change in breast size and shape [21, 23]. However, DBT may be useful in patients with suspected saline implant rupture and equivocal clinical findings. Findings on DBT are diagnostic, in which a collapsed implant shell is visible.

Variant 3:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
B. Mammography diagnostic

For patients 30 to 39 years of age, diagnostic mammography may be complementary to US. Rupture of saline implants is usually clinically evident because the saline is resorbed by the body over a period of days and the patient experiences a change in breast size and shape [21, 23]. However, diagnostic mammography may be useful in patients with suspected saline implant rupture and equivocal clinical findings. Findings on mammography are diagnostic, in which a collapsed implant shell is visible.

Variant 3:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
C. MRI breast without and with IV contrast

There is no role for MRI without and with IV contrast in the evaluation of saline implants [21].

Variant 3:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
D. MRI breast without IV contrast

There is no role for MRI without IV contrast in the evaluation of saline implants [21].

Variant 3:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
E. US breast

For patients 30 to 39 years of age, US may be complementary to diagnostic mammography or diagnostic DBT. In cases of saline implant rupture, the collapsed implant shell is visible by US. If a patient is uncertain which type of implant is in place, the implant type can be determined at US by examining the implant at its margin and witnessing the effect the implant has on surrounding normal tissue [22]. Because the speed of sound through silicone (997 m/sec) is slower than that through soft tissues and saline (1,540 m/sec), it will take longer for sound waves to travel through a silicone implant compared with through a saline-filled implant, causing a step-off appearance at the edge of the silicone implant, which is not seen in saline implants [22].

Variant 4:Adult age 40 years or older. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.

The goal of imaging is to detect saline breast implant rupture in cases in which rupture is clinically suspected. The information from imaging is expected to differentiate patients with saline implant rupture needing further management from those without saline implant rupture. The expected outcome is appropriate triage of patients with ruptured saline implant to further management while avoiding unnecessary procedures for patients without saline implant rupture.

Variant 4:Adult age 40 years or older. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
A. Digital breast tomosynthesis diagnostic

For patients ≥40 years of age, DBT would typically be performed for an area of clinical concern and could be complementary with US. Rupture of saline implants is usually clinically evident because the saline is resorbed by the body over a period of days and the patient experiences a change in breast size and shape [21, 23]. However, DBT may be useful in patients with suspected saline implant rupture and equivocal clinical findings. Findings on DBT are diagnostic when a collapsed implant shell is visible.

Variant 4:Adult age 40 years or older. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
B. Mammography diagnostic

For patients ≥40 years of age, diagnostic mammography would typically be performed for an area of clinical concern and could be complementary with US. Rupture of saline implants is usually clinically evident because the saline is resorbed by the body over a period of days and the patient experiences a change in breast size and shape [21, 23]. However, diagnostic mammography may be useful in patients with suspected saline implant rupture and equivocal clinical findings. Findings on mammography are diagnostic, in which a collapsed implant shell is visible.

Variant 4:Adult age 40 years or older. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
C. MRI breast without and with IV contrast

There is no role for MRI without and with IV contrast in evaluation of saline implants [21].

Variant 4:Adult age 40 years or older. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
D. MRI breast without IV contrast

There is no role for MRI without IV contrast in the evaluation of saline implants [21].

Variant 4:Adult age 40 years or older. Female or transfeminine. Evaluation of saline breast implants. Suspected implant rupture. Initial imaging.
E. US breast

For patients ≥40 years of age, US would typically be performed for an area of clinical concern and could be complementary with diagnostic mammography or diagnostic DBT. In patients with suspected saline implant rupture, US may be useful if the mammographic findings are equivocal or the patient is unable to undergo mammography. In cases of saline implant rupture, the collapsed implant shell is visible by US. For patients ≥40 years of age unable to undergo mammography, US may be used as an alternative option.

Variant 5:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Less than 5 years after implant placement. Initial imaging.

The goal of imaging is early detection of silicone breast implant rupture before the development of symptoms. There are no expected benefits from imaging silicone breast implants fewer than 5 years after initial placement in patients without clinical symptoms of rupture.

Variant 5:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Less than 5 years after implant placement. Initial imaging.
A. Digital breast tomosynthesis diagnostic

There is no role for diagnostic DBT for implant evaluation in asymptomatic patients with silicone implants. However, female and transfeminine patients should follow breast cancer screening protocols as outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with DBT in which high-density silicone is seen outside the implant contour. DBT does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. DBT has a low sensitivity for the detection of implant rupture due to the silicone implant appearing extremely radiopaque [22]. Silicone implants are normally oval, smooth, and uniformly dense at mammography, preventing any internal substructural evaluation, so with the limited ability to evaluate implants internally, intracapsular ruptures go unseen [22]. Although internal evaluation of the implant is impeded at mammography, the contour of a silicone implant merits close inspection [22]. Comparison with prior mammograms is useful to identify subtle contour changes over time, such as the appearance of undulations, which potentially indicate a problem with implant integrity [22]. Frank bulges or herniations represent areas of weakening of the fibrous capsule and potential weak points of the elastomer shell [22]. An implant that becomes more rounded in appearance may signify the presence of capsular contracture rather than implying a problem with implant integrity. Calcifications along the fibrous capsule, thought to arise as a consequence of a chronic inflammatory response, are more frequently encountered in older implants that have been in place for multiple years. Capsular calcifications correlate with implant age, but calcifications alone do not necessarily imply capsular contracture or implant rupture. Capsular contracture is a clinical diagnosis made based on the patient's symptoms. Although insensitive for identifying intracapsular rupture, DBT is useful in detecting extracapsular silicone. When silicone escapes the confines of the fibrous capsule and enters the surrounding breast parenchyma, DBT can often reveal the high-density free silicone. In the absence of a prior history of implant rupture or revision, the presence of silicone outside the expected contour of the implant signifies extracapsular rupture and, by extension, intracapsular rupture [22, 25].

Variant 5:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Less than 5 years after implant placement. Initial imaging.
B. Mammography diagnostic

There is no role for diagnostic mammography for implant evaluation in asymptomatic patients with silicone implants. However, female and transfeminine patients should follow breast cancer screening protocols as outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with mammography in which high-density silicone is seen outside the implant contour.

Mammography does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. Mammography has a low sensitivity for the detection of implant rupture due to the silicone implant appearing extremely radiopaque [22]. Silicone implants are normally oval, smooth, and uniformly dense at mammography, preventing any internal substructural evaluation, so with the limited ability to evaluate implants internally, intracapsular ruptures go unseen [22]. Although internal evaluation of the implant is impeded at mammography, the contour of a silicone implant merits close inspection [22]. Comparison with prior mammograms is useful to identify subtle contour changes over time, such as the appearance of undulations, which potentially indicate a problem with implant integrity [22]. Frank bulges or herniations represent areas of weakening of the fibrous capsule and potential weak points of the elastomer shell [22]. An implant that becomes more rounded in appearance may signify the presence of capsular contracture rather than implying a problem with implant integrity. Calcifications along the fibrous capsule, thought to arise as a consequence of a chronic inflammatory response, are more frequently encountered in older implants that have been in place for multiple years. Capsular calcifications correlate with implant age, but calcifications alone do not necessarily imply capsular contracture or implant rupture. Although insensitive for identifying intracapsular rupture, mammography is useful in detecting extracapsular silicone. When silicone escapes the confines of the fibrous capsule and enters the surrounding breast parenchyma, mammography can often reveal the high-density free silicone. In the absence of a prior history of implant rupture or revision, the presence of silicone outside the expected contour of the implant signifies extracapsular rupture and, by extension, intracapsular rupture [22, 25].

Variant 5:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Less than 5 years after implant placement. Initial imaging.
C. MRI breast without and with IV contrast

There is no relevant literature to support the use of MRI without and with IV contrast in the evaluation of asymptomatic silicone implants less than 5 years after implant placement.

Variant 5:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Less than 5 years after implant placement. Initial imaging.
D. MRI breast without IV contrast

There is no relevant literature to support the use of MRI without IV contrast in the evaluation of asymptomatic silicone implants less than 5 years after implant placement. Note that in the updated FDA recommendations for asymptomatic patients with silicone implants, the first US or MRI should be performed at 5 to 6 years postoperatively, then every 2 to 3 years thereafter [1].

Variant 5:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Less than 5 years after implant placement. Initial imaging.
E. US breast

There is no relevant literature to support the role of US breast in the evaluation of an

asymptomatic patient with silicone implants that have been in place less than 5 years. Note that in the updated FDA recommendations for asymptomatic patients with silicone implants, the first US or MRI should be performed at 5 to 6 years postoperatively, then every 2 to 3 years thereafter [1].

Variant 6:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Initial imaging at 5 to 6 years after implant placement and follow-up imaging every 2 to 3 years after initial negative imaging.

The goal of imaging is early detection of silicone breast implant rupture before the development of symptoms. Imaging differentiates patients with silicone implant rupture requiring further management from patients without silicone implant rupture. The information from imaging is expected to differentiate patients with silicone implant rupture needing further management from those without silicone implant rupture. The expected outcome for patients who are found to have silicone implant rupture is earlier surgical intervention and fewer associated clinical complications.

Variant 6:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Initial imaging at 5 to 6 years after implant placement and follow-up imaging every 2 to 3 years after initial negative imaging.
A. Digital breast tomosynthesis diagnostic

There is no role for diagnostic DBT for implant evaluation in asymptomatic patients with silicone implants. However, female and transfeminine patients should follow breast cancer screening protocols as outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with DBT in which high-density silicone is seen outside the implant contour. DBT does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. DBT has a low sensitivity for the detection of implant rupture due to the silicone implant appearing extremely radiopaque [22]. Silicone implants are normally oval, smooth, and uniformly dense at mammography, preventing any internal substructural evaluation, so with the limited ability to evaluate implants internally, intracapsular ruptures go unseen [22]. Although internal evaluation of the implant is impeded at mammography, the contour of a silicone implant merits close inspection [22]. Comparison with prior mammograms is useful to identify subtle contour changes over time, such as the appearance of undulations, which potentially indicate a problem with implant integrity [22]. Frank bulges or herniations represent areas of weakening of the fibrous capsule and potential weak points of the elastomer shell [22]. An implant that becomes more rounded in appearance may signify the presence of capsular contracture rather than implying a problem with implant integrity.

Calcifications along the fibrous capsule, thought to arise as a consequence of a chronic inflammatory response, are more frequently encountered in older implants that have been in place for multiple years. Capsular calcifications correlate with implant age, but calcifications alone do not necessarily imply capsular contracture or implant rupture. Although insensitive for identifying intracapsular rupture, DBT is useful in detecting extracapsular silicone. When silicone escapes the confines of the fibrous capsule and enters the surrounding breast parenchyma, DBT can often reveal the high-density free silicone. In the absence of a history of implant rupture or revision, the presence of silicone outside the expected contour of the implant signifies extracapsular rupture and, by extension, intracapsular rupture [22, 25].

Variant 6:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants.

Asymptomatic. Initial imaging at 5 to 6 years after implant placement and follow-up imaging every 2 to 3 years after initial negative imaging.
B. Mammography diagnostic

There is no role for diagnostic mammography for implant evaluation in asymptomatic patients with silicone implants. However, female and transfeminine patients should follow breast cancer screening protocols as outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with mammography in which high-density silicone is seen outside the implant contour.

Mammography does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. Mammography has a low sensitivity for the detection of implant rupture due to the silicone implant appearing extremely radiopaque [22]. Silicone implants are normally oval, smooth, and uniformly dense at mammography, preventing any internal substructural evaluation, so with the limited ability to evaluate implants internally, intracapsular ruptures go unseen [22]. Although internal evaluation of the implant is impeded at mammography, the contour of a silicone implant merits close inspection [22]. Comparison with prior mammograms is useful to identify subtle contour changes over time, such as the appearance of undulations, which potentially indicate a problem with implant integrity [22]. Frank bulges or herniations represent areas of weakening of the fibrous capsule and potential weak points of the elastomer shell [22]. An implant that becomes more rounded in appearance may signify the presence of capsular contracture rather than implying a problem with implant integrity. Calcifications along the fibrous capsule, thought to arise as a consequence of a chronic inflammatory response, are more frequently encountered in older implants that have been in place for multiple years. Capsular calcifications correlate with implant age, but calcifications alone do not necessarily imply capsular contracture or implant rupture. Although insensitive for identifying intracapsular rupture, mammography is useful in detecting extracapsular silicone. When silicone escapes the confines of the fibrous capsule and enters the surrounding breast parenchyma, mammography can often reveal the high-density free silicone. In the absence of a history of implant rupture or revision, the presence of silicone outside the expected contour of the implant signifies extracapsular rupture and, by extension, intracapsular rupture [22, 25].

Variant 6:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Initial imaging at 5 to 6 years after implant placement and follow-up imaging every 2 to 3 years after initial negative imaging.
C. MRI breast without and with IV contrast

There is no relevant literature to support the use of MRI without and with IV contrast in the evaluation of asymptomatic silicone implants.

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15].

Variant 6:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Initial imaging at 5 to 6 years after implant placement and follow-up

imaging every 2 to 3 years after initial negative imaging.
D. MRI breast without IV contrast

MRI without IV contrast is helpful for imaging silicone implants. The FDA updated guidance recommends that for asymptomatic patients, the first US or MRI should be performed at 5 to 6 years postoperatively, then every 2 to 3 years thereafter [1].

T1- and T2-weighted, short tau inversion recovery, and silicone-suppressed sequences allow for optimal imaging of implant integrity [21]. There is currently no consensus on whether ruptured implants require surgery in asymptomatic patients, and the benefits of screening for implant rupture are controversial. Some authors [34] have advocated a patient-centered approach with shared decision making between the patient and surgeon rather than generalized recommendations for all patients with silicone implants. Most studies focused on symptomatic women, in whom the expected prevalence of rupture would be higher than among asymptomatic women. In addition, numerous studies evaluating the rupture rate of more modern implants have shown this rate to be low [35-38]. Studies of asymptomatic women have reported sensitivities of 64% to 89%, specificities of 77% to 97%, accuracies of 92% to 94%, positive predictive values (PPVs) of 99%, and negative predictive values (NPVs) of 79% for MRI detection of intracapsular and extracapsular rupture [29, 30, 39].

Variant 6:Adult of any age. Female or transfeminine. Evaluation of silicone breast implants. Asymptomatic. Initial imaging at 5 to 6 years after implant placement and follow-up imaging every 2 to 3 years after initial negative imaging.
E. US breast

In the updated FDA recommendations, for asymptomatic patients with silicone implants, the first US or MRI should be performed at 5 to 6 years postoperatively, then every 2 to 3 years thereafter [1].

A single-lumen silicone implant is most often featureless and anechoic, which provides reliable US evidence that the implant remains intact and undamaged. A normal implant exhibits a smooth contour outlined by a trilaminar margin, which corresponds to the capsule-shell complex. Implants will often infold on themselves within the surgical pocket created by the plastic surgeon. These radial folds are a common feature of implants and should be recognized as a normal infolding of the elastomer shell rather than mistaken for evidence of intracapsular rupture. Most silicone implant ruptures are intracapsular. Numerous US findings of intracapsular silicone implant rupture, including the stepladder, keyhole, or subcapsular sign, have been described [22, 26-28], but the variability in reported accuracy of sonographic findings [29-33], combined with the well-known user dependence of this technology, often makes sonographic findings somewhat equivocal. Several US intracapsular-rupture mimics exist and include reverberation artifact, radial folds, or silicone implant impurities creating spurious echoes within the implant, which can give a false impression of intracapsular rupture [22]. At US, extracapsular silicone demonstrates a classic "snowstorm" appearance that is characterized by a highly echogenic pattern of scattered and reverberating echoes with a well-defined anterior margin and loss of detail posteriorly.

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer

Screening" [14] and "Transgender Breast Cancer Screening" [15].

Variant 7:Adult younger than 30 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.

The goal of imaging is the detection of silicone breast implant rupture in patients with suspected implant complication. The information from imaging is expected to differentiate patients with silicone implant rupture needing further management from those without silicone implant rupture. The expected outcome is appropriate triage of patients with ruptured silicone implants to further management while avoiding unnecessary procedures for patients without silicone implant rupture.

Variant 7:Adult younger than 30 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
A. Digital breast tomosynthesis diagnostic

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. DBT is typically not performed as the initial imaging study in patients under the age of 30. Extracapsular silicone implant ruptures, although only a minority of all implant ruptures, frequently present with palpable findings or other symptoms. The diagnosis of silicone implant rupture can be challenging, however, with clinical examination known to be unreliable [24]. DBT can identify extracapsular silicone [25, 26, 28, 40], which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants, and comparison with priors is critical. Intracapsular silicone implant rupture is frequently asymptomatic and may not be reliably diagnosed with DBT.

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses" [16].

Variant 7:Adult younger than 30 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
B. Mammography diagnostic

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. Diagnostic mammography is typically not performed as the initial imaging study in patients under the age of 30. Extracapsular silicone implant ruptures, although only a minority of all implant ruptures, frequently present with palpable findings or other symptoms. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with mammography in which high-density silicone is seen outside the implant contour. Mammography does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. Mammography can identify extracapsular silicone [25, 26, 28, 40], which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may

represent residual silicone rather than rupture of the new implants, and comparison with priors is critical.

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses" [16].

Variant 7:Adult younger than 30 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
C. MRI breast without and with IV contrast

There is no relevant literature to support the use of MRI without and with IV contrast in the evaluation of symptomatic silicone implants.

Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses" [16].

Variant 7:Adult younger than 30 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
D. MRI breast without IV contrast

In symptomatic patients with silicone breast implants or patients with equivocal US results for rupture at any time postoperatively, an MRI is recommended by the FDA [1]. MRI without IV contrast is particularly helpful in identifying intracapsular ruptures, which are not evident on mammography and can be difficult to diagnose by US. Most implant ruptures are intracapsular, and these are most often asymptomatic. MRI findings of both intracapsular and extracapsular rupture have been described [21, 26, 28, 31, 40]. An incomplete intracapsular rupture has been referred to by a variety of names, including the "inverted-loop sign," "keyhole sign," or "teardrop sign." A complete intracapsular rupture has been called the "linguini" or "wavy-line" sign and is the most specific sign of intracapsular implant rupture. Pooled data from a meta-analysis [41] showed a sensitivity of 87% and a specificity of 89.9% for MRI. Of note, most studies in the meta-analysis focused on symptomatic women, in whom the expected prevalence of rupture would be higher than among asymptomatic women. Studies of asymptomatic women have reported sensitivities of 64% to 89%, specificities of 77% to 97%, accuracies of 92% to 94%, PPVs of 99%, and NPVs of 79% for MRI detection of intracapsular and extracapsular rupture [29, 30, 39].

Variant 7:Adult younger than 30 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
E. US breast

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. However, US can identify extracapsular silicone [25, 26, 28, 40], which presents as a classic "snowstorm" pattern. In patients without prior explantation of silicone implants, this finding is diagnostic of extracapsular rupture. However, in patients who have had

prior silicone implants, this may represent residual silicone rather than rupture of the new implants.

A single-lumen silicone implant is most often featureless and anechoic, which provides reliable US evidence that the implant remains intact and undamaged. A normal implant exhibits a smooth contour outlined by a trilaminar margin, which corresponds to the capsule-shell complex. Implants will often infold on themselves within the surgical pocket created by the plastic surgeon. These radial folds are a common feature of implants and should be recognized as a normal infolding of the elastomer shell rather than mistaken for evidence of intracapsular rupture. Most silicone implant ruptures are intracapsular. Numerous US findings of intracapsular silicone implant rupture, including the stepladder, keyhole, noose, or subcapsular sign, have been described [22, 26-28], but the variability in reported accuracy of sonographic findings [29-33], combined with the well-known user dependence of this technology, often makes sonographic findings somewhat equivocal. Several US intracapsular-rupture mimics exist and include reverberation artifact, radial folds, or silicone implant impurities creating spurious echoes within the implant, which can give a false impression of intracapsular rupture [22]. At US, extracapsular silicone demonstrates a classic "snowstorm" appearance that is characterized by a highly echogenic pattern of scattered and reverberating echoes with a well-defined anterior margin and loss of detail posteriorly.

Sonographic findings of intracapsular rupture have been described [26-28], including a "stepladder" appearance of the collapsed implant shell. Some authors have reported excellent agreement of US with MRI and surgical findings [31, 32]. However, other studies have reported much lower sensitivities and accuracies for US diagnosis of intracapsular silicone implant rupture [29, 30, 33], with an accuracy of 72%, sensitivity of 30%, and specificity of 77%. For the assessment of appropriateness, it is assumed the procedure is performed and interpreted by an expert. In a more recent study by Rukanskiene et al [42], US was very accurate in the evaluation of implant integrity, with diagnostic accuracy of 94.7%, sensitivity of 98.3%, specificity of 89.2%, and NPV of 97.1%. In the case of an intact implant, all 3 signs of implant integrity on US (even implant shell, homogeneous content, and normal axillary lymph nodes) were observed most frequently at 93.6% [42]. In cases of ruptured implants, more than 2 signs of implant rupture on US were observed in 82.8% and only 1 sign of implant rupture on US was documented in 15.5% (abnormal implant shell) [42]. Therefore, these results suggest that if more than 2 signs of a ruptured implant are detected on US, US findings can be acted upon; if only 1 sign of a ruptured implant is found, MRI can be helpful [42].

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses"[16].

Variant 8:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.

The goal of imaging is the detection of silicone breast implant rupture in patients with suspected implant complication. The information from imaging is expected to differentiate patients with silicone implant rupture needing further management from those without silicone implant rupture. The expected outcome is appropriate triage of patients with ruptured silicone implants to further

management while avoiding unnecessary procedures for patients without silicone implant rupture.

Variant 8:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
A. Digital breast tomosynthesis diagnostic

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. However, DBT can identify extracapsular silicone. Extracapsular silicone implant ruptures, although only a minority of all implant ruptures, frequently present with palpable findings or other symptoms. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with DBT in which high-density silicone is seen outside the implant contour. DBT does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. DBT will identify extracapsular silicone, which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants, and comparison with priors is critical.

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses" [16].

Variant 8:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
B. Mammography diagnostic

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. However, diagnostic mammography can identify extracapsular silicone. Extracapsular silicone implant ruptures, although only a minority of all implant ruptures, frequently present with palpable findings or other symptoms. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with mammography in which high-density silicone is seen outside the implant contour. Mammography does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. Mammography can identify extracapsular silicone [25, 26, 28, 40], which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants, and comparison with priors is critical.

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for

areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses" [16].

Variant 8:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
C. MRI breast without and with IV contrast

There is no relevant literature to support the use of MRI without and with IV contrast in the evaluation of symptomatic silicone implants.

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses" [16].

Variant 8:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
D. MRI breast without IV contrast

In symptomatic patients with silicone breast implants or patients with equivocal US results for rupture at any time postoperatively, an MRI is recommended by the FDA [1]. MRI without IV contrast is particularly helpful in identifying intracapsular ruptures, which are not evident on mammography and can be difficult to diagnose by US. Most implant ruptures are intracapsular, and these are most often asymptomatic. MRI findings of both intracapsular and extracapsular rupture have been described [21, 26, 28, 31, 40]. An incomplete intracapsular rupture has been referred to by a variety of names, including the "inverted-loop sign," "keyhole sign," "teardrop sign," or "hang noose sign." A complete intracapsular rupture has been called the "linguini" or "wavy-line" sign and is the most specific sign of intracapsular implant rupture. Pooled data from a meta-analysis [41] showed a sensitivity of 87% and a specificity of 89.9% for MRI. Of note, most studies in the meta-analysis focused on symptomatic women, in whom the expected prevalence of rupture would be higher than among asymptomatic women. Studies of asymptomatic women have reported sensitivities and specificities of 64% and 77% [29], accuracy of 94% [30], accuracy of 92%, sensitivity of 89%, specificity of 97%, PPV of 99%, and NPV of 79% [39]. In symptomatic patients [43], MRI sensitivity of 96%, specificity of 77%, PPV of 90%, NPV of 90%, and accuracy of 90%.

Variant 8:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
E. US breast

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. However, US can identify extracapsular silicone [25, 26, 28, 40], which presents as a classic "snowstorm" pattern. In patients without prior explantation of silicone implants, this finding is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants.

A single-lumen silicone implant is most often featureless and anechoic, which provides reliable US evidence that the implant remains intact and undamaged. A normal implant exhibits a smooth contour outlined by a trilaminar margin, which corresponds to the capsule-shell complex. Implants

will often infold on themselves within the surgical pocket created by the plastic surgeon. These radial folds are a common feature of implants and should be recognized as a normal infolding of the elastomer shell rather than mistaken for evidence of intracapsular rupture. Most silicone implant ruptures are intracapsular. Numerous US findings of intracapsular silicone implant rupture, including the stepladder, keyhole, noose, or subcapsular sign, have been described [22, 26-28], but the variability in reported accuracy of sonographic findings [29-33], combined with the well-known user dependence of this technology, often makes sonographic findings somewhat equivocal. Several US intracapsular-rupture mimics exist and include reverberation artifact, radial folds, or silicone implant impurities creating spurious echoes within the implant, which can give a false impression of intracapsular rupture [22]. At US, extracapsular silicone demonstrates a classic "snowstorm" appearance that is characterized by a highly echogenic pattern of scattered and reverberating echoes with a well-defined anterior margin and loss of detail posteriorly.

Sonographic findings of intracapsular rupture have been described [26-28], including a "stepladder" appearance of the collapsed implant shell. Some authors have reported excellent agreement of US with MRI and surgical findings [31, 32]. However, other studies have reported much lower sensitivities and accuracies for US diagnosis of intracapsular silicone implant rupture [29, 30, 33], with an accuracy of 72%, sensitivity of 30%, and specificity of 77%. For the assessment of appropriateness, it is assumed the procedure is performed and interpreted by an expert. In a more recent study by Rukanskiene et al [42], US was very accurate in the evaluation of implant integrity, with a diagnostic accuracy of 94.7%, sensitivity of 98.3%, specificity of 89.2%, and NPV of 97.1%. In the case of an intact implant, all 3 signs of implant integrity on US (even implant shell, homogeneous content, and normal axillary lymph nodes) were observed most frequently at 93.6% [42]. In cases of ruptured implants, more than 2 signs of implant rupture on US were observed in 82.8% and only 1 sign of implant rupture on US was documented in 15.5% (abnormal implant shell) [42]. Therefore, these results suggest that if more than 2 signs of a ruptured implant are detected on US, US findings can be acted upon; if only 1 sign of a ruptured implant are found, MRI can be helpful [42].

The FDA recommendations regarding evaluation for implant rupture do not replace additional imaging that may be warranted based upon each patient's underlying medical history or circumstances [1]. Breast cancer screening recommendations for feminine and transfeminine patients are outlined in the ACR Appropriateness Criteria® topics on "Female Breast Cancer Screening" [14] and "Transgender Breast Cancer Screening" [15]. Imaging recommendations for areas of clinical concern unrelated to suspected implant complications may be found in the ACR Appropriateness Criteria® topic on "Palpable Breast Masses" [16].

Variant 9:Adult age 40 years or older. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.

The goal of imaging is the detection of silicone breast implant rupture in patients with suspected implant complication. The information from imaging is expected to differentiate patients with silicone implant rupture needing further management from those without silicone implant rupture. The expected outcome is appropriate triage of patients with ruptured silicone implants to further management while avoiding unnecessary procedures for patients without silicone implant rupture.

Variant 9:Adult age 40 years or older. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
A. Digital breast tomosynthesis diagnostic

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. However, DBT can identify extracapsular silicone. DBT can be useful in the evaluation of suspected extracapsular silicone implant rupture, which frequently presents with palpable findings or other symptoms. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with DBT in which high-density silicone is seen outside the implant contour. DBT does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. DBT can identify extracapsular silicone [25-28, 40], which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this finding is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants, and comparison with priors is critical.

Variant 9:Adult age 40 years or older. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
B. Mammography diagnostic

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. However, diagnostic mammography can identify extracapsular silicone. Diagnostic mammography can be useful in the evaluation of suspected extracapsular silicone implant rupture, which frequently presents with palpable findings or other symptoms. The diagnosis of silicone implant rupture can be challenging, with clinical examination known to be unreliable [24]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with mammography in which high-density silicone is seen outside the implant contour. Mammography does not detect intracapsular silicone implant rupture. Both standard craniocaudal and mediolateral oblique and implant-displaced views should be obtained. Mammography can identify extracapsular silicone [25-28, 40], which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this finding is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants, and comparison with priors is critical.

Variant 9:Adult age 40 years or older. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
C. MRI breast without and with IV contrast

There is no relevant literature to support the use of MRI without and with IV contrast in the evaluation of symptomatic silicone implants.

Variant 9:Adult age 40 years or older. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
D. MRI breast without IV contrast

In symptomatic patients with silicone breast implants or patients with equivocal US results for rupture at any time postoperatively, an MRI is recommended by the FDA [1]. MRI without IV contrast is generally a helpful imaging study for evaluation of silicone implant rupture. It is particularly helpful in identifying intracapsular ruptures, which are not evident on mammography

and can be difficult to diagnose by US. Most implant ruptures are intracapsular, and these are most often asymptomatic. MRI findings of both intracapsular and extracapsular rupture have been described [21, 26, 28, 31, 40]. An incomplete intracapsular rupture has been referred to by a variety of names, including the "inverted-loop sign," "keyhole sign," "teardrop sign," or "hang noose sign." A complete intracapsular rupture has been called the "linguini" or "wavy-line" sign and is the most specific sign of intracapsular implant rupture. Pooled data from a meta-analysis [41] showed a sensitivity of 87% and a specificity of 89.9% for MRI. Of note, most studies in the meta-analysis focused on symptomatic women, in whom the expected prevalence of rupture would be higher than among asymptomatic women. Studies of asymptomatic women have reported sensitivities and specificities of 64% and 77% [29], accuracy of 94% [30], accuracy of 92%, sensitivity of 89%, specificity of 97%, PPV of 99%, and NPV of 79% [39]. In symptomatic patients [43], an MRI sensitivity of 96%, specificity of 77%, PPV of 90%, NPV of 90%, and accuracy of 90%.

Variant 9:Adult age 40 years or older. Female or transfeminine. Evaluation of silicone breast implants. Suspected implant complication. Initial imaging.
E. US breast

In symptomatic patients with silicone breast implants, an MRI is recommended by the FDA to evaluate for rupture [1]. However, US can identify extracapsular silicone. Extracapsular rupture is disruption of both the polymer and fibrous capsules with leak of silicone into the breast tissue. Rupture of silicone implants, however, may be asymptomatic, especially if the rupture is intracapsular (contained by the fibrous shell formed by the body around the implant). If the rupture is extracapsular, patients may present with palpable masses or changes in breast contour. Diagnosis of extracapsular rupture of silicone implants is often made with mammography and/or US, in which high-density silicone is identified outside the confines of the implant shell. The rate of implant ruptures increases with time, and most of them do not cause any clinical symptoms. Once an implant ruptures, free silicone can migrate. Most frequently, free silicone infiltrates the adjacent breast tissues and sometimes can mimic breast cancer. US can identify extracapsular silicone [25, 26, 28, 40], which presents as a classic "snowstorm" pattern and may be useful if mammographic findings are equivocal or the patient cannot undergo mammography.

Sonographic findings of intracapsular rupture have been described [26-28], including a "stepladder" appearance of the collapsed implant shell. Some authors have reported excellent agreement of US with MRI and surgical findings [31, 32]. However, other studies have reported much lower sensitivities and accuracies for US diagnosis of intracapsular silicone implant rupture [29, 30, 33], showing an accuracy of 72%, sensitivity of 30%, and specificity of 77%. For the assessment of appropriateness, it is assumed the procedure is performed and interpreted by an expert. In a more recent study by Rukanskiene et al, US was very accurate in the evaluation of implant integrity, with a diagnostic accuracy of 94.7%, sensitivity of 98.3%, specificity of 89.2%, and NPV of 97.1%. In the case of an intact implant, all 3 signs of implant integrity on US (even implant shell, homogeneous content, and normal axillary lymph nodes) were observed most frequently at 93.6% [42]. In cases of ruptured implants, more than 2 signs of implant rupture on US were observed in 82.8%, and only 1 sign of implant rupture on US was documented in 15.5% (abnormal implant shell) [42]. Therefore, these results suggest that if more than 2 signs of a ruptured implant are detected on US, US findings can be acted upon; if only 1 sign of a ruptured implant are found, MRI can be helpful [42].

Variant 10:Adult younger than 30 years of age. Female or transfeminine. Evaluation of

unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.

The goal of imaging is the diagnosis of silicone lymphadenopathy in patients with unexplained axillary adenopathy. The information from imaging is expected to differentiate patients whose axillary adenopathy can be explained by benign uptake of silicone from those needing further evaluation for occult malignancy or systemic illness. The expected outcome is avoiding unnecessary biopsy for patients with benign silicone lymphadenopathy while appropriately proceeding to biopsy for patients whose axillary adenopathy is not definitively explained by silicone.

Variant 10:Adult younger than 30 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging. A. Digital breast tomosynthesis diagnostic

DBT is typically not performed as the initial imaging study in patients under the age of 30. DBT may be useful as a complementary imaging modality to evaluate unexplained axillary adenopathy in patients <30 years of age when suspicious sonographic findings are identified. Silicone within low axillary nodes may also be seen on DBT.

Variant 10:Adult younger than 30 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging. B. Mammography diagnostic

Diagnostic mammography is typically not performed as the initial imaging study in patients under the age of 30. Diagnostic mammography may be useful as a complementary imaging modality to evaluate for unexplained axillary adenopathy in patients <30 years of age when suspicious sonographic findings are identified. Silicone within low axillary nodes may also be seen on diagnostic mammography.

Variant 10:Adult younger than 30 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging. C. MRI breast without and with IV contrast

There is no relevant literature to support MRI without and with IV contrast as the initial imaging study in this setting. However, it is needed if biopsy shows axillary metastatic disease from a mammographically and sonographically occult primary breast carcinoma.

Variant 10:Adult younger than 30 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging. D. MRI breast without IV contrast

There is no relevant literature to support MRI without IV contrast as the initial imaging examination in the evaluation of unexplained axillary adenopathy in patients <30 years of age. Although MRI can identify silicone in lymph nodes, US is a more useful initial imaging test.

Variant 10:Adult younger than 30 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging. E. US breast

For patients <30 years of age with unexplained axillary adenopathy in this clinical scenario, US can be helpful in diagnosing silicone adenitis, in which a "snowstorm” [27] appearance will be seen in the axillary nodes containing free silicone. In addition, US can identify morphologically abnormal lymph nodes that may represent metastatic disease from a previously unsuspected breast cancer or may be from a variety of other causes such as lymphoma, infection, or systemic illnesses, including autoimmune diseases.

Variant 11:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.

The goal of imaging is the diagnosis of silicone lymphadenopathy in patients with unexplained axillary adenopathy. The information from imaging is expected to differentiate patients whose axillary adenopathy can be explained by benign uptake of silicone from those needing further evaluation for occult malignancy or systemic illness. The expected outcome is avoiding unnecessary biopsy for patients with benign silicone lymphadenopathy while appropriately proceeding to biopsy for patients whose axillary adenopathy is not definitively silicone-related.

Variant 11:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
A. Digital breast tomosynthesis diagnostic

DBT may help to evaluate unexplained axillary adenopathy in patients 30 to 39 years of age. Silicone within low axillary nodes may be seen on DBT. When DBT is performed, axillary US is complementary and may be performed at the same time.

Variant 11:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
B. Mammography diagnostic

Diagnostic mammography may help to evaluate unexplained axillary adenopathy in patients 30 to 39 years of age. Silicone within low axillary nodes may be seen on mammography and DBT. When mammography is performed, axillary US is complementary and may be performed at the same time.

Variant 11:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
C. MRI breast without and with IV contrast

There is no relevant literature to support MRI without and with IV contrast in this setting as the initial imaging study in this setting. However, it is needed if biopsy shows axillary metastatic disease from a mammographically and sonographically occult primary breast carcinoma.

Variant 11:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
D. MRI breast without IV contrast

MRI without IV contrast is of limited value as the initial imaging examination in the evaluation of unexplained axillary adenopathy in patients 30 to 39 years of age. Although MRI can identify silicone in lymph nodes, mammography and US are more useful as initial imaging tests.

Variant 11:Adult 30 to 39 years of age. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
E. US breast

US may be considered for patients 30 to 39 years of age with unexplained axillary adenopathy. The second most common place for free silicone migration is regional lymph nodes (axillary lymph nodes), and silicone aggregates in lymph nodes can also mimic malignant processes. Occasionally, free silicone travels to distant regions (arm/forearm, thoracic cavity, abdominal wall, legs, back). US can diagnose silicone adenitis, in which a "snowstorm” [27] appearance will be seen in the axillary nodes containing free silicone. In addition, US can identify morphologically abnormal lymph nodes that may represent metastatic disease from a previously unsuspected breast cancer or may be from a variety of other causes, such as lymphoma, infection, or systemic illnesses, including

autoimmune diseases. If morphologically abnormal lymph nodes are identified, further evaluation of the breast parenchyma is indicated. For patients 30 to 39 years of age, this often includes mammography or DBT and US.

Variant 12:Adult age 40 years or older. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.

The goal of imaging is the diagnosis of silicone lymphadenopathy in patients with unexplained axillary adenopathy. The information from imaging is expected to differentiate patients whose axillary adenopathy can be explained by benign uptake of silicone from those needing further evaluation for occult malignancy or systemic illness. The expected outcome is avoiding unnecessary biopsy for patients with benign silicone lymphadenopathy while appropriately proceeding to biopsy for patients whose axillary adenopathy is not definitively silicone-related.

Variant 12:Adult age 40 years or older. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
A. Digital breast tomosynthesis diagnostic

DBT can evaluate for unexplained axillary adenopathy in patients ≥40 years of age and may identify a breast cancer that has metastasized to the axilla. Silicone within low axillary nodes may also be seen on DBT. US is complementary and may be done in conjunction with DBT during evaluation, regardless of findings on mammography or DBT.

Variant 12:Adult age 40 years or older. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
B. Mammography diagnostic

Mammography can evaluate for unexplained axillary adenopathy in patients ≥40 years of age and may identify a breast cancer that has metastasized to the axilla. Silicone within low axillary nodes may also be seen on mammography. US is complementary and may be done in conjunction with mammography during evaluation, regardless of findings on mammography or DBT.

Variant 12:Adult age 40 years or older. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
C. MRI breast without and with IV contrast

MRI without and with IV contrast may not be ideal in this setting. However, it is needed if biopsy shows axillary metastatic disease from a mammographically and sonographically occult primary breast carcinoma.

Variant 12:Adult age 40 years or older. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
D. MRI breast without IV contrast

MRI without IV contrast is of limited value as the initial imaging examination in the evaluation of unexplained axillary adenopathy in patients ≥40 years of age. Although MRI can identify silicone in lymph nodes, mammography and US are more useful as initial imaging tests.

Variant 12:Adult age 40 years or older. Female or transfeminine. Evaluation of unexplained axillary adenopathy. Silicone breast implants current or prior. Initial imaging.
E. US breast

US is complementary to mammography or DBT and can diagnose silicone adenitis, in which a "snowstorm" [27] appearance will be seen in the axillary nodes containing free silicone. In addition, US can identify morphologically abnormal lymph nodes that may represent metastatic disease

from primary breast cancer or may be from a variety of other causes, such as lymphoma, infection, or systemic illnesses, including autoimmune diseases. If morphologically abnormal lymph nodes are identified, further evaluation of the breast parenchyma is indicated. This often begins with diagnostic mammography or DBT and may include targeted US of any suspicious findings. The second most common place for free silicone migration is regional lymph nodes (axillary lymph nodes), and silicone aggregates in lymph nodes can also mimic malignant processes. Occasionally, free silicone travels to distant regions (arm/forearm, thoracic cavity, abdominal wall, legs, back). To avoid these complications, it is of crucial importance to detect implant rupture as soon as possible and to remove or replace a ruptured implant [42].

Variant 13:Adult of any age. Female or transfeminine. Suspected breast implant-associated malignancy. Breast implant of any type. Initial imaging.

The goal of imaging is the detection of implant-associated malignancy. The information from imaging is expected to guide appropriate management including biopsy for diagnosis and subsequent treatment if malignancy is confirmed. The expected outcome is prompt diagnosis of implant-associated malignancy which will reduce delays in treatment initiation.

Variant 13:Adult of any age. Female or transfeminine. Suspected breast implant-associated malignancy. Breast implant of any type. Initial imaging.
A. Digital breast tomosynthesis diagnostic

If the patient is =40 years, DBT may be considered. DBT has a low sensitivity and specificity for BIA malignancy, but it may be used to assess for any potential mimics or masses and other diagnoses including in situ and invasive primary breast malignancy [19, 54]. In cases of BIA-ALCL, the capsule may be thickened and the membrane contour may be disrupted [19]. In general, DBT findings include nonspecific capsular thickening, circumferential asymmetry around the implant, or irregular mass [20]. DBT may detect a change in implant appearance related to a new fluid collection or an associated mass. Distinguishing between fluid and solid tissue typically requires US. One meta-analysis [19] reported a sensitivity of 73% and a specificity of 50% for mammography in the detection of an abnormality.

Variant 13:Adult of any age. Female or transfeminine. Suspected breast implant-associated malignancy. Breast implant of any type. Initial imaging.
B. Mammography diagnostic

If the patient is 40 years, mammography may be considered. Mammography has a low sensitivity and specificity for BIA malignancy, but it may be used to assess for any potential mimics or masses and other diagnoses including in situ and invasive primary breast malignancy [19, 54]. In cases of BIA-ALCL, the capsule may be thickened and the membrane contour may be disrupted [19]. In general, diagnostic mammography findings include nonspecific capsular thickening, circumferential asymmetry around the implant, or irregular mass [20]. Diagnostic mammography may detect a change in implant appearance related to a new fluid collection or an associated mass. Distinguishing between fluid and solid tissue typically requires US. One meta-analysis [19] reported a sensitivity of 73% and a specificity of 50% for mammography in the detection of an abnormality.

Variant 13:Adult of any age. Female or transfeminine. Suspected breast implant-associated malignancy. Breast implant of any type. Initial imaging.
C. MRI breast without and with IV contrast

MRI without and with IV contrast can be helpful in the evaluation of patients presenting with late seroma and possible BIA malignancy [11, 51, 52]. The American Society of Plastic Surgery

recommends MRI with and without IV contrast for all patients presenting with late seroma and NCCN guidelines recommend US or MRI as the initial imaging test for these patients [18]. MRI has a reported sensitivity of 82% for the detection of effusion and 50% for detection of a mass, with corresponding specificities of 33% and 93%, respectively [19]. MRI findings include peri-implant tissue edema and effusion, as well as capsular mass lesions, including small volume mass components not detected with US [53] [51, 52]. The principal MRI signs seen in the Rotili et al [52] study of BIA-ALCL included liquid-serous effusion, peri-implant and capsule related masses, enhancement of the capsule, irregular thickness of the capsule, and subcutaneous nodules of local recurrence of ALCL after capsulectomy. MRI of BIA-SCC can show a mass arising from the breast capsule and can evaluate for chest wall involvement [53].

Variant 13:Adult of any age. Female or transfeminine. Suspected breast implant-associated malignancy. Breast implant of any type. Initial imaging.
D. MRI breast without IV contrast

MRI without IV contrast may identify a fluid collection associated with the implant but is of limited value in the detection of an associated mass. US provides an easier means to assess for effusion and has the added benefit of guiding aspiration for cytologic diagnosis. MRI breast without IV contrast may serve to evaluate for the presence of implant rupture when there is a silicone implant [20].

Variant 13:Adult of any age. Female or transfeminine. Suspected breast implant-associated malignancy. Breast implant of any type. Initial imaging.
E. US breast

Initial workup should include US evaluation for peri-implant fluid collection, breast masses, and enlarged regional lymph nodes [10, 19, 44]. US will frequently identify a fluid collection or mass if present and provides image guidance for diagnostic aspiration of the fluid for cytology or core biopsy of a mass lesion [4]. More data are available for appearance of BIA-ALCL than for BIA-SCC given the small number of reported cases of BIA-SCC. For BIA-ALCL, in cases in which a mass (or masses) is present, it most commonly appears as an oval, hypoechoic, and circumscribed solid mass without hypervascularity, although a complex-cystic mass has also been observed [20]. Adrada et al [19] reported an 84% sensitivity for detection of effusion and a 46% sensitivity for detection of a mass, with a corresponding specificity of 75% and 100%, respectively.

Early diagnosis of BIA malignancy can often be made from cytological analysis of the fluid and is critical because patients with disease limited to the implant capsule have a much better prognosis than those with tumor extending beyond the capsule [10, 19, 45-50]. Peri-implant effusions (>10 mL) should undergo aspiration, and any suspicious mass should undergo tissue biopsy; specimens should be sent for cytology and flow cytometry [4, 10].

Ideally, a minimum of 50 mL of fluid should be sent to the laboratory with a specific request to evaluate for BIA malignancy (both BIA-ALCL and BIA-SCC) [10]. Before aspiration or tissue sampling, the radiologist should consider contacting colleagues within pathology to discuss how best to collect and send the fluid and tissue samples for the specific analyses required for diagnosis of BIA malignancy [10, 11]. ASPS recommends that specimens be evaluated for CD30, ALK, CK 5/6, and p63 on immunohistochemistry and T cells, squamous cells, and keratin on flow

cytometry [17]. A multidisciplinary team of plastic surgeons, surgical oncologists, hematologists, and pathologists should be assembled for the diagnosis and management of BIA malignancy.

Abnormal ipsilateral axillary lymph nodes with cortical thickening or diffusely hypoechoic lymph node(s) without evident fatty hilum may be present in the setting of BIA malignancy [51].

Summary of Highlights

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

- Variant 1: Imaging is usually not appropriate for initial imaging in an asymptomatic female or transfeminine adult patient of any age for saline breast implant evaluation.
- Variant 2: US breast is usually appropriate for initial imaging in a female or transfeminine adult patient younger than 30 years of age with saline breast implant and suspected implant rupture.
- Variant 3: US breast is usually appropriate for initial imaging in a female or transfeminine adult patient 30 to 39 years of age with saline breast implant and suspected implant rupture. The panel did not agree on recommending diagnostic DBT or diagnostic mammography in this clinical scenario. There is insufficient medical literature to conclude whether or not these patients would benefit from these 2 modalities in this scenario. Imaging in this patient population is controversial but may be appropriate.
- Variant 4: Diagnostic DBT and diagnostic mammography are usually appropriate for initial imaging in a female or transfeminine adult patient age 40 years or older with saline breast implant and suspected implant rupture. These procedures are alternative (ie, only one 1 of these 2 two procedures will be ordered).
- Variant 5: Imaging is usually not appropriate for initial imaging in an asymptomatic female or transfeminine adult patient of any age for silicone breast implant evaluation less than 5 years after implant placement.
- Variant 6: Initial imaging with US breast or MRI breast without IV contrast is usually appropriate for an asymptomatic female or transfeminine adult of any age for silicone breast implant evaluation at 5 to -6 years after implant placement. Follow-up imaging is performed every 2 to 3 years after initial negative imaging. These procedures are alternatives (i.e., only one 1 procedure will be ordered for initial imaging).
- Variant 7: MRI breast without IV contrast is usually appropriate for initial imaging in a female or transfeminine adult younger than 30 years of age for silicone breast implant evaluation with a suspected implant complication. The panel did not agree on recommending US breast in this clinical scenario. There is insufficient medical literature to conclude whether or not these patients would benefit from this modality in this scenario. Imaging in this patient population is controversial but may be appropriate.
- Variant 8: MRI breast without IV contrast is usually appropriate for initial imaging in a female or transfeminine adult patient 30 to 39 years of age for silicone breast implant evaluation with a suspected implant complication. The panel did not agree on recommending diagnostic DBT or diagnostic mammography in this clinical scenario. There is insufficient medical literature to conclude whether or not these patients would benefit from these 2 modalities in this scenario. Imaging in this patient population is controversial but may be appropriate.
- Variant 9: MRI breast without IV contrast is usually appropriate for initial imaging in a female

or transfeminine adult patient age 40 years or older for silicone breast implant evaluation with a suspected implant complication. The panel did not agree on recommending diagnostic DBT or diagnostic mammography in this clinical scenario. There is insufficient medical literature to conclude whether or not these patients would benefit from these 2 modalities in this scenario. Imaging in this patient population is controversial but may be appropriate.

- Variant 10: US breast is usually appropriate for the initial imaging in a female or transfeminine adult patient younger than 30 years of age with current or prior silicone breast implants for the evaluation of unexplained axillary adenopathy.
- Variant 11: US breast, diagnostic DBT, and diagnostic mammography are usually appropriate for initial imaging in a female or transfeminine adult patient age 30 to 39 with current or prior silicone breast implants for the evaluation of unexplained axillary adenopathy. US is complementary with diagnostic DBT or mammography (i.e., more than one 1 procedure is ordered as a set or simultaneously where in which each procedure provides unique clinical information to effectively manage the patient's care). Diagnostic DBT and diagnostic mammography are alternatives (i.e., only one 1 of these two 2 procedures will be ordered for initial imaging).
- Variant 12: US breast, diagnostic DBT, and diagnostic mammography are usually appropriate for initial imaging in a female or transfeminine adult patient age 40 years or older with current or prior silicone breast implants for the evaluation of unexplained axillary adenopathy. US is complementary with diagnostic DBT or mammography (i.e., more than one 1 procedure is ordered as a set or simultaneously where in which each procedure provides unique clinical information to effectively manage the patient's care). Diagnostic DBT and diagnostic mammography are alternatives (i.e., only one 1 of these two 2 procedures will be ordered for initial imaging).
- Variant 13: US breast and MRI breast without and with IV contrast are usually appropriate for initial imaging in a female or transfeminine adult patient of any age with suspected breast implant-associated BIA malignancy with breast implants of any type. These procedures are alternatives (i.e., only one 1 procedure will be ordered for initial imaging). Diagnostic DBT and diagnostic mammography may be appropriate if the patient is 40 years or older. In that scenario, diagnostic DBT and diagnostic mammography are complementary examinations to US and MRI (i.e., more than one 1 procedure is ordered as a set or simultaneously where in which each procedure provides unique clinical information to effectively manage the patient's care). Diagnostic DBT and diagnostic mammography are alternatives (i.e., only one 1 of these two 2 procedures will be ordered).

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.

Gender Equality and Inclusivity Clause

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

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.

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv

☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., 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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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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