OVERVIEW
Scintimammography refers to the use of radiotracers with nuclear medicine imaging as a diagnostic tool for abnormalities of the breast.

PRIOR AUTHORIZATION
Not Applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial:
Scintimammography or breast-specific gamma imaging is considered not medically necessary in all applications, including but not limited to its use as an adjunct to mammography or in staging the axillary lymph nodes as there is insufficient peer-reviewed scientific literature that demonstrates the procedure/service is effective.

Scintimammography or breast-specific gamma imaging is considered not medically necessary in all applications, including but not limited to its use as an adjunct to mammography or in staging the axillary lymph nodes as there is insufficient clinical data to determine its effectiveness. This applies to all BCBSRI products.

MEDICAL CRITERIA
None.

BACKGROUND
Scintimammography is a diagnostic modality using radiopharmaceuticals to detect tumors of the breast. After injection of a radiopharmaceutical, the breast is evaluated with 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. Scintimammography using conventional imaging modalities has relatively poor sensitivity in detecting smaller lesions (e.g., smaller than 15 mm), because of the relatively poor resolution of conventional gamma cameras in imaging the breast. Breast-specific gamma imaging (BSGI) and molecular breast imaging (MBI) were developed to address this issue. 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. The detector head(s) is immediately next to the breast, increasing resolution, and the images can be compared with the mammographic images. Breast-specific gamma imaging and molecular breast imaging differ primarily in the type and number of detectors used (multi-crystal arrays of cesium iodide or sodium iodide versus semiconductor materials, such as cadmium zinc telluride, respectively). In some configurations, a detector is placed on each side of the breast and used to lightly compress it. The maximum distance between the detector and the breast is therefore from the surface to the midpoint of the breast. Much of the research on BSGI and MBI has been conducted at the Mayo Clinic. The radiotracer usually utilized is technetium Tc99m sestamibi. MBI imaging takes approximately 40 minutes. (1)

Breast-specific gamma imaging and molecular breast imaging have been suggested for a variety of applications. In practice guidelines for breast scintigraphy with breast-specific gamma cameras, the Society for Nuclear Medicine provides a list of common uses, as follows:
1. Among patients with recently detected breast malignancy, initial staging; detecting multicentric, multifocal, or bilateral disease; and assessing response to neoadjuvant chemotherapy.

2. Among patients at high risk for malignancy, evaluating suspected recurrence or using it when a mammogram is limited or a previous malignancy was occult on mammogram.

3. Among patients with indeterminate breast abnormalities and remaining diagnostic concerns, evaluating lesions identified by other breast imaging techniques, palpable or non-palpable, aiding in biopsy targeting, and a number of others.

4. Among patients with technically difficult breast imaging, such as radiodense breast tissue or implants, free silicone, or paraffin injections.

5. Among patients for whom breast magnetic resonance imaging (MRI) is indicated but contraindicated, e.g., patients with implanted pacemakers or pumps, or as an alternative for patients who meet MRI screening criteria, such as BRCA1, BRCA2 mutations.

6. Among patients undergoing preoperative chemotherapy, for monitoring tumor response in order to determine the impact of therapy on plan for residual disease.

The guideline also mentions other efforts, such as the American College of Radiology’s Appropriateness Criteria and the American College of Surgeons’ Consensus Conference III.

The evidence to date does not provide sufficient support for any of the uses discussed. The published literature on BSGI, MBI, and scintimammography with breast-specific gamma camera is limited by a number of factors. The studies include populations that usually do not represent those encountered in clinical practice and that have mixed indications. There are methodologic limitations in the available studies, which have been judged to have medium to high risk of bias, and they lack information on the impact on therapeutic efficacy. Limited evidence on the diagnostic accuracy of BSGI reports that the test has a relatively high sensitivity and specificity for detecting malignancy. However, the evidence does not establish that BSGI improves outcomes when used as an adjunct to mammography for breast cancer screening. In the available studies, the negative predictive value of BSGI has not been high enough to preclude biopsy in patients with inconclusive mammograms. The relatively high radiation dose also should be taken into account. In addition, the evidence is not sufficient to conclude that BSGI is better than MRI for this purpose. Larger, higher-quality studies are required to determine whether BSGI has a useful role as an adjunct to mammography. For these reasons, BSGI is considered not medically necessary as there is no proven efficacy.

Scintimammography is a diagnostic imaging technique using radiopharmaceuticals to reveal images of tumors of the breast. Also referred to as breast-specific gamma imaging (BSGI) or molecular breast imaging (MBI) when gamma cameras, specifically devoted to breast imaging, are used. Scintimammography has been proposed as an adjunct to mammography and physical examination in patients who have had abnormal mammograms as a technique to improve patient selection for biopsy.

Scintimammography involves the injection of a radiopharmaceutical and the breast is evaluated with planar or single positron emission computed tomography (SPECT) radionuclide imaging. If sufficiently predictive of a benign lesion, scintimammography might be used to recommend against performing a biopsy, thus reducing the number of negative biopsies. Alternatively, if predictive of a malignant lesion in someone whose mammogram is interpreted as benign, then the sensitivity of screening would be improved. If scintimammography accurately assesses axillary lymph node status, patients might either undergo needed axillary dissection or avoid it when unnecessary.

At present, the only radiopharmaceutical that has specific U.S. Food and Drug Administration (FDA) approval for use in breast imaging, is technetium 99m sestamibi. The labeling states that technetium 99m sestamibi is a second-line diagnostic test after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or breast mass. It is not indicated for breast cancer screening or to
confirm the presence or absence of malignancy, and it is not an alternative to biopsy prompted by an abnormal mammogram or breast mass.

Several gamma cameras have general 510(k) marketing clearance from the FDA, which states that they are cleared for “use in imaging the distribution of radionuclides in the human body using planar imaging techniques.” Two examples of gamma cameras used in scintimammography/breast-specific gamma imaging are Dilon 6800 (Dilon Technologies) and LumaGEM™ (Gamma Medica Instruments).

After assessment, it was determined that as a second-line diagnostic test after mammography, the sensitivity and corresponding negative predictive value of scintimammography are not high enough to influence treatment decisions. Also, there were inadequate data to permit conclusions regarding the use of scintimammography for the staging of axillary lymph node.

**COVERAGE**

BlueCHiP for Medicare and Commercial:
Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, or Subscriber agreement for the applicable services deemed not medically necessary.

**CODING**

BlueCHiP for Medicare and Commercial:
The following code is considered not medically necessary:

| S8080 |

**RELATED POLICIES**

None.

**PUBLISHED**

| Provider Update | 2013 |
| Provider Update | Mar 2012 |
| Provider Update | Feb 2011 |

**REFERENCES**


7. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Breast-specific gamma imaging (BSGI), molecular breast imaging (MBI), or scintimammography with breast-specific gamma camera. TEC Assessments 2013; Volume 28; in press.

