Medical Coverage Policy

Scintimammography/Breast-Specific Gamma Imaging

☐ Device/Equipment    ☐ Drug    ☐ Medical    ☐ Surgery    ☒ Test    ☐ Other

| Effective Date: | 12/7/2010 | Policy Last Updated: | 12/20/2011 |

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

Description:

Scintimammography is a diagnostic imaging technique using radiopharmaceuticals to reveal images of tumors of the breast. It is 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 nodes.

Medical Criteria:
Not applicable.

Policy:
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.

Coverage:
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.

Codes:
The following HCPCS is considered not medically necessary:
S8080 Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

Related topics:
Not applicable.

Published:
Provider Update, February 2011
Provider Update, March 2012

References:

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication;
however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.