

**American College of Radiology
ACR Appropriateness Criteria®
Breast Imaging of Lactating Women**

Variant: 1 Breast cancer screening during lactation. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
Mammography screening	Usually Appropriate	☢☢
US breast	May Be Appropriate	○
MRI breast without and with IV contrast	Usually Not Appropriate	○
MRI breast without IV contrast	Usually Not Appropriate	○
Sestamibi MBI	Usually Not Appropriate	☢☢☢

Panel Members

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Summary of Literature Review

Introduction/Background

Pregnancy-associated breast cancer (PABC) is defined as breast cancer diagnosed during pregnancy, throughout the first postpartum year, or during lactation [1-4]. With a reported incidence of 1 in 3,000 to 10,000 pregnancies, breast cancer is the most common invasive cancer diagnosed during pregnancy [5-10]. Representing up to 3% of all breast cancer diagnoses, PABC is increasing as more women delay child bearing into the fourth decade of life when the incidence of breast cancer is higher [7,10,11]. Breast imaging during lactation is challenging because of the unique physiologic and structural breast changes that increase the difficulty of clinical and radiological evaluation.

Throughout pregnancy, there is an increase in the size and number of breast ducts and lobules, an increase in the fluid content of the breast, and involution of stromal adipose tissue [9,12]. After delivery, prolactin stimulates secretory changes and the lobular acini become distended with milk [9,13-15]. These physiologic changes lead to increased breast volume, firmness, and nodularity, thereby making the detection of palpable abnormalities on clinical examination more difficult. As a result, there is often a delay in the diagnosis of PABC, and women typically present with more advanced disease exhibiting larger tumors and a higher likelihood of axillary nodal disease compared to nonpregnant women of the same age [8,16].

There is ongoing controversy as to whether delayed diagnosis and young patient age account for the poor prognosis of PABC, or if there may be additional factors causing increased biologic aggressiveness of gestational breast cancer when matched for age and stage [17-19]. Significant

vascular and stromal remodeling is necessary to support the expanded epithelium of pregnancy and lactation, and these changes in the breast microenvironment could potentially be leveraged by breast cancer cells, leading to an increase in biologic aggressiveness [2,18,20]. Despite the long-term decreased risk of breast cancer with pregnancy, there are some data to suggest that there may be a transient increased risk for breast cancer during pregnancy and lactation [6]. Some studies show that women with BRCA gene mutations are overrepresented in PABC, and pregnant and lactating women are more likely to have hormone-negative breast cancer than age-matched controls [7,18,21,22]. Although the underlying cause for these observations is not clear, they support the possibility that the tumor biology of PABC is more aggressive than non-PABC breast cancer in young women with equivalent stage and prognostic factors.

The most common presentation of PABC is a palpable mass. Therefore, imaging evaluation of a palpable lesion in a lactating woman should not be delayed [7,20,23,24]. Less common presenting complaints include focal pain, diffuse breast enlargement, nipple discharge, and, rarely, unilateral milk rejection in which the infant rejects milk from the breast harboring cancer [7,24]. The imaging appearance of PABC is similar to breast cancer in nonpregnant patients. Because of the young age of these women and higher likelihood of triple negative breast cancer, PABC is more likely to demonstrate areas of necrosis[13,25]. In addition, PABC may have a falsely benign appearance presenting as a mass with relatively circumscribed margins, parallel orientation, and posterior acoustic enhancement [1,7].

Although PABC most commonly presents as a palpable mass, greater than 80% of palpable masses that are biopsied in pregnant and breastfeeding women are benign [10,25]. Benign palpable masses may be due to enlargement of pre-existing benign masses, such as fibroadenomas and hamartomas, or they may represent masses unique to lactation, such as lactating adenomas and galactoceles [9,13]. When pre-existing lesions enlarge because of hormonal stimulation, they may appear atypical secondary to infarction or proliferative and lactational changes within the lesion [9,10,13]. These changes may lead to concerning imaging features and warrant further evaluation with biopsy. Some benign palpable masses are definitively benign on imaging evaluation (ie, cysts), whereas other masses may have benign imaging characteristics that allow for close follow-up.

Isolated bloody nipple discharge without associated palpable mass most commonly due to benign causes. The proliferative epithelial changes and associated increased breast vascularity may result in unilateral or bilateral bloody nipple discharge that is considered physiologic and sometimes referred to as the "rusty pipe syndrome" [26,27]. This condition may occur during early lactation and is usually self-limited. However, persistent unilateral bloody nipple discharge may be secondary to infection, papilloma, or, less commonly, breast cancer. A review of limited available data from an older report suggests that in nonpregnant patients of similar age, up to 12% of cases of isolated bloody nipple discharge may be due to breast cancer [28,29]. Therefore, diagnostic imaging workup of persistent unilateral bloody nipple discharge is recommended in lactating patients.

The physiologic increased breast vascularity of lactation may limit the sensitivity of dynamic contrast-enhanced (DCE) breast MRI [12,30-32]. Biopsy should be recommended for any suspicious imaging findings, and patients should be informed regarding the possibility of milk fistula and increased risk of bleeding.

Breast cancer screening in lactating women has several important considerations, as outlined below. However, diagnostic breast imaging during lactation is the same as for nonlactating women. See the ACR Appropriateness Criteria® for "[Palpable Breast Masses](#)" [33], "[Evaluation of Nipple Discharge](#)" [29], and "[Female Breast Cancer Screening](#)" [34].

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: Breast cancer screening during lactation. Initial imaging.

There is limited evidence on breast cancer screening in lactating women. Because of the potential increased risk of breast cancer in this population, consider continued screening during lactation dependent upon the level of underlying risk and the expected duration of lactation.

Variant 1: Breast cancer screening during lactation. Initial imaging.

A. Mammography and DBT

With the onset of lactation, mammographic density increases to variable degrees among patients because of the distention of lobules with milk. Sonographic evaluation of the distribution of glandular and adipose tissue during lactation has shown that up to half of the breast volume continues to consist of adipose tissue [14]. Nursing or pumping before mammography may decrease parenchymal density and thereby improve sensitivity of mammography in lactating patients [9,10,13,35]. There is no contraindication to performing mammography during lactation. There are limited data available concerning screen-detected PABC. In one recent study, 9 of 117 (7.7%) cancers in patients with PABC were subclinical, and 5 of these cases were detected only with screening mammography in high-risk women [7]. In another small study, 2 of 22 cases of PABC were detected on screening mammography [24]. Therefore, screening mammography may be of benefit in lactating women, in accordance with ACR Appropriateness Criteria® for "[Female Breast Cancer Screening](#)" [34], and breastfeeding or pumping should be encouraged prior to the examination to minimize breast density and optimize the sensitivity of screening mammography.

There are no studies specifically evaluating DBT in this patient population. The increased breast density seen in younger women and in the hormonally altered breasts of lactating women is more likely to mask small lesions. Therefore, this population may benefit from the ability of 3-D mammography to decrease the masking effect of dense breast tissue.

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B. US Breast

There are no studies specifically evaluating hand-held or automated whole-breast US screening in women who are breastfeeding. Given the increased mammographic density during lactation, screening US could be considered as a supplemental screening option in lactating women at intermediate and high risk for breast cancer. It is, however, important to keep in mind that screening US may increase the false-positive rate and prompt additional biopsies with small additional risk of milk fistula in lactating women [36,37].

Variant 1: Breast cancer screening during lactation. Initial imaging.

C. MRI Breast

The physiologic increased vascularity of lactation causes a marked increase in background parenchymal enhancement on breast DCE-MRI. Although this may limit the sensitivity for detecting small enhancing masses and nonmass enhancement, studies have shown that breast DCE-MRI can differentiate enhancing breast cancer from background parenchymal enhancement based on kinetics and morphology [19,31,32,35,38]. A study of 53 patients with known PABC demonstrated moderate or marked background parenchymal enhancement in 58% of patients. Despite increased background parenchymal enhancement, there was 98% sensitivity for detection of known PABC; however, it is unknown how many women were lactating at the time of the MRI [19]. There are scant data on MRI screening in lactating women. In one study, 4 breast cancers in 3 patients were detected on high-risk screening MRI [7]. It may be helpful to wait until 3 months after cessation of breastfeeding. However, if a woman plans to nurse for a long period, or is at very high risk for breast cancer, screening breast MRI during lactation may be considered [10]. The amount of gadolinium excreted in human breast milk over the first 24 hours after IV contrast administration is <1% of the permitted dose for neonates [39]. Up-to-date recommendations with regard to breastfeeding following IV administration of gadolinium are outlined in detail in the ACR Manual on Contrast Media [30]. Therefore, although not the initial imaging tool of choice, screening breast MRI is not contraindicated during lactation and may be considered in lactating women with a high lifetime risk of breast cancer. An informed decision should be made by the mother regarding continuation of breastfeeding after the examination [3,30,39].

Variant 1: Breast cancer screening during lactation. Initial imaging.

D. Sestamibi MBI

There is no role for molecular breast imaging (MBI) in breast cancer screening during lactation.

Summary of Recommendations

- **Variant 1:** For lactating women, screening with DBT or mammography is indicated in age appropriate patients.

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at <https://acsearch.acr.org/list>. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents, please go to the ACR website at <https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria>.






Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable 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
0	0 mSv	0 mSv
	<0.1 mSv	<0.03 mSv
	0.1-1 mSv	0.03-0.3 mSv
	1-10 mSv	0.3-3 mSv
	10-30 mSv	3-10 mSv
	30-100 mSv	10-30 mSv

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

The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient’s clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient’s condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

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