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

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

Variant 1: **Newly diagnosed. Initial workup. Rule out bone metastases.**

Radiologic Procedure	Rating	Comments	RRL*
FDG-PET/CT whole body	2		⊗⊗⊗⊗
Tc-99m bone scan whole body	1		⊗⊗⊗
X-ray skeletal survey	1		⊗⊗⊗
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 2: **Newly diagnosed. Initial workup. Rule out thoracic metastases.**

Radiologic Procedure	Rating	Comments	RRL*
CT chest without IV contrast	2		⊗⊗⊗
CT chest with IV contrast	2		⊗⊗⊗
CT chest without and with IV contrast	2		⊗⊗⊗
FDG-PET/CT whole body	2		⊗⊗⊗⊗
X-ray chest	1		⊗
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 3: **Newly diagnosed. Initial workup. Rule out liver metastases.**

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen without IV contrast	2		⊗⊗⊗
CT abdomen with IV contrast	2		⊗⊗⊗
CT abdomen without and with IV contrast	2		⊗⊗⊗⊗
US abdomen	2		O
MRI abdomen without IV contrast	2		O
MRI abdomen without and with IV contrast	2		O
FDG-PET/CT whole body	2		⊗⊗⊗⊗
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition: Stage I Breast Cancer: Initial Workup and Surveillance for Local Recurrence and Distant Metastases in Asymptomatic Women. Rule Out Metastases

Variant 4: Newly diagnosed. Initial workup. Rule out brain metastases.

Radiologic Procedure	Rating	Comments	RRL*
MRI head without IV contrast	2		O
MRI head without and with IV contrast	2		O
FDG-PET/CT whole body	2		☼☼☼☼
CT head without IV contrast	1		☼☼☼
CT head with IV contrast	1		☼☼☼
CT head without and with IV contrast	1		☼☼☼
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 5: Surveillance. Rule out bone metastases.

Radiologic Procedure	Rating	Comments	RRL*
Tc-99m bone scan whole body	1		☼☼☼
X-ray skeletal survey	1		☼☼☼
FDG-PET/CT whole body	1		☼☼☼☼
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 6: Surveillance. Rule out thoracic metastases.

Radiologic Procedure	Rating	Comments	RRL*
X-ray chest	1		☼
CT chest without IV contrast	1		☼☼☼
CT chest with IV contrast	1		☼☼☼
CT chest without and with IV contrast	1		☼☼☼
FDG-PET/CT whole body	1		☼☼☼☼
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

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

Variant 7: **Surveillance. Rule out liver metastases.**

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen without IV contrast	1		☼☼☼
CT abdomen with IV contrast	1		☼☼☼
CT abdomen without and with IV contrast	1		☼☼☼☼
US abdomen	1		O
MRI abdomen without IV contrast	1		O
MRI abdomen without and with IV contrast	1		O
FDG-PET/CT whole body	1		☼☼☼☼
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Variant 8: **Surveillance. Rule out brain metastases.**

Radiologic Procedure	Rating	Comments	RRL*
MRI head without IV contrast	1		O
MRI head without and with IV contrast	1		O
CT head without IV contrast	1		☼☼☼
CT head with IV contrast	1		☼☼☼
CT head without and with IV contrast	1		☼☼☼
FDG-PET/CT whole body	1		☼☼☼☼
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

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

Variant 9: Surveillance. Rule out local recurrence.

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic bilateral	9	Mammography may be designated as a diagnostic examination in patients with prior breast conserving therapy, even if asymptomatic. Frequency of imaging and duration of diagnostic surveillance may vary by institution, based on local protocol.	☼☼
Digital breast tomosynthesis diagnostic	9	Mammography may be designated as a diagnostic examination in patients with prior breast conserving therapy, even if asymptomatic. Frequency of imaging and duration of diagnostic surveillance may vary by institution, based on local protocol.	☼☼
Mammography screening	8	Patients with prior breast conserving therapy may be returned to routine screening at some point, dependent upon institutional protocol.	☼☼
Digital breast tomosynthesis screening	8	Patients with prior breast conserving therapy may be returned to routine screening at some point, dependent upon institutional protocol.	☼☼
MRI breast without and with IV contrast bilateral	5	In selected patients, depending on risk assessment. May also be used as an adjunct tool in cases of scar versus recurrence. Should be performed in addition to, not as a replacement for, mammography.	O
US breast bilateral	5	As an adjunct screening alternative to MRI, in selected patients, if MRI is contraindicated. Should be performed in addition to, not as a replacement for, mammography.	O
MRI breast without IV contrast bilateral	1		O
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

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

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Summary of Literature Review

Introduction/Background

The incidence of breast cancer has increased with more than 200,000 women diagnosed with invasive carcinoma yearly [1]. Fortunately, breast cancer mortality has decreased due to advances in screening and improved treatment [2]. 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 [3]. 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 [3].

Initial Workup

This appropriateness guideline criteria segment addresses the initial imaging workup of women with stage I breast carcinoma, specifically regarding which imaging tests should be done to rule out unexpected metastatic disease.

Skeletal Metastases

Radionuclide scanning is more effective than conventional radiography for detecting skeletal metastases because radionuclide scans have higher sensitivity and can survey the entire skeleton in one examination [4]. However, several investigations have revealed that bone scanning is not useful in stage I breast carcinoma because of its low yield and lack of proven effect on management or survival.

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 [5]. 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 carcinoma [6-9]. Despite the low yield of bone scans, many clinicians order baseline bone scans for comparison with subsequent scans performed when patients develop symptoms or convert to an abnormal routine scan. In fact, routine baseline bone scans are unlikely to be useful in stage I disease because few patients will convert to positive scans. Also, earlier detection of metastases does not reduce overall mortality [7,10,11]. Furthermore, several studies have reported false-positive scans when screening for metastases in asymptomatic patients [10].

The use of positron emission tomography (PET) combined with computed tomography (CT) in the initial staging of early-stage primary breast cancer is not well defined. It is uncertain whether PET/CT will serve as a replacement for current imaging technologies [12-14].

A retrospective study of 163 women with suspected metastatic breast cancer showed high concordance between PET/CT and bone scan in detecting bony metastases [15]. 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

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in breast cancer in 132 lesions [16]. 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 and prostate cancers [17]. Although PET/CT is more sensitive with similar specificity to scintigraphy, PET/CT is not routinely indicated for women with stage I breast cancer due to the very low incidence of metastatic disease.

Lung Metastases

Methods for detecting lung metastases include conventional chest radiography and CT. Because of its relatively low cost, conventional chest radiography is considered the most reasonable approach for detecting unsuspected disease as a baseline for monitoring and for routine follow-up [18]. No information is available regarding whether PET/CT offers an advantage over current methods for detecting lung metastases.

Despite its relatively low cost, investigators have questioned the use of routine chest radiography in patients with breast cancer, especially those with stage I disease. One problem is its low yield, reported to be <0.5% in asymptomatic women who had routine chest radiographs after the diagnosis of stage I breast carcinoma [5,19,20]. 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 [21]. Furthermore, false-positive chest radiographs can lead to expensive diagnostic workups. Two large Italian randomized control studies failed to show a significant outcome benefit when routine chest radiography was used to detect metastases earlier [11,22].

A recent retrospective study investigated the value of preoperative chest CT in detecting lung and liver metastases among 1,703 patients [23]. 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. Only one patient with stage I disease had a true metastasis. They concluded that routine preoperative chest CT was not useful in detecting asymptomatic liver and lung metastasis in patients with early breast cancer.

Liver Metastases

It is rarely indicated to perform imaging to detect hepatic metastases in patients with stage I disease. Although liver metastases are not as common as lung or bone metastases, the appearance of liver metastases is associated with the worst prognosis [24]. Ultrasound (US) can identify liver metastases ≥ 2 cm, and it is often used to localize these lesions for biopsy [25,26]. No information is available regarding whether PET/CT offers an advantage over current methods for detecting liver metastases.

As with screening for bone and lung metastases, the yield of screening with radionuclide scans or 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% [5]. A review of 4 studies evaluating a total of 423 women with stage I breast carcinoma found on liver US that no women had metastatic lesions [27]. In a study of 412 women with newly diagnosed breast cancer, liver US only showed metastasis in women previously classified as having stage III disease. Large randomized control studies have failed to show a benefit from screening for liver metastases with US [11,22].

In the retrospective study described above, the sensitivity, specificity, and positive predictive value of CT were 100%, 97.6%, and 18.4%, respectively, for liver metastasis [23]. Although CT and MRI may show more lesions than radionuclide scanning or US [28], there is no evidence in the literature that routine imaging of the liver with either of the more sensitive modalities has clinical utility in asymptomatic patients with breast carcinoma.

Brain Metastases

Breast cancer is second only to lung carcinoma as a cause of intracerebral and orbital metastases, but few patients have brain metastases at the time of breast cancer diagnosis, particularly when the tumor is detected at stage I [29,30]. One review of patients with breast cancer at all stages concluded that radionuclide brain scanning and CT failed to identify brain metastases in the absence of neurologic symptoms [31]. A recent study prospectively explored the incidence of brain metastases during and after adjuvant trastuzumab administration in 258 patients with early-stage HER2+ breast carcinoma [32]. They concluded that brain metastases are rare during adjuvant treatment and that brain CT screening is not justified in asymptomatic patients with early HER2+ breast carcinoma.

Because of its greater sensitivity, MRI has largely replaced CT for detecting and evaluating brain lesions [33]. Gadolinium-enhanced MRI increases the number of suspected cerebral metastases that can be detected [29].

Contrast-enhanced MRI has also been shown to be superior to double-dose delayed CT for detecting brain metastases [34]. However, no studies suggest any usefulness of routine imaging with any modality for detecting cerebral metastases in asymptomatic women with breast cancer.

Surveillance

The most widely accepted guidelines regarding the surveillance of asymptomatic women with a history of breast cancer are from 2 national organizations: the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) [35,36]. 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. Several observational studies concluded that surveillance mammography detected locoregional recurrence and may reduce breast cancer mortality [37-39].

Local Recurrence

Local recurrence is defined as the return of cancer to the breast, lymph nodes, or chest wall after treatment. Most local recurrences occur within the first 5 years after diagnosis [40]. 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 [41]. The risk of recurrence also depends on the status of the lymph nodes. 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% [42]. If the lymph nodes are positive, the chance is 11% [42]. The risk of local recurrence with lumpectomy plus radiation therapy can be lowered with chemotherapy and adjuvant hormonal therapy after surgery [40].

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 about 6% for women with negative lymph nodes [43]. If 1 to 3 lymph nodes are positive, the chance of local recurrence in 5 years is about 16%. Radiation therapy can reduce this risk to about 2% [43].

Mammography is the imaging study used to follow women with a history of breast cancer. The role of breast MRI in screening women with a history of breast cancer is still being investigated. In 2007 the American Cancer Society published its guidelines for breast cancer screening with MRI as an adjunct to mammography [44]. These 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 [44]. Brennan et al [45] found a cancer yield of (17/144) 12% in women with a personal history of breast cancer using screening MRI. High-risk women with prior lumpectomy and a very strong family history may be considered for MRI screening. See the ACR Appropriateness Criteria[®] on "[Breast Cancer Screening](#)" [46].

Digital breast tomosynthesis (DBT) addresses some of the limitations encountered with standard 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 reveal the true nature of potential false positive findings. DBT can be useful in the diagnostic setting, improving lesion characterization [47-50] in noncalcified lesions, when compared to conventional mammographic workup. Interpretation time for DBT images is greater than for standard mammography [51,52]. Additionally, dose is increased if standard 2-D images are obtained in addition to DBT images. However, synthesized reconstructed images (a virtual planar image created from the tomographic data set) may replace the need for a 2-D correlative view; and current data suggests that these synthetic images perform as well as standard full-field digital images [53,54].

Distant Recurrence (Metastasis)

Metastasis is the main cause of breast cancer death. The risk of distant recurrence is the same for women who undergo lumpectomy and radiation therapy or women who have a mastectomy [41]. The most common sites for distant metastases from breast carcinoma are the skeleton, lung, liver, and brain [24,55]. Surveys of patients with breast cancer indicate that most of them prefer an intensive follow-up to detect asymptomatic disease, including metastases [56]. Surveys of physicians indicate that most of them also favor intensive surveillance programs in asymptomatic patients [57]. However, because of cost constraints there should be a reasonable expected effect on patient management and outcome when imaging examinations are ordered on asymptomatic patients. In a review by the Cochrane Collaboration of 4 randomized, controlled clinical trials that included 3,055 women, Rojas et al [58] 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 of examination in detecting recurrent breast cancer.

Two multicenter randomized prospective clinical trials were performed in Italy in the 1980s in asymptomatic breast cancer survivors. 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 [22]. The intensive surveillance included radionuclide bone scanning, 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 [11]. 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.

As discussed above, national guidelines advise against routine surveillance testing (at regular predefined intervals), including routine blood tests, blood tests for tumor markers, chest radiographs, bone scans, liver US, abdominal CT scans, and PET/CT scans. However, clinical practices often do not adhere to these guidelines. Using the Surveillance, Epidemiology, and End Results (SEER) Medicare data, Keating et al [3] studied 44,591 women who were diagnosed with stage I/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. Overall, the rates of testing decreased over time. Rates of tumor antigen testing and chest radiographs decreased faster than chest/abdominal imaging.

Panageas et al [59] recently evaluated the use of high technology radiologic imaging (HTRI) for surveillance after curative treatment for early-stage breast cancer. Using the SEER-Medicare data, they identified 25,555 women who were diagnosed with stage I/II breast cancer between 1998 and 2003 who survived more than 48 months. Over time, the use of CT, bone scans, breast MRI, and PET increased from 34% of women diagnosed in 1998 to 43% in women diagnosed in 2003. Forty percent of their cohort had at least one advanced imaging examination, and 30% had CT scans. Factors associated with HTRI use were women age <80, higher comorbidity index, stage II disease, and more recent diagnosis. Crivello et al [60] found similar results when they reviewed the preoperative use of advanced imaging modalities in early-stage breast cancer. Using the SEER Medicare data from 1992–2005, the authors identified 67,874 stage I/II breast cancer patients. Approximately 19% (n=12,740) had preoperative advanced imaging. The proportion of patients having CT scans, PET scans, and brain MRI scans increased from 5.7% to 12.4% ($P<.0001$), 0.8% to 3.4% ($P<.0001$), and 0.2% to 1.1% ($P=.008$), respectively, from 1992 to 2005. Bone scans declined from 20.1% to 10.7% ($P<.0001$). They concluded that greater adherence to current guidelines is warranted.

Similarly, Grunfeld et al [61] 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 (PCPs). 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 US, CT, or MRI. Higher comorbidity, having a mastectomy, and seeing a PCP plus an oncologist increased the odds of having greater than recommended imaging for metastatic disease.

Han et al [62] found similar results with overuse of blood tests and imaging tests. Of 1,098 PCPs and oncologists, 84% of PCPs and 72% of oncologists reported beliefs consistent with blood test overuse, whereas 50% of PCPs and 27% of oncologists had beliefs consistent with imaging test overuse. In this study, more PCPs ordered additional tests, and these results conflict with Keating et al. The variable findings suggest that both groups of physicians often don't adhere to national guidelines. In 2009, a national survey of 2,002 PCPs and oncologists, the Survey of Physician Attitudes Regarding the Care of Cancer Survivors, evaluated their practices for the follow-up care of breast cancer survivors. They concluded that both physician groups recommended unnecessary tumor marker and imaging studies in response to a hypothetical vignette of a 4-year asymptomatic breast cancer survivor [63]. Over half of PCPs and 31% of oncologists recommended tumor markers; 42% of PCPs and 22% of

oncologists recommended chest radiographs; and 23% of PCPs and 3% of oncologists recommended bone scans. Although 85% of oncologists were “very confident” about appropriate tests for detecting recurrent disease, only 40% of PCPs expressed this level of confidence ($P<.001$). They concluded that PCPs require more education to enhance their knowledge and confidence about follow-up care. Also, efforts should be directed at both groups of physicians to reduce routine use of nonguideline surveillance testing [63].

Quality-of-Life Issues

Imaging tests to detect an occult metastasis in a breast cancer survivor may be beneficial, for example, by allowing patients to avoid unnecessary surgery or potentially allowing for less aggressive treatment that could impact quality of life [59]. However, the lack of adherence to guidelines for imaging tests to detect recurrent breast cancer is associated with higher medical costs and additional radiation risks. Studies estimate that intensive surveillance testing adds an additional \$260 million to \$630 million to the annual cost of breast cancer survivors without demonstrated benefit compared with a strategy that follows national guidelines [64,65].

In addition, the radiation risk from imaging studies, especially CT and PET/CT, raises the concern of a new or different cancer developing as a result of these studies. Berrington de Gonzalez et al [66] estimated future cancer risks from CT scan use in the United States using risk models. They determined that approximately 29,000 future cancers could be the result of the 72 million CT scans performed in the United States in 2007, predominantly from CT scans of the abdomen and pelvis. Brenner and Hall [67] suggested that 1.5% to 2% of cancers in the United States might be attributable to CT scans. In response to these concerns, new imaging protocols with low-dose CT scans are being incorporated into routine imaging.

A large randomized controlled study in Italy investigated quality-of-life issues related to surveillance for metastatic disease in patients with breast cancer [22]. The results suggested that type of follow-up (eg, intensive surveillance versus routine clinical management) does not affect various dimensions of health-related quality of life. These dimensions include overall health and quality-of-life perception, emotional well-being, body image, social functioning, symptoms, and satisfaction with care. No differences in any quality-of-life issues were statistically significant between the 2 groups with different surveillance protocols. Nonetheless, more than 70% of the asymptomatic subjects said they wanted to be seen frequently by a physician and undergo diagnostic tests. This preference for intensive surveillance was not affected by whether the patient had been assigned to the intensive or minimalist follow-up regimen.

Occasionally, the additional imaging studies will generate false-positive examinations. These findings may lead to follow-up imaging studies, biopsies, and possibly surgery. Hillman and Goldsmith [68] concluded that we have sold our patients on the promise of advanced imaging and neglected to educate them about the detrimental effects of excess exposure to radiation, additional testing brought about by chasing false-positive results, or the anxiety related to these studies. Ordering advanced imaging studies may provide patients with short-term reassurance but seldom allays long-term fears of recurrence that are ubiquitous in cancer survivors [59].

Summary of Recommendations

- Given the lack of difference in survival or quality of life, there is little justification for imaging to detect or rule out metastasis in asymptomatic women with newly diagnosed stage I breast cancer.
- Women and health care professionals generally prefer intensive follow-up after a diagnosis of breast cancer. Women with other risk factors that increase their lifetime risk for breast cancer may warrant evaluation with breast MRI. However, quality of life is similar for women who undergo intensive surveillance compared with those who do not.
- ASCO and NCCN guidelines state that annual mammography is the only imaging examination that should be performed to detect a localized breast recurrence in asymptomatic patients; more imaging may be needed if the patient has locoregional symptoms (eg, palpable abnormality).
- There are no survival differences between women who obtain intensive screening and surveillance with imaging and laboratory studies compared with women who only undergo testing due to the development of symptoms or findings on clinical examinations.

Summary of Evidence

Of the 68 references cited in the ACR Appropriateness Criteria® *Stage I Breast Cancer: Initial Workup and Surveillance for Local Recurrence and Distant Metastases in Asymptomatic Women* document, 63 references are

categorized as diagnostic references including 3 well designed studies, 6 good quality studies, and 15 quality studies that may have design limitations. There are 42 references that may not be useful as primary evidence. There are 2 references that are meta-analysis studies.

The 68 references cited in the ACR Appropriateness Criteria® *Stage I Breast Cancer: Initial Workup and Surveillance for Local Recurrence and Distant Metastases in Asymptomatic Women* document were published from 1978-2014.

While there are references that report on studies with design limitations, 9 well designed or good quality studies provide good evidence.

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, both because of 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 to 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 (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as “Varies”.

Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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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.