Use of gamma detection following radiopharmaceutical administration may be considered medically necessary for localization of sentinel lymph nodes in patients with breast cancer.

Scintimammography, breast-specific gamma imaging (BSGI), and molecular breast imaging (MBI) are considered investigational in all applications, including but not limited to their use as an adjunct to mammography or in staging the axillary lymph nodes.

The most commonly used radiopharmaceutical in breast-specific gamma imaging or molecular breast imaging is technetium 99m (Tc 99m) sestamibi. The following HCPCS code is specific for this radiopharmaceutical:

- **A9500**: Technetium Tc-99m sestamibi, diagnostic, per study dose

The 2013 Breast Imaging Reporting and Data System (BI-RADS) breast assessment and breast tissue categories are in Table PG1.

**Table PG1. 2013 BI-RADS Breast Assessment and Breast Tissue Categories**

<table>
<thead>
<tr>
<th>Grading Schema</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incomplete</td>
</tr>
<tr>
<td>1</td>
<td>Negative</td>
</tr>
<tr>
<td>2</td>
<td>Benign</td>
</tr>
<tr>
<td>3</td>
<td>Probably benign</td>
</tr>
<tr>
<td>4</td>
<td>Suspicious</td>
</tr>
<tr>
<td>5</td>
<td>Highly suggestive of malignancy</td>
</tr>
<tr>
<td>6</td>
<td>Known biopsy-proven malignancy</td>
</tr>
</tbody>
</table>

**Breast tissue categories**

- a: Breasts are almost entirely fatty
- b: Scattered areas of fibroglandular density
- c: Heterogeneously dense
- d: Extremely dense

BI-RADS: Breast Imaging Reporting and Data System.

The most commonly used radiopharmaceuticals for sentinel lymph node detection using either lymphoscintigraphy or hand-held gamma detection include Tc 99m-labeled colloids (e.g., sulfur colloid).

The HCPCS code for this particular radiopharmaceutical is:

- **A9541**: Technetium Tc-99m sulfur colloid, diagnostic, per study dose, up to 20 millicuries

Among the other possible radiopharmaceuticals is Lymphoseek®, which is reported with the following HCPCS code:

- **A9520**: Technetium Tc-99m tilmanocept, diagnostic, up to 0.5 millicuries

The following HCPCS code is specific to scintimammography:

- **S8080**: Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical
Description

Scintimammography, breast-specific gamma imaging (BSGI), and molecular breast imaging (MBI) use radiotracers with nuclear medicine imaging as a diagnostic tool for abnormalities of the breast. These tests are distinguished by the use of differing gamma camera technology, which may improve diagnostic performance for detecting small lesions with BSGI or MBI. BSGI uses single-head breast-specific gamma camera and a compression device; whereas, MBI uses dual-head breast-specific gamma cameras that also produce breast compression. Preoperative lymphoscintigraphy and/or intraoperative hand-held gamma detection of sentinel lymph nodes is a method of identifying sentinel lymph nodes for biopsy after radiotracer injection. Surgical removal of one or more sentinel lymph nodes is an alternative to full axillary lymph node dissection for staging evaluation and management of breast cancer.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Several scintillation (gamma) cameras have been cleared for marketing by the FDA through the 510(k) process for “measuring and imaging the distribution of radionuclides in the human body by means of photon detection.” Examples of gamma cameras used in BSGI are the Dilon 6800® (Dilon Technologies, Newport News, VA) and single-head configurations of Discovery NM750b (GE Healthcare, Milwaukee, WI). Dual-head cameras used in MBI include LumaGEM™ (Gamma Medical, Salem, NH) (FDA product code IYX) and Discovery NM750b (GE Healthcare, Milwaukee, WI).

Tc-99m sestamibi (marketed by Draxis Specialty Pharmaceuticals, Cardinal Health 14, Mallinckrodt, and Pharmalucence) has been approved by the FDA with the following labeling: “Breast Imaging: Technetium TC 99M Sestamibi is indicated for planar imaging as a second-line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass. Technetium TC 99M Sestamibi is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy.”

In March 2013, Tc 99m tilmanocept (Lymphoseek; Navidea Biopharmaceuticals) was first approved by the FDA for use in breast cancer and melanoma as a radioactive diagnostic imaging agent to help localize lymph nodes.

Technetium-99m-sulfur colloid has been approved by the FDA through the new drug application (GE Healthcare, NDA 017456; Mallinckrodt, NDA 017724) process although these products appear to be marketed no longer. In addition, in 2011, Technetium Tc 99m Sulfur Colloid Kit
Pharmaceluce was approved by the FDA through the NDA process (NDA 017858) for use as an injection to localize lymph nodes in breast cancer patients.

**Rationale**

**Background**

**Mammography**

Mammography is the main screening modality for breast cancer, despite its limitations in terms of less than ideal sensitivity and specificity. Limitations of mammography are a particular issue for women at high risk of breast cancer, for whom cancer risk exceeds the inconvenience of more frequent screening, starting at a younger age, with more frequent false-positive results. Furthermore, the sensitivity of mammography is lower in women with radiographically dense breasts, which is more common among younger women. The clinical utility of adjunctive screening tests is primarily in the evaluation of women with inconclusive results on mammography. A biopsy is generally performed on a breast lesion if imaging cannot rule out malignancy with certainty. Therefore, adjunctive tests will be most useful in women with inconclusive mammograms if they have a high negative predictive value (NPV) and can preclude the need for biopsy. Additional imaging for asymptomatic women who have dense breasts and negative mammograms has been suggested, but the best approach is subject to debate (see the 2013 Blue Cross Blue Shield Association Technology Evaluation Center [TEC] Special Report).

**Scintimammography**

Scintimammography is a diagnostic modality using radiopharmaceuticals to detect breast tumors. After intravenous injection of a radiopharmaceutical, the breast is evaluated using planar imaging. Scintimammography is performed with the patient lying prone, and the camera positioned laterally, which increases the distance between the breast and the camera. Special camera positioning to include the axilla may be included when the area of interest is an evaluation for axillary metastases. Scintimammography using conventional imaging modalities has relatively poor sensitivity in detecting smaller lesions (e.g., <15 mm), because of the relatively poor resolution of conventional gamma cameras in imaging the breast.

**Breast-Specific Gamma Imaging**

Breast-specific gamma imaging (BSGI) and molecular breast imaging (MBI) were developed to address the poor resolution of conventional gamma cameras. Breast-specific gamma cameras acquire images while the patient is seated in a position similar to that in mammography and the breast is lightly compressed. Detector heads are immediately next to the breast, increasing resolution, and images can be compared with mammographic images. BSGI and MBI differ primarily in the number and type of detectors used (e.g., multicrystal arrays of cesium iodide or sodium iodide, or nonscintillating, semiconductor materials, such as cadmium zinc telluride). In some configurations, a detector is placed on each side of the breast and used to compress it lightly. The maximum distance between the detector and the breast is therefore from the surface to the midpoint of the breast. The radiotracer typically used is technetium 99m (Tc 99m) sestamibi, and MBI takes approximately 40 minutes.

**Lymphoscintigraphy and Hand-Held Gamma Detection**

Preoperative lymphoscintigraphy and/or intraoperative hand-held gamma detection of sentinel lymph nodes is a method of identifying sentinel lymph nodes for biopsy after radiotracer injection. Surgical removal of one or more sentinel lymph nodes is an alternative to full axillary lymph node dissection for staging evaluation and management of breast cancer. Several trials have compared outcomes following sentinel lymph node biopsy with axillary lymph node dissection for managing patients who have breast cancer. The National Surgical Adjuvant Breast and Bowel Project (NSABP) trial B-32 examined whether sentinel lymph node dissection (SLND) provides similar survival and regional control as full axillary lymph node dissection in the surgical staging and management of patients with clinically invasive breast cancer. This multicenter randomized controlled trial included 5611 women and observed statistically similar results for...
overall survival, disease-free survival, and regional control based on 8-year Kaplan-Meier estimates. Moreover, additional 3-year follow-up of morbidity after surgical node dissection revealed lower morbidity in the SLND group, including lower rates of arm swelling, numbness, tingling, and fewer early shoulder abduction deficits. A recent systematic review and meta-analysis by Ram et al (2014) reported no significant difference in overall survival (hazard ratio [HR], 0.94; 95% confidence interval [CI], 0.79 to 1.19), no significant difference in disease-free survival (HR=0.83; 95% CI, 0.60 to 1.14), and similar rates of locoregional recurrence. However, axillary node dissection was associated with significantly greater surgical morbidity (e.g., wound infection, arm swelling, motor neuropathy, numbness) than sentinel node biopsy.

**Radiopharmaceuticals**

Scintimammography, BSGI, and MBI
The primary radiopharmaceutical used with BSGI or MBI is Tc 99m sestamibi. The product label states that Tc 99m sestamibi is “indicated for planar imaging as a second-line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass. Technetium Tc-99m sestamibi is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy.” Technetium TC-99m tetrofosmin (Myoview™), a gamma-emitter used in some BSGI studies, is approved by the Food and Drug Administration (FDA) only for cardiac imaging.

**Pre- or Intraoperative Lymphoscintigraphy and/or Hand-Held Gamma Detection of Sentinel Lymph Nodes**
The primary radiopharmaceuticals used for lymphoscintigraphy include Tc 99m pertechnetate-labeled colloids and Tc 99m tilmanocept (Lymphoseek). Whereas, Tc 99m sulfur colloid may frequently be used for intraoperative injection and detection of sentinel lymph nodes using hand-held gamma detection probe.

**Radiation Exposure**
Scintimammography, BSGI, and MBI
The radiation dose associated with BSGI is substantial for diagnostic breast imaging modalities. According to Appropriateness Criteria from American College of Radiology (ACR), the radiation dose from BSGI is 10 to 30 mSv, which is 15 to 30 times higher than the dose from a digital mammogram. According to ACR, at these levels, BSGI is not indicated for breast cancer screening.

According to a 2015 study by Hruska and O’Connor (who reported receiving royalties from licensed technologies by an agreement with Mayo Clinic and Gamma Medica), the effective dose from a lower “off-label” administered dose of 240 to 300 MBq (6.5-8 mCi) of Tc 99m sestamibi that is made feasible with newer dual-head MBI systems, is 2.0 to 2.5 mSv. For comparison, the effective dose (i.e., mean glandular dose) of digital mammography is estimated to be about 0.5 mSv. However, it is important to note that the dose for MBI is given to the entire body. The authors compared this dose with the estimated annual background radiation, which varies worldwide between 2.5 mSv and 10 mSv, and asserted that the effective dose from MBI “is considered safe for use in routine screening.”

A 2010 article calculated mean glandular doses, and from those, lifetime attributable risks (LARs) of cancer, due to film mammography, digital mammography, BSGI, and positron emission mammography (PEM). The author of this study, a consultant to GE Healthcare and a member of the medical advisory boards of Koning (manufacturer of dedicated breast computed tomography [CT]) and Bracco (magnetic resonance contrast agents), used group risk estimates from the Biological Effects of Ionizing Radiation VII report to assess the risk of radiation-induced cancer and mortality from breast imaging studies. For a patient with average-sized breasts (compressed thickness during mammography of 5.3 cm per breast), estimated LARs of cancer at age 40 were:
5 per 100,000 for digital mammography (breast cancer only),
7 per 100,000 for screen film mammography (breast cancer only),
55 to 82 per 100,000 for BSGI (depending on the dose of Tc 99m sestamibi), and
75 for 100,000 for PEM.

Corresponding LARs of cancer mortality at age 40 were:
1.3 per 100,000 for digital mammography (breast cancer only),
1.7 per 100,000 for screen film mammography (breast cancer only),
26 to 39 per 100,000 for BSGI, and
31 for 100,000 for PEM.

A major difference in the impact of radiation between mammography, on the one hand, and
BSGI or PEM, on the other, is that, for mammography, the substantial radiation dose is limited to
the breast. With BSGI and PEM, all organs are irradiated, increasing the risks associated with BSGI
and PEM.

Notes: The term molecular breast imaging is used in different ways, sometimes for any type of
breast imaging involving molecular imaging, including PEM, and sometimes it is used
synonymously with the term breast-specific gamma camera, as used in this review.

Use of single-photon emission computed tomography and positron emission tomography of the
breast are not addressed in this review.

Literature Review
This topic has been informed by a 2013 TEC Assessment. However, lymphoscintigraphy and
radioactive localization for sentinel lymph node biopsy were not discussed in that TEC
Assessment. The scope of this evidence review was expanded to include lymphoscintigraphy
and radioactive localization for sentinel lymph node biopsy (SLNB).

A few studies have reported on the change in patient management after imaging, but there
were insufficient data to determine whether these changes led to improvement in health
outcomes. A subsequent 2013 TEC Special Report reviewed evidence for asymptomatic women
undergoing breast cancer screening, including those with dense breasts or at high risk of breast
cancer. Retrospective studies included women with a mix of indications. For all indications,
evidence was insufficient.

Scintimammography, Breast-Specific Gamma Imaging, and Molecular Breast Imaging
Dense Breasts or High Risk for Breast Cancer
Several studies have assessed breast-specific gamma imaging (BSGI; using either BSGI or
molecular breast imaging [MBI]) in women at high risk for breast cancer. Rhodes et al (2011)
prospectively compared MBI (with dual-head cadmium zinc telluride detectors),
mammography, and a combination of the 2 modalities in 936 asymptomatic women with
heterogeneously or extremely dense breasts on a prior mammogram, as well as additional risk
factors (BRCA variants, a personal history of breast cancer). The risk in these different
populations varies substantially. Eleven (1.2%) of 936 women were diagnosed with cancer.
Overall sensitivity was 82% (95% confidence interval [CI], 52% to 95%) for MBI, 27% (95% CI, 10% to
57%) for mammography, and 91% (95% CI, 62% to 98%) for both combined. Specificity was 93%
(95% CI, 1% to 94%) for MBI, 91% (95% CI, 89% to 93%) for mammography, and 85% (95% CI, 83% to
87%) for both (sensitivity and specificity for MBI vs mammography, both p = 0.07). The number of breast cancers diagnosed per number of biopsies performed was 28% for MBI and 18% for
mammography.

In 2015, Rhodes et al reported on a similar prospective study that evaluated MBI using a lower
dose of technetium Tc 99m (Tc 99m) sestamibi (dispensed activity, 300 MBq [≈2.4 mSv] vs 740
MBq in conventional doses). Like the earlier study by this research group, study participants
were asymptomatic and had heterogeneously or extremely dense breasts. More than half (57%)
had an additional risk factor for breast cancer, conferring varying degrees of risk (e.g., 10% had a personal history of breast cancer) and 22% (without personal history of breast cancer) had elevated Gail model risk. Of 1651 eligible women, 1585 (96%) underwent both mammography and MBI. Images were interpreted by radiologists blinded to results of the other test using a standardized lexicon, and reference standards included follow-up of both positive and negative test results for 11 months minimum. Twenty-one (1.3%) of 1583 women were diagnosed with cancer. For detection of all cancers (invasive cancers plus ductal carcinoma in situ [DCIS]), sensitivity was 24% (95% CI, 11% to 45%) for mammography and 91% (95% CI, 71% to 97%) for mammography plus MBI (p < 0.001); specificity was 89% (95% CI, 88% to 91%) and 83% (95% CI, 81% to 85%) p < 0.001; positive predictive value (PPV) was 3% (95% CI, 1% to 7%) and 7% (95% CI, 4% to 10%) p = 0.021; and negative predictive value (NPV) was 99% (95% CI, 98% to 99%) and 100% (95% CI, 99% to 100%) p < 0.001, all respectively. The addition of MBI increased the recall rate from 11% with mammography alone to 18% (p < 0.001), and the biopsy rate from 1% to 4% (p < 0.001).

Several studies have evaluated the diagnostic accuracy of BSGI in patients with dense breasts or high risk for breast cancer who had normal mammographic findings. Brem et al (2005) prospectively evaluated 94 women with BSGI who considered at high risk of breast cancer despite normal mammographic findings. High risk was defined as a 5-year breast cancer risk of 1.66%, as determined by the Gail model. Of 94 women in the study, 35 (37%) had a history of some type of breast cancer or atypical hyperplasia. Sixteen (17%) women had abnormal BSGI findings. Follow-up ultrasounds in 11 of them identified a hypoechoic lesion that was biopsied. The 5 remaining patients had normal ultrasound results and were followed with repeat BSGI at 6 months, which was normal in all 5. Among the 11 women who underwent ultrasound-guided biopsy, 2 (12%) invasive cancers were identified. The sensitivity of BSGI was 100% (95% CI, 22% to 100%) and the specificity was 85%. The study was limited by the small number of cancers detected.

Two retrospective studies were published in 2016. Shermis et al reported on women with dense breasts and negative mammograms. The study sample was taken from a population of asymptomatic women who presented for routine breast cancer screening with mammography; a subset of these women were referred for supplemental screening. Women with Breast Imaging Reporting and Data System (BI-RADS) category 1 or 2 findings on mammography (i.e., negative or benign) who had a BI-RADS density category C or D (i.e., heterogeneously or extremely dense) and whose lifetime risk was fewer than 20% according to the Gail model were recommended for supplemental MBI screening. (Women with similar characteristics but a 20% or greater lifetime risk of breast cancer were recommended for magnetic resonance imaging [MRI] screening.) The MBI protocol was similar to that used in the Rhodes clinic studies (i.e., use of 300 MBq of Tc 99m sestamibi). Of 1696 women who received supplemental MBI, 143 (8.4%) had a positive finding, and 13 (9%) of these 143 women were confirmed histopathologically as malignancies. Two of the malignancies were DCIS, and 11 were invasive malignancies. Thus, the incremental cancer detection rate with MBI was 0.77% (13/1696) and an invasive cancer rate of 0.65% (11/1696). The recall rate was 8.4% (143/1696). As the authors noted, follow-up was not conducted on all 1696 women so the sensitivity and specificity of MBI in this study population could not be determined.

Also in 2016, Brem et al retrospectively reviewed findings of BSGI in 849 women at increased risk of breast cancer (e.g., BRCA1, BRCA2, family history of breast cancer) whose mammogram findings were classified as negative, benign, or probably benign (BI-RADS categories 1, 2, or 3). BSGI examinations were performed with a single-head high-resolution breast-specific gamma camera, initially at a mean of 781 MBq Tc 99m sestamibi (n = 653) but the protocol was then modified to a mean of 296 MBq (n = 196). A total of 212 (25%) of 849 women had a positive BSGI examination (recall rate). Fourteen (6.6%) of the 212 women who tested positive were found to have breast cancer. Eight of the 14 cancers were DCIS. The incremental cancer detection rate with BSGI was 1.6% (14/849), and the invasive cancer rate was 0.7% (6/849).
Although the use of BSGI (or MBI) has been proposed for women at high risk of breast cancer, there is controversy and speculation over whether some women (e.g., those with BRCA variants) have a heightened radiosensitivity.\cite{22, 23} If women with BRCA variants are more radiosensitive than the general population, studies may underestimate the risks of breast imaging with ionizing radiation (i.e., mammography, BSGI, MBI, positron emission mammography, single-photon emission computed tomography/computed tomography, breast-specific computed tomography, and tomosynthesis) in these women. In contrast, ultrasonography and MRI do not use radiation. More research is needed to resolve this issue. Also, the risk associated with radiation exposure will be greater for women at high risk of breast cancer, whether or not they are more radiosensitive because they start screening at a younger age when the risks associated with radiation exposure are greater.

**Section Summary: Dense Breasts or High Risk for Breast Cancer**

Three prospective studies have compared the incremental difference in diagnostic accuracy when BSGI or MBI is added to mammography in women at increased risk, and both MBI studies were by the same research group. Sensitivity was higher with combined BSGI (or MBI) and mammography, but specificity was lower. Studies of women at increased risk of breast cancer and negative mammograms found that a small number of additional cancers were detected, but the recall rate was relatively high. Studies tended to include women at different risk levels (e.g., women with dense breasts and those with BRCA1). Moreover, any potential benefits need to be weighed against potential risks of additional radiation exposure and risks to breast biopsy for false-negative findings. Even in studies that used a reduced dose of Tc 99m sestamibi, the effective dose (2.4 mSv) exceeded that of digital mammography (≈0.5 mSv) by a factor of 4.8. In addition, a large, high-quality, head-to-head comparison of BSGI (or MBI) and MRI would be needed, especially for women at high risk of breast cancer, because MRI, alternated with mammography, is currently the recommended screening technique.

**Indeterminate or Suspicious Breast Lesions**

Several studies have addressed BSGI in women who have indeterminate or suspicious lesions. Spanu et al (2012) assessed the clinical impact of BSGI (using Tc 99m tetrofosmin) in a prospective study of 467 women who had suspicious lesions on physical examination, MRI, ultrasound, or mammogram.\cite{24} Histopathology reports were obtained in all cases. BSGI results were true-positives in 408 of 420 breast cancer patients (sensitivity, 97%), including the detection of multifocal, multicentric disease and bilateral disease, and were false-negatives in 12 breast cancer patients. BSGI results were true-negatives in 40 of 47 patients with benign lesions (specificity, 85%). The authors calculated that BSGI provided additional value compared with mammography in 141 (30%) of 467 patients, 108 with breast cancer and 33 with benign lesions.

In a 2008 study by Hruska et al, 150 patients with BI-RADS classification 4 or 5 lesions smaller than 2 cm identified on mammography or ultrasound who were scheduled for biopsy underwent MBI using a dual-head, breast-specific gamma camera.\cite{25} Results from 3 blinded readers were averaged. In 88 patients, 128 cancer tumors were found. The per-lesion sensitivity with the dual-head camera was 90% (115/128) for all lesions and 82% (50/61) for lesions 1 cm or smaller. Overall, MBI specificity (across patients) was 69%. The proportion of patients with cancer in this study was higher than might be expected in a screening population with suspicious lesions on mammography. In selecting patients, preference was given to those who had a high suspicion of cancer or were likely to have multifocal or multicentric disease.

Spanu et al (2008) evaluated 145 consecutive patients scheduled for breast biopsy with MBI (using Tc 99m tetrofosmin).\cite{26} With an 86% prevalence of disease, sensitivity of MBI was 98% per patient (100% for tumors >10 mm, 91% for tumors ≤10 mm). Per-lesion specificity was 86%. Four cancers were missed, three of which were detected by mammography. The authors suggested using MBI for surgical planning or avoiding biopsy, but the NPV (83%) was not high enough to forgo biopsy.
Brem et al (2007) compared BSGI with MRI in 23 women who had 33 indeterminate lesions. Eight patients had 9 pathologically confirmed cancers. BSGI demonstrated a significantly greater specificity (71% [95% CI, 49% to 87%] vs MRI, 25% [95% CI, 11% to 47%]; p < 0.05) and comparable sensitivity (BSGI, 89% [95% CI, 51% to 99%] vs MRI, 100% [95% CI, 63% to 100%]), PPV (BSGI, 53% [95% CI, 27% to 78%] vs MRI, 33% [95% CI, 17% to 54%]), and NPV (BSGI, 94% [95% CI, 71% to 100%] vs MRI, 100% [95% CI, 52% to 100%]). The authors noted that the 100% sensitivity and 25% specificity of MRI would likely have been due to the small number of cancers in the study.

In 2014, Tan et al assessed the diagnostic accuracy of dual-phase BSGI (at 10-15 minutes and at 90-120 minutes) in 76 women at a single institution in China who had suspicious breast masses. On pathologic review, 54 (59%) of 92 tumors were malignant, and 38 (41%) were benign. Using receiver operating characteristic-determined cut points for visual and semiquantitative interpretation, sensitivity and specificity were maximized when a combination of visual and early-phase semiquantitative interpretation was used (85% and 92%, respectively) compared with either analysis or delayed-phase semiquantitative analysis alone.

Meissnitzer et al (2015) in Austria evaluated BSGI in the diagnostic workup of 67 patients with 92 breast lesions identified on mammography and/or ultrasonography. Biopsy results were obtained as the reference standard in all patients, and 67 (73%) of 92 lesions were malignant. BSGI images were interpreted visually and semiquantitatively. Overall BSGI sensitivity and specificity were 90% and 56%, respectively, compared with ultrasound sensitivity and specificity of 99% and 20%, respectively. For lesions smaller than 1 cm, the sensitivity of BSGI was 60%.

In 2016, Cho et al retrospectively reviewed breast lesions in 162 women diagnosed with BI-RADS category 4 lesions (suspicious) on mammography or ultrasonography. Patients had subsequently undergone BSGI with Tc 99m sestamibi at 925 to 1110 MBq. Using biopsy-confirmed pathologic evaluation as the criterion standard, 66 (40.7%) of 162 lesions were found to be malignant. The sensitivity and specificity of BSGI were 90.9% (95% CI, 81.3% to 96.6%) and 78.1% (95% CI, 68.5% to 85.9%), respectively. The PPV was 74.1% (95% CI, 63.1% to 83.2%) and the NPV was 92.6% (95% CI, 84.6% to 97.2%). For lesions less than 1 cm, the sensitivity of BSGI was 88.0% (95% CI, 68.6% to 97.5%) and the specificity was 86.8% (95% CI, 71.9% to 95.6%). For lesions greater than 1 cm, the sensitivity was higher (92.7%; 95% CI, 80.1% to 98.5%) and the specificity was lower (61.5% [95% CI, 44.6% to 76.6%]).

**Section Summary: Indeterminate or Suspicious Breast Lesions**

A number of studies have evaluated the diagnostic accuracy of BSGI (or MBI) of suspicious lesions. Compared with biopsy, the NPV in studies that reported this outcome varied from 83% to 94%. The value of BSGI in evaluating indeterminate or suspicious lesions must be compared with other modalities that would be used (e.g., spot views ultrasound, MRI) for diagnostic mammography. Given the relative ease and diagnostic accuracy of the criterion standard (biopsy), coupled with the adverse consequences of missing a breast cancer, the NPV of BSGI would have to be extremely high to alter treatment decisions. Because NPV is partially determined by disease prevalence, NPV will be lower in a population of patients with mammographic abnormalities highly suggestive of breast cancer than in a population of patients with mammographic abnormalities not suggestive of breast cancer. Therefore, any clinical utility of BSGI as an adjunct to mammography would vary by type of mammographic abnormalities included in the studies.

**Detection of Residual Tumor After Neoadjuvant Therapy**

A 2016 systematic review and meta-analysis by Guo et al identified 14 studies investigating the performance of BSGI with Tc 99m for evaluating the response to neoadjuvant therapy in patients with breast cancer. In all studies, histopathologic results were obtained after surgery and used as the criterion standard. Study sizes ranged from 14 to 122 patients (total N = 503 patients). Most studies had fewer than 30 patients. Thirteen studies were prospective and 1 retrospective. Only 3 studies conducted BSGI both before and after treatment. The sensitivity of BSGI for identifying...
residual disease ranged from 33% to 100%, with a pooled sensitivity of 86% (95% CI, 78% to 92%). The specificity ranged from 17% to 95%, and the pooled specificity was 69% (95% CI, 64% to 74%).

The largest study, published by Lee et al in 2014, was retrospective and single-center. It evaluated BSGI detection of residual tumor after neoadjuvant chemotherapy (primarily anthracycline and taxane-based) in 122 women who had pathologically confirmed invasive breast cancer. All patients underwent BSGI and dynamic contrast-enhanced breast MRI after completing neoadjuvant therapy. Surgeons consulted BSGI and MRI for surgical planning (i.e., either breast-conserving therapy [64%] or mastectomy [36%]). Of 122 patients, 104 (85%) had residual disease by pathologic review. BSGI sensitivity was 74%, specificity was 72%, NPV was 33%, and PPV was 94%. The sensitivity of BSGI varied with cellularity and size of residual tumor (greater sensitivity with greater cellularity and greater tumor size).

No studies were identified that compared imaging methods (e.g., BSGI vs MRI or fluorine 18 fluorodeoxyglucose positron emission tomography) for detection of residual tumor after neoadjuvant therapy. In addition, no studies were identified on the clinical utility of BSGI, ie, changes in patient management strategies (e.g., the extent of surgery) or in health outcomes (e.g., disease-specific survival).

**Section Summary: Detection of Residual Tumor After Neoadjuvant Therapy**

A meta-analysis of studies evaluating BSGI for detecting residual tumor after neoadjuvant therapy found a pooled sensitivity of 86% and a pooled specificity of 69%, compared with histopathologic analysis. No studies were identified that compared the diagnostic accuracy of BSGI with other imaging approaches, or that investigated the impact of BSGI on patient management decisions or health outcomes.

**Surgical Planning for Breast-Conserving Therapy**

Edwards et al (2013) retrospectively assessed changes in the surgical management of 218 women who had breast cancer and were eligible for breast-conserving therapy. All patients had undergone preoperative BSGI or MRI. Twelve percent of patients who had BSGI and 29% of those who had MRI changed to mastectomy. On pathologic review, no patient who underwent mastectomy was eligible for breast-conserving therapy. Of patients who received breast-conserving therapy, 15% of those who had BSGI and 19% of those who had MRI required a single re-excision because of positive surgical margins, and 14% and 6%, respectively, required mastectomy. Based on this retrospective study, the clinical utility of BSGI for guiding surgical decision making in breast cancer patients would appear limited.

**Section Summary: Surgical Planning for Breast-Conserving Therapy**

One retrospective study is insufficient to determine the clinical utility of BSGI for guiding surgical decision making in breast cancer patients. In this study, it appeared as if MRI identified more patients than BSGI who were not appropriate candidates for breast-conserving therapy. Prospective comparative studies are needed.

**Detection of Axillary Metastases**

Regarding the use of scintimammography to detect axillary metastases, a 1999 review of studies published between 1994 and 1998 showed a sensitivity of 77% and specificity of 89%. Slightly more recent studies (2001, 2002) using different radiopharmaceuticals have shown sensitivities in the high 80% to 90% range. A 2011 meta-analysis reviewed 45 studies of scintimammography and also reported sensitivities and specificities in this range, with summary estimates of 83% (95% CI, 82% to 84%) for sensitivity and 85% (95% CI, 83% to 86%) for specificity. The test still is not accurate enough to replace surgical nodal dissection. No studies have examined patient outcomes comparing the strategy of using scintimammography to aid in decision making regarding nodal dissection with going directly to nodal dissection.
Section Summary: Detection of Axillary Metastases
Current evidence on BSGI for detection of axillary metastases comprises small studies and systematic reviews of these studies. A meta-analysis of 45 small studies found that pooled sensitivity was 93% and pooled specificity was 85% the diagnostic accuracy of BSGI as reported in the available literature is not high enough for this technology to replace the current standard practice (surgical nodal dissection). Moreover, clinical utility studies of scintimammography to guide decision making in this setting are lacking.

Localization of Sentinel Lymph Nodes Using Radiopharmaceutical and Gamma Detection
Pesek et al (2012) published a meta-analysis based on search between 1993 and 2011; 183 articles met inclusion criteria (total N=9306 patients).38 This analysis examined the results for the false-negative rate (FNR) of sentinel node biopsy in patients with breast cancer separately by use of localization technique: radioactive tracer alone, dye alone, or combination of radioactive tracer and dye. The FNR was highest for dye-only group at 8.6% (95% CI, 6.7% to 10.8%) while the tracer-only group had an FNR of 7.4% (95% CI, 5.6% to 9.3%), and the combination of dye-and-tracer had the lowest FNR at 5.9% (95% CI, 4.8% to 7.1%). The Q statistic for heterogeneity indicated that the 3 groups were not all equal (p=0.050). Subsequent pairwise comparisons revealed a difference between the dye-only and the dye-and-tracer categories (p=0.018), but no significant difference was seen between tracer-only and dye-only (p=0.370) or between tracer-only and dye-and-tracer (p=0.178).

A randomized study by van der Vorst et al (2012) compared Tc 99m radiotracer plus near-infrared fluorescence imaging using indocyanine green with or without the use of a patent blue dye for localization of sentinel lymph nodes.39 Twenty-four consecutive breast cancer patients who were all undergoing SLNB were studied. Of the 23 cases where sentinel lymph node mapping was successful, the sentinel lymph nodes were both radioactive and fluorescent in 100% of cases, whereas only 84% of the sentinel lymph nodes showed blue dye staining. In addition, for 25% of cases, the gamma probe was needed to identify and locate the sentinel nodes during the first 15 minutes of localization.

Johnson et al (2011) reported a single institution study assessing 699 patients with operable breast cancer for SLNB.40 Using intraoperative Tc 99m-labeled radiopharmaceutical tracer subareolar injection, the sentinel node was localized in 98.6% of cases.

Martin et al (2000) reported a prospective multi-institutional study examining 758 patients who were clinical stage T1-2, N0, M0 invasive breast cancer and who had an injection of both radioactive colloid and isosulfan blue dye before axillary SLNB.41 Localization of sentinel nodes was successful in 89% of cases and 33% of histologically positive sentinel lymph nodes showed no blue dye staining.

Some studies have examined whether preoperative lymphoscintigraphy improves sentinel node localization and detection in clinically node-negative patients and have found little or no incremental value for lymphoscintigraphy imaging of the axilla.42-44 Note that lymphoscintigraphy uses planar or tomographic imaging that differs from the use of hand-held gamma detection probe of radioactive nodes during surgery.

Section Summary: Localization of Sentinel Lymph Nodes Using Radiopharmaceutical and Gamma Detection
For individuals who have breast cancer undergoing SLNB for detection of axillary metastases who receive radiopharmaceutical and gamma detection for localization of sentinel lymph nodes, the evidence includes 3 studies and a meta-analysis. These studies provide consistent evidence that diagnostic performance using radiopharmaceutical and gamma detection yields high success rates in identifying sentinel lymph nodes; further, these studies suggest that diagnostic performance trends toward better detection rates using radiopharmaceutical (as opposed to alternative methods using only blue dye). Clinical utility is demonstrated for this indication when the high diagnostic yield of sentinel lymph nodes using radiopharmaceutical
and gamma detection is considered together with the evidence that SLNB provides similar long-
term outcomes as full axillary lymph node dissection for control of breast cancer and offers more
favorable early results with reduced arm swelling and postsurgical morbidity.

**Summary of Evidence**

**Scintimammography, BSGI, and MBI**
For individuals who have dense breasts or high risk for breast cancer who receive
scintimammography, BSGI, or MBI as an adjunct to mammography, the evidence includes
diagnostic accuracy studies. Relevant outcomes are overall survival, disease-specific survival,
test accuracy and validity, and treatment-related morbidity. Three prospective studies have
assessed the incremental difference in diagnostic accuracy when BSGI or MBI is added to
mammography in women at increased risk. Sensitivity was higher with combined BSGI or MBI
and mammography, but specificity was lower. Studies of women at increased risk of breast
cancer and negative mammograms found that a small number of additional cancers were
detected, but the recall rate was relatively high. Studies tended to include women at different
risk levels (e.g., women with dense breasts and those with BRCA1). Moreover, any potential
benefits need to be weighed against potential risks of additional radiation exposure. The
evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have indeterminate or suspicious breast lesions who receive
scintimammography, BSGI, or MBI, the evidence includes diagnostic accuracy studies. Relevant
outcomes are overall survival, disease-specific survival, test accuracy and validity, and
treatment-related morbidity. In the available studies, compared with biopsy, the negative
predictive value (NPV) of BSGI (or MBI) varied from 83% to 94%. Given the relative ease and
diagnostic accuracy of the criterion standard of biopsy, coupled with the adverse
consequences of missing a breast cancer, the NPV of BSGI (or MBI) would have to be extremely
high to alter treatment decisions. The evidence to date does not demonstrate this level of NPV.
Moreover, the value of BSGI in evaluating indeterminate or suspicious lesions must be compared
with other modalities that would be used, such as spot views for diagnostic mammography. The
evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have breast cancer undergoing detection of residual tumor after
neoadjuvant therapy who receive scintimammography and BSGI, the evidence includes
diagnostic accuracy studies and a meta-analysis. Relevant outcomes are overall survival,
disease-specific survival, test accuracy and validity, and treatment-related morbidity. The meta-
analysis of studies evaluating the accuracy of BSGI for detecting residual tumor after
neoadjuvant therapy found a pooled sensitivity of 86% and a pooled specificity of 69%
compared with histopathologic analysis. No studies were identified that compared the
diagnostic accuracy of BSGI with other imaging approaches, or that investigated the clinical
utility of this potential application of BSGI. The evidence is insufficient to determine the effects of
the technology on health outcomes.

For individuals who have breast cancer undergoing surgical planning for breast-conserving
therapy who receive scintimammography and BSGI, the evidence includes a retrospective
observational study. Relevant outcomes are overall survival, disease-specific survival, test
accuracy and validity, and treatment-related morbidity. In the retrospective study, results
suggested that magnetic resonance imaging identified more patients than BSGI who were not
appropriate candidates for breast-conserving therapy. Prospective comparative studies are
needed. The evidence is insufficient to determine the effects of the technology on health
outcomes.

For individuals who have breast cancer undergoing detection of axillary metastases who
receive scintimammography and BSGI, the evidence includes diagnostic accuracy studies and
systematic reviews of diagnostic accuracy studies. Relevant outcomes are overall survival,
disease-specific survival, test accuracy and validity, and treatment-related morbidity. A meta-
analysis of the available diagnostic accuracy studies found that the sensitivity and specificity of
BSGI are not high enough for this technology to replace the current standard practice, surgical nodal dissection. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Localization of Sentinel Lymph Nodes Using Radiopharmaceutical and Gamma Detection**

For individuals who have breast cancer undergoing sentinel lymph node biopsy for detection of axillary metastases who receive radiopharmaceutical and gamma detection for localization of sentinel lymph nodes, the evidence includes 3 studies and a meta-analysis. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and treatment-related morbidity. A meta-analysis and 3 additional studies have provided evidence that a diagnostic performance, using radiopharmaceutical and gamma detection for localization of sentinel lymph nodes, yields high success rates in identifying sentinel lymph nodes; additionally, the diagnostic performance generally offers better detection rates with radiopharmaceutical than with alternative methods (e.g., using only blue dye). The evidence has indicated that sentinel lymph node biopsy provides similar long-term outcomes as full axillary lymph node dissection for control of breast cancer and offers more favorable early results with reduced arm swelling and better quality of life. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**Society of Nuclear Medicine**
The Society of Nuclear Medicine released a 2010 procedure guideline on breast scintigraphy using breast-specific gamma cameras. The guideline was based on consensus, not on a systematic review of the literature or assessment of study quality, and most of it discusses procedures and specifications of the examination, documentation and recording, quality control, and radiation safety.

**American College of Obstetricians and Gynecologists**
In 2017 the American College of Obstetricians and Gynecologists updated its 2011 practice bulletin on breast cancer screening. There is no discussion or recommendation for scintimammography for routine screening in the 2017 practice bulletin.

**American College of Radiology**
Appropriateness Criteria from the American College of Radiology rated breast-specific gamma imaging a 1 or 2, indicating “usually not appropriate” for breast cancer screening (last reviewed in 2016), palpable breast masses (last reviewed in 2017), and workup of breast pain (last reviewed in 2016).

**American Society of Clinical Oncology**
In 2016, the American Society of Clinical Oncology reaffirmed its 2014 recommendations on the use of sentinel node biopsy (SNB) for patients with early-stage breast cancer. The recommendations were based on randomized controlled trials, systematic reviews, meta-analyses, and clinical practice guidelines from 2012 through July 2016. The recommendations included:

> "Women without sentinel lymph node (SLN) metastases should not receive axillary lymph node dissection (ALND). Women with one to two metastatic SLNs who are planning to undergo breast-conserving surgery with whole-breast radiotherapy should not undergo ALND (in most cases). Women with SLN metastases who will undergo mastectomy should be offered ALND. These three recommendations are based on randomized controlled trials. Women with operable breast cancer and multicentric tumors, with ductal carcinoma in situ, who will undergo mastectomy, who previously underwent breast and/or axillary surgery, or who received preoperative/neoadjuvant systemic therapy may be offered SNB. Women who have large or locally advanced invasive breast cancer (tumor size T3/T4), inflammatory..."
breast cancer, or ductal carcinoma in situ (when breast-conserving surgery is planned) or
are pregnant should not undergo SNB.”

**National Comprehensive Cancer Network**
The National Comprehensive Cancer Network guideline (v.2.2017) for invasive breast cancer
with clinical stage I, IIA, IIB, and IIIA T3, N1, M0 (BINV-D) includes sentinel node mapping and
excision for clinically node-negative patients at time of diagnosis or following negative fine-
needle aspiration or core biopsy of clinically positive nodes at time of diagnosis.50 If the sentinel
nodes are found to be negative on pathological examination, then no further axillary surgery is
suggested (category 1 recommendation).

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination. In the absence of a national coverage
determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 1.

### Table 1. Summary of Key Trials

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</table>

NCT: national clinical trial.

**References**

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special
   report: screening symptomatic women with dense breasts and normal mammograms for
   Aug 2009;9(8):1073-1080. PMID 19671027
   conventional axillary-lymph-node dissection in clinically node-negative patients with
   breast cancer: overall survival findings from the NSABP B-32 randomised phase 3 trial.
   sentinel lymph node dissection versus axillary dissection. J Surg Oncol. Aug 1
   2010;102(2):111-118. PMID 20648579
5. Ram R, Singh J, McCaig E. Sentinel node biopsy alone versus completion axillary node
dissection in node positive breast cancer: systematic review and meta-analysis. Int J
   Breast Cancer. 2014;2014:513780. PMID 25383226
6. Lantheus Medical Imaging. Cardiolite® kit for the preparation of technetium Tc99m
   sestamibi for injection. 2016; http://www.cardiolite.com/healthcare-
7. Hruska CB, O’Connor MK. Nuclear imaging of the breast: translating achievements in
9. GE Healthcare. Myoview™ kit for the preparation of technetium Tc99m tetrofosmin for
   injection. 2011 May; http://www3.gehealthcare.com/~media/documents/us-


42. Unkart J, Wallace A. Use of lymphoscintigraphy with Tc-99m tilmanocept does not affect the number of nodes removed during sentinel node biopsy in breast cancer [abstract]. J Nucl Med. 2016;57(Suppl 2):615. PMID


### Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Name and reason for testing
  - Mammogram report

### Post Service

- Procedure (imaging) report

### Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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<td>78803</td>
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### Type

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### ICD-10 Procedure

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### ICD-10 Diagnosis

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### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<td>11/02/2002</td>
<td>Coding Update</td>
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<td>01/07/2011</td>
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<td>Policy revision with no position change</td>
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<tr>
<td>06/30/2015</td>
<td>Coding update</td>
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### Definitions of Decision Determinations

**Medically Necessary**: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental**: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation**: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.