

**American College of Radiology  
ACR Appropriateness Criteria®**

**Stage I Breast Cancer: Initial Workup and Surveillance for Local Recurrence and Distant Metastases in Asymptomatic Women**

**Variant 1:**                      **Newly diagnosed. Stage I breast cancer. Asymptomatic. Rule out bone metastases. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
FDG-PET/CT whole body	Usually Not Appropriate	⚠⚠⚠⚠
Radiography skeletal survey	Usually Not Appropriate	⚠⚠⚠
Bone scan whole body	Usually Not Appropriate	⚠⚠⚠

**Variant 2:**                      **Newly diagnosed. Stage I breast cancer. Asymptomatic. Rule out thoracic metastases. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
CT chest with IV contrast	Usually Not Appropriate	⚠⚠⚠
CT chest without and with IV contrast	Usually Not Appropriate	⚠⚠⚠
CT chest without IV contrast	Usually Not Appropriate	⚠⚠⚠
FDG-PET/CT whole body	Usually Not Appropriate	⚠⚠⚠⚠
Radiography chest	Usually Not Appropriate	⚠

**Variant 3:**                      **Newly diagnosed. Stage I breast cancer. Asymptomatic. Rule out abdominal metastases. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
CT abdomen with IV contrast	Usually Not Appropriate	⚠⚠⚠
CT abdomen without and with IV contrast	Usually Not Appropriate	⚠⚠⚠⚠
CT abdomen without IV contrast	Usually Not Appropriate	⚠⚠⚠
FDG-PET/CT whole body	Usually Not Appropriate	⚠⚠⚠⚠
MRI abdomen without and with IV contrast	Usually Not Appropriate	○
MRI abdomen without IV contrast	Usually Not Appropriate	○
US abdomen	Usually Not Appropriate	○

**Variant 4:**                      **Newly diagnosed. Stage I breast cancer. Asymptomatic. Rule out brain metastases. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
MRI head without and with IV contrast	Usually Not Appropriate	○
MRI head without IV contrast	Usually Not Appropriate	○
FDG-PET/CT whole body	Usually Not Appropriate	⚠⚠⚠⚠
CT head without IV contrast	Usually Not Appropriate	⚠⚠⚠
CT head without and with IV contrast	Usually Not Appropriate	⚠⚠⚠
CT head with IV contrast	Usually Not Appropriate	⚠⚠⚠

**Variant 5:** Surveillance. Stage I breast cancer. Asymptomatic. Rule out bone, thoracic, abdominal, and brain metastases. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
CT abdomen with IV contrast	Usually Not Appropriate	☢☢☢
CT abdomen without and with IV contrast	Usually Not Appropriate	☢☢☢☢
CT abdomen without IV contrast	Usually Not Appropriate	☢☢☢
CT chest with IV contrast	Usually Not Appropriate	☢☢☢
CT chest without and with IV contrast	Usually Not Appropriate	☢☢☢
CT chest without IV contrast	Usually Not Appropriate	☢☢☢
CT head with IV contrast	Usually Not Appropriate	☢☢☢
CT head without and with IV contrast	Usually Not Appropriate	☢☢☢
CT head without IV contrast	Usually Not Appropriate	☢☢☢
FDG-PET/CT whole body	Usually Not Appropriate	☢☢☢☢
MRI abdomen without and with IV contrast	Usually Not Appropriate	○
MRI abdomen without IV contrast	Usually Not Appropriate	○
MRI head without and with IV contrast	Usually Not Appropriate	○
MRI head without IV contrast	Usually Not Appropriate	○
Radiography chest	Usually Not Appropriate	☢
Radiography skeletal survey	Usually Not Appropriate	☢☢☢
Bone scan whole body	Usually Not Appropriate	☢☢☢
US abdomen	Usually Not Appropriate	○

**Variant 6:** Surveillance. Stage I breast cancer. Asymptomatic. Rule out local recurrence.

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

## STAGE I BREAST CANCER: INITIAL WORKUP AND SURVEILLANCE FOR LOCAL RECURRENCE AND DISTANT METASTASES IN ASYMPTOMATIC WOMEN

Expert Panel on Breast Imaging: Alana A. Lewin, MD<sup>a</sup>; Linda Moy, MD<sup>b</sup>; Paul Baron, MD<sup>c</sup>; Aarati D. Didwania, MD<sup>d</sup>; Roberta M. diFlorio-Alexander, MD, MS<sup>e</sup>; Jessica H. Hayward, MD<sup>f</sup>; Huong T. Le-Petross, MD<sup>g</sup>; Mary S. Newell, MD<sup>h</sup>; Amar Rewari, MD, MBA<sup>i</sup>; John R. Scheel, MD, PhD, MPH<sup>j</sup>; Ashley R. Stuckey, MD<sup>k</sup>; W. Warren Suh, MD, MPH<sup>l</sup>; Gary A. Ulaner, MD, PhD<sup>m</sup>; Nina S. Vincoff, MD<sup>n</sup>; Susan P. Weinstein, MD<sup>o</sup>; Priscilla J. Slanetz, MD, MPH.<sup>p</sup>

### Summary of Literature Review

#### **Introduction/Background**

Although more than 200,000 women are diagnosed with invasive cancer annually [1], breast cancer mortality has decreased because of advances in screening and improved treatment [2]. Routine mammographic screening improves early stage cancer detection, potentially decreasing the need for more extensive treatment and improving chances for better overall prognosis [3]. Early stage breast cancer includes stage I breast cancer, which is divided into stage IA and IB. Stage IA breast cancer is defined as a tumor  $\leq 20$  mm and negative lymph nodes. Stage IB is defined as a tumor  $\leq 20$  mm with micrometastases in movable ipsilateral level I and II axillary lymph node(s), or no evidence of primary tumor in the breast but with micrometastases in movable ipsilateral level I and II axillary lymph node(s). Studies have shown that the 5-year disease-specific survival for stage IA/IB breast cancer is 99.1% [4].

As the proportion of women diagnosed with early stage breast cancer increases, so too does the population of breast cancer survivors, emphasizing the importance of follow-up care for these women. The premise for intense monitoring in breast cancer survivors is that the detection of an early recurrence, prior to the development of symptoms, will allow for earlier treatment and can improve overall survival [5]. However, randomized controlled trials have found that routine testing for distant metastatic disease provides no benefit in survival or health-related quality of life, and an intensive approach to surveillance is costly. Moreover, although many physicians and patients favor intensive initial workup and surveillance, patients overestimate the value of laboratory and imaging studies and may incorrectly perceive the significance of a normal test [5]. Unnecessary imaging can delay care, which is problematic because a delay in treatment has been shown to affect breast cancer stage and outcomes [6].

#### **Discussion of Procedures by Variant**

##### **Variant 1: Newly diagnosed. Stage I breast cancer. Asymptomatic. Rule out bone metastases. Initial imaging.**

National and international guidelines (American Society of Clinical Oncology [ASCO], National Comprehensive Cancer Network [NCCN], European Society for Medical Oncology [ESMO], Spanish Society of Medical Oncology [SEOM], and the European School of Oncology [ESO]) discourage the use of staging imaging for asymptomatic patients newly diagnosed with stage 0 to II breast cancer, even if there is nodal involvement [7-10].

#### **Radiography Skeletal Survey**

A large nonrandomized clinical study in Italy confirmed the lack of value of regular preoperative radiographs and radionuclide bone scanning performed on stage I asymptomatic breast cancer patients [11]. Only 1 of 633 patients with stage I disease had metastatic bone disease detected. Therefore, a radiography skeletal survey is not routinely indicated for asymptomatic women with newly diagnosed stage I breast cancer.

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### **FDG-PET/CT Whole Body**

Studies show that the use of advanced imaging modalities, including bone scans, CT, and PET, for staging asymptomatic women with early breast cancer has a low yield to detect occult metastatic disease [6,12]. Therefore, advanced imaging should only be performed in patients with early breast cancer who have focal signs or symptoms that are concerning for metastatic disease [6].

A retrospective study of 163 women with suspected metastatic breast cancer showed high discordance between PET/CT and bone scan in detecting bony metastases [13]. Their results support the use of PET/CT in detecting osseous metastases and suggest that PET/CT may render bone scintigraphy unnecessary. Another study compared fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG)-PET/CT and bone scintigraphy for detection of bone metastases in breast cancer in 132 lesions [14]. The authors concluded that on a lesion basis whole-body PET/CT is more sensitive and equally specific for the detection of bone metastases compared with bone scintigraphy. Similarly, another study showed that PET/CT is significantly more accurate than bone scintigraphy for detecting bony metastases from breast cancer [15]. Although PET/CT is more sensitive with similar specificity to scintigraphy, PET/CT is not routinely indicated for women with stage I breast cancer that is due to the very low incidence of metastatic disease. According to breast cancer guidelines, such as NCCN, ESMO, SEOM, and the National Institute for Care Excellence (NICE), FDG-PET/CT is not indicated in women with apparently early stage I breast cancer for detection of osseous metastases [16].

### **Bone Scan Whole Body**

A large nonrandomized clinical study in Italy confirmed the lack of value of regular preoperative radiography and radionuclide bone scanning performed on stage I asymptomatic breast cancer patients [11]. Only 1 of 633 patients with stage I disease had metastatic bone disease detected. Several other nonrandomized clinical studies have also documented the low yield and lack of utility of radionuclide bone scanning for patients with stage I breast cancer [17-20]. Also, earlier detection of metastases does not reduce overall mortality [18,21,22]. Several studies have reported false-positive scans when screening for metastases in asymptomatic patients [21]. Therefore, a Tc-99m bone scan whole body is not routinely indicated for asymptomatic women with newly diagnosed stage I breast cancer.

### **Variant 2: Newly diagnosed. Stage I breast cancer. Asymptomatic. Rule out thoracic metastases. Initial imaging.**

National and international guidelines (ASCO, NCCN, ESMO, SEOM, and ESO) discourage the use of staging imaging for asymptomatic patients newly diagnosed with stage 0 to II breast cancer, even if there is nodal involvement [7-10].

### **Radiography Chest**

A conventional chest radiograph is considered the most reasonable approach for detecting unsuspected disease as a baseline for monitoring and for routine follow-up [23].

However, investigators have questioned the use of routine chest radiographs in patients with breast cancer, especially those with stage I disease. One issue is its low yield, reported to be <0.5% in asymptomatic women who had routine chest radiographs after the diagnosis of stage I breast cancer [11,24,25]. In a study of 412 women with newly diagnosed breast cancer, chest radiographs only showed metastases in women previously classified as having stage III disease [12]. Furthermore, false-positive chest radiographs can lead to expensive diagnostic workups. Two large randomized Italian control studies failed to show a significant outcome benefit when routine chest radiography was used to detect metastases earlier [22,26]. Therefore, chest radiographs are not routinely indicated for asymptomatic women with newly diagnosed stage I breast cancer.

### **CT Chest**

A recent retrospective study investigated the value of preoperative chest CT in detecting lung and liver metastases among 1,703 patients with asymptomatic breast cancer (stages I–III) [27]. Abnormal CT findings in the lung or liver were found in 266 patients (15.6%). Only 26 patients (1.5% of all patients and 9.8% of patients with abnormal CT findings) had true metastases, of which only 1 patient with stage I disease had metastasis. They concluded that routine preoperative chest CT was not useful in detecting asymptomatic liver or lung metastasis in patients with early breast cancer. Therefore, chest CT, with or without intravenous (IV) contrast, is not routinely indicated for asymptomatic women with newly diagnosed stage I breast cancer.

### **FDG-PET/CT Whole Body**

According to breast cancer guidelines, such as NCCN, ESMO, SEOM, and NICE, FDG-PET/CT is not indicated in women with apparently early stage I breast cancer [16].

Studies show that the use of advanced imaging modalities, including bone scans, CT, and PET, for staging asymptomatic women with early breast cancer has a low yield to detect occult metastatic disease [6,12]. Therefore, advanced imaging should only be performed in patients with early breast cancer who have focal signs or symptoms that are concerning for metastatic disease [6].

### **Variant 3: Newly diagnosed. Stage I breast cancer. Asymptomatic. Rule out abdominal metastases. Initial imaging.**

National and international guidelines (ASCO, NCCN, ESMO, SEOM, and ESO) discourage the use of staging imaging for asymptomatic patients newly diagnosed with stage 0 to II breast cancer, even if there is nodal involvement [7-10].

Although liver metastases are not as common as lung or bone metastases, the presence of liver metastases is associated with the worst prognosis [28]. Nevertheless, it is rarely indicated to perform imaging to detect abdominal metastases, specifically liver metastases, in patients with stage I breast cancer.

### **CT Abdomen**

A retrospective study investigated the value of preoperative chest CT in detecting lung and liver metastases among 1,703 patients with asymptomatic breast cancer [27]. Abnormal CT findings in the lung or liver were found in 266 patients (15.6%). Only 26 patients (1.5% of all patients and 9.8% of patients with abnormal CT findings) had true metastases, of which only 1 patient with stage I disease had metastasis. The sensitivity, specificity, and positive predictive value of CT were 100%, 97.6%, and 18.4%, respectively, for liver metastasis [27]. Although CT and MRI may show more lesions than ultrasound (US) [29], there is no evidence in the literature that routine imaging of the liver with either CT or MRI has clinical utility in asymptomatic women with stage I breast cancer.

### **MRI Abdomen**

Although CT and MRI may show more lesions than US [29], there is no evidence in the literature that routine imaging of the liver with either CT or MRI has clinical utility in asymptomatic women with stage I breast cancer.

### **US Abdomen**

US can identify liver metastases  $\geq 2$  cm, and it is often used to localize these lesions for biopsy [30,31]. As with screening for bone and lung metastases, the yield of screening with US to detect asymptomatic liver metastases is low. A study showed the yield for detecting metastases using radionuclide scans or US to be  $<0.5\%$  [11]. A review of 4 studies evaluating a total of 423 women with stage I breast cancer found no metastatic lesions on liver US [32]. In a study of 412 women with newly diagnosed breast cancer, liver US showed metastasis in women previously classified as having stage III disease only. Large randomized control studies have failed to show a benefit from screening for liver metastases with US [26]. Therefore, an abdominal US is not routinely indicated for asymptomatic women with newly diagnosed stage I breast cancer.

### **FDG-PET/CT Whole Body**

According to breast cancer guidelines, such as NCCN, ESMO, SEOM, and NICE, FDG-PET/CT is not indicated in women with apparently early stage I breast cancer [16].

Studies show that the use of advanced imaging modalities, including bone scans, CT, and PET, for staging asymptomatic women with early breast cancer has a low yield to detect occult metastatic disease [6,12]. Therefore, advanced imaging should only be performed in patients with early breast cancer who have focal signs or symptoms that are concerning for metastatic disease [6].

### **Variant 4: Newly diagnosed. Stage I breast cancer. Asymptomatic. Rule out brain metastases. Initial imaging.**

National and international guidelines (ASCO, NCCN, ESMO, SEOM, and ESO) discourage the use of staging imaging for asymptomatic patients newly diagnosed with stage 0 to II breast cancer, even if there is nodal involvement [7-10].

Although breast cancer is second only to lung cancer as a cause of intracerebral and orbital metastases, few patients have brain metastases at the time of breast cancer diagnosis, particularly when the tumor is detected at stage I [33,34].

### **CT Head**

One review of patients with breast cancer at all stages concluded that radionuclide brain scanning and head CT failed to identify brain metastases in the absence of neurologic symptoms [35]. A study prospectively explored the incidence of brain metastases during and after adjuvant trastuzumab administration in 258 patients with early stage HER2+ breast cancer [36]. They concluded that brain metastases are rare during adjuvant treatment and that head CT screening is not justified in asymptomatic patients with early HER2+ breast cancer. Therefore, a head CT is not routinely indicated for asymptomatic women with newly diagnosed stage I breast cancer.

### **MRI Head**

Because of its greater sensitivity, MRI has largely replaced CT for detecting and evaluating brain lesions [37]. Gadolinium-enhanced MRI increases the number of suspected brain metastases that can be detected [33]. Contrast-enhanced MRI has also been shown to be superior to double-dose delayed CT for detecting brain metastases [38]. However, no studies suggest any usefulness of routine imaging with any modality for detecting brain metastases in asymptomatic women with breast cancer. Therefore, a brain MRI is not routinely indicated for asymptomatic women with newly diagnosed stage I breast cancer.

### **FDG-PET/CT Whole Body**

According to breast cancer guidelines, such as NCCN, ESMO, SEOM, and NICE, FDG-PET/CT is not indicated in women with apparently early stage I breast cancer [16].

Studies show that the use of advanced imaging modalities, including bone scans, CT, and PET, for staging asymptomatic women with early breast cancer has a low yield to detect occult metastatic disease [6,12]. Therefore, advanced imaging should only be performed in patients with early breast cancer who have focal signs or symptoms that are concerning for metastatic disease [6].

### **Variant 5: Surveillance. Stage I breast cancer. Asymptomatic. Rule out bone, thoracic, abdominal, and brain metastases.**

In asymptomatic patients with a history of stage I breast cancer that received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of bone scan, US, CT, and PET imaging to screen for distant disease recurrence [7-10,39]. However, clinical practices often do not adhere to these guidelines.

Two randomized control trials in asymptomatic breast cancer survivors investigated whether outcomes differed in patients receiving standard care compared with intensive surveillance. One study randomized 1,320 women into a study group that would undergo “intensive surveillance” and a control group having only tests that were ordered as a result of subsequent clinical findings uncovered at routine medical visits [26]. The intensive surveillance included radionuclide bone scan, chest radiography, and liver US. The study, which included 739 node-negative women, found that metastases of all kinds were detected only an average of 1 month earlier in the intensive surveillance group. The earlier detection of these metastases had no significant effect on overall survival. A second large clinical trial in Italy randomized 1,243 women into “intensive” and “clinical” follow-up protocols to determine whether early detection of bone and intrathoracic metastases was effective in reducing mortality in the intensive follow-up group [22]. Fifty-two percent of the women in the latter study were node-negative. Although more bone and lung metastases were found in the intensive follow-up group, there was no significant difference in the overall 5-year survival rates between the 2 groups. In a review by the Cochrane Collaboration of 4 randomized, controlled clinical trials that included 3,055 women, Rojas et al [40] found no difference in overall or disease-free survival rates for women who underwent intensive radiologic and laboratory testing compared with those managed with clinical visits and mammography. They concluded that a regular physical and yearly mammogram is as effective as more intense methods to detect recurrent breast cancer.

However, surveys of patients with breast cancer indicate that most of them prefer an intensive follow-up to detect asymptomatic disease, including metastases [41]. Surveys of physicians indicate that most of them also favor intensive surveillance programs in asymptomatic patients [42]. It is not unreasonable to expect a positive impact on patient management or outcome when imaging examinations are ordered on asymptomatic patients. Multiple studies have shown wide variability in imaging surveillance in asymptomatic women with prior breast cancer.

Using the Surveillance, Epidemiology, and End Results Medicare data, Keating et al [5] studied 44,591 women who were diagnosed with stage I or II breast cancer from 1992 to 1999 and followed through 2001. They found that women receiving care from medical oncologists had substantially higher rates of testing with more bone scans, tumor antigen tests, chest radiographs, and other chest/abdominal imaging than women followed by their primary health provider did. Overall, the rates of testing decreased over time.

Similarly, Grunfeld et al [43] conducted a retrospective study of 11,219 asymptomatic breast cancer survivors that were followed for 5 years. They found substantial variation in adherence to guideline recommendations among oncologists and primary care physicians. Overall, one-quarter of the women had fewer than the recommended surveillance mammograms and half had more than the recommended surveillance for metastatic disease. These imaging examinations included bone scans, chest radiographs, or chest CT scans, and abdomen/pelvic imaging with CT, MRI, or US. Higher comorbidity, having a mastectomy, and seeing a primary care physician plus an oncologist increased the odds of having greater than recommended imaging for metastatic disease.

It is important to underscore the goal of surveillance in early stage breast cancer, which is to detect early locoregional or contralateral recurrence, as early detection of breast cancer recurrence is correlated with improved survival. The goal is not to detect asymptomatic metastatic cancer, as there is no data that early detection of metastases in asymptomatic patients improves clinical outcome [6].

### **Radiography Skeletal Survey**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support the use of a radiographic skeletal survey for surveillance of bone metastases in asymptomatic women with a history of stage I breast cancer.

### **Bone Scan Whole Body**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support the use of Tc-99m bone scan whole body for surveillance of bone metastases in asymptomatic women with a history of stage I breast cancer.

### **Radiography Chest**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support the use of chest radiographs for surveillance of thoracic metastases in asymptomatic women with a history of stage I breast cancer.

### **CT Chest**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support the use of CT chest for surveillance of thoracic metastases in asymptomatic women with a history of stage I breast cancer.

### **CT Abdomen**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support the use of CT abdomen for surveillance of abdominal metastases in asymptomatic women with a history of stage I breast cancer.

### **MRI Abdomen**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support

the use of MRI abdomen for surveillance of abdominal metastases in asymptomatic women with a history of stage I breast cancer.

### **US Abdomen**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support the use of US abdomen for surveillance of abdominal metastases in asymptomatic women with a history of stage I breast cancer.

### **CT Head**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support the use of CT head for surveillance of brain metastases in asymptomatic women with a history of stage I breast cancer.

### **MRI Head**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. There is insufficient evidence to support the use of MRI head for surveillance of brain metastases in asymptomatic women with a history of stage I breast cancer.

### **FDG-PET/CT Whole Body**

In asymptomatic patients with a history of stage I breast cancer who received treatment for curative intent, there is no role for imaging to screen for distant recurrences. ASCO, NCCN, ESMO, and ESO all recommend against the routine use of imaging to screen for distant disease recurrence [7-10]. Therefore, there is no evidence to support the use of FDG-PET/CT whole body for surveillance of bone, thoracic, abdominal, and brain metastases in asymptomatic women with a history of stage I breast cancer.

### **Variant 6: Surveillance. Stage I breast cancer. Asymptomatic. Rule out local recurrence.**

Local recurrence is defined as the return of cancer to the breast, regional lymph nodes, or chest wall after treatment. Most local recurrences occur within the first 5 years after diagnosis [44]. The best predictor of local recurrence is whether the tumor margins contain cancer cells. The likelihood of local recurrence is lower when the tumor margins are negative [45]. The risk of recurrence also depends on the status of the lymph nodes at the time of initial diagnosis. Fortunately, most women are diagnosed with early stage breast cancer, and the likelihood of local recurrence in 5 years for node-negative disease is 6.7% [46]. If the lymph nodes are positive, the chance of local recurrence is 11% [46]. The risk of local recurrence with lumpectomy plus radiation therapy can be lowered with chemotherapy and adjuvant hormonal therapy after surgery [44]. With mastectomy, the best predictor of local recurrence is how far the cancer has spread in the lymph nodes. The chance of local recurrence in 5 years is approximately 6% for women with negative lymph nodes [47]. If 1 to 3 lymph nodes are positive, the chance of local recurrence in 5 years is approximately 16%. Radiation therapy can reduce this risk to approximately 2% [47].

### **Mammography Screening**

The most widely accepted guidelines regarding the surveillance of asymptomatic women with a history of breast cancer come from two national organizations: ASCO and NCCN [8,39]. Both organizations state that routine surveillance with an annual mammogram is the only imaging test that should be performed to detect an in-breast recurrence or a new primary breast cancer, although sensitivity of mammography is decreased due to post-treatment changes from surgery and radiation therapy [48]. Although some centers perform semiannual mammographic ipsilateral surveillance following breast conservation therapy, the preponderance of data shows that it is not indicated if margins were negative [49]. Several observational studies concluded that surveillance mammography detected locoregional recurrence and may reduce breast cancer mortality [50-52].

### **Mammography Diagnostic Bilateral**

Mammography is the imaging study used to follow women with a history of breast cancer. According to one study, patients who have had breast conservation therapy for their initial breast cancer should undergo annual



diagnostic mammograms for the first 3 years after diagnosis as there are often postsurgical and postradiation changes in the breast [6]. After that time, routine screening mammography can be initiated.

### **Digital Breast Tomosynthesis Screening**

Mammography is the imaging study used to follow women with a history of breast cancer. Digital breast tomosynthesis (DBT) addresses some of the limitations encountered with standard 2-D mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that may decrease the lesion-masking effect of overlapping normal tissue and reveals the true nature of potential false positive findings. Interpretation time for DBT images is greater than for standard mammography [53,54]. However, synthesized reconstructed images (a virtual planar image created from the tomographic data set) may replace the need for a 2-D correlative view. Current data suggest that these synthetic images perform as well as standard full-field digital images [55,56].

### **Digital Breast Tomosynthesis Diagnostic**

Mammography is the imaging study used to follow women with a history of breast cancer. DBT can be useful in the diagnostic setting, improving lesion characterization [57-60] in noncalcified lesions when compared with conventional mammographic workup. According to Bychkovsky and Lin [6], patients who have had breast conservation therapy for their initial breast cancer should undergo annual diagnostic mammograms for the first 3 years after diagnosis as there are often evolving postsurgical and postradiation changes in the breast. Therefore, it is reasonable for patients to undergo diagnostic DBT for the first 3 years after breast conservation therapy.

### **MRI Breast**

For most breast cancer survivors, there is insufficient evidence for or against the use of breast MRI to detect disease recurrence. The effectiveness of breast MRI in post-treatment surveillance has not been documented and it is not recommended currently in lieu of mammography [61]. A 2012 review, which included 10 case series (n = 494) found that there was no role for breast MRI to detect disease recurrence [62]. In 2007, the American Cancer Society published its guidelines for breast cancer screening with MRI as an adjunct to mammography [63]. Breast MRI can be used if there is a suspicion of a disease recurrence on examination, and mammography and US are inconclusive. The American Cancer Society guidelines state that in women with a personal history of breast cancer and no other risk factor, there is insufficient evidence to recommend for or against breast MRI [63]. Brennan et al [64] found a cancer yield of 12% (17/144) in women with a personal history of breast cancer using screening MRI.

However, breast cancer survivors are a heterogeneous patient population with variable risk factors that may affect their lifetime risk of developing a second breast malignancy. According to “Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations from the ACR,” MRI surveillance is beneficial for women diagnosed with breast cancer before age 65 and especially before age 50. A multi-institutional study involving 754 women with breast-conserving therapy at age 50 or younger showed that the addition of MRI improves the detection of early stage but biologically aggressive tumors and decreases interval cancers. Women with personal histories of breast cancer and dense breast tissue also benefit from MRI, as this combination of risk factors is likely to indicate a lifetime risk of 20% or higher [65,66]. See the ACR Appropriateness Criteria® topic on “[Breast Cancer Screening](#)” [67].

### **US Breast**

In a study by Berg et al [68] among 1,400 women with a personal history of breast cancer, 28 (2.0%) were found to have breast cancer, with 9 of 28 (32%) seen only on screening US. In this elevated-risk study population, the overall sensitivity of mammography was 50% and the sensitivity of mammography plus US was 77.5%. Although the positive predictive value was only 8% in this study, it may be reasonable to offer supplemental screening US for surveillance of local recurrence in asymptomatic women with a history of stage I breast cancer.

### **Summary of Recommendations**

- **Variante 1:** Imaging is not recommended for the initial imaging of newly diagnosed asymptomatic women with stage I breast cancer to rule out bone metastases.
- **Variante 2:** Imaging is not recommended for the initial imaging of newly diagnosed asymptomatic women with stage I breast cancer to rule out thoracic metastases.
- **Variante 3:** Imaging is not recommended for the initial imaging of newly diagnosed asymptomatic women with stage I breast cancer to rule out abdominal metastases.

- **Variant 4:** Imaging is not recommended for the initial imaging of newly diagnosed asymptomatic women with stage I breast cancer to rule out brain metastases.
- **Variant 5:** Imaging is not recommended for the surveillance of asymptomatic women with stage I breast cancer to rule out bone, thoracic, abdominal, and brain metastases.
- **Variant 6:** Either diagnostic bilateral mammography, diagnostic DBT, screening mammography, or screening DBT is usually appropriate for the surveillance of asymptomatic women with stage I breast cancer to rule out local recurrences. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care).

### 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 rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents go to [www.acr.org/ac](http://www.acr.org/ac).

### Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

### Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document [69].

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
○	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 (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as “Varies.”		

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging 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.