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

Panel Members

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Summary of Literature Review

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 clinically 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].

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" [1] and "Transgender Breast Cancer Screening" [2]. 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" [1] and "Transgender Breast Cancer Screening" [2]. 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 [3]. 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 [3]. 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

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