04-78000-14

Original Effective Date: 09/15/01

Reviewed: 10/24/24

Revised: 11/15/24

Subject: Scintimammography and Gamma Imaging of the Breast

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DESCRIPTION:

Scintimammography, breast specific-gamma imaging (BSGI) or molecular breast imaging (MBI), refers to the use of radiotracers with nuclear medicine cameras used to generate diagnostic images of the breast. This is done with the intent of improving the diagnostic performance imaging in the detection of breast malignancies.

Scintimammography is a diagnostic modality which uses radiopharmaceuticals to detect tumors of the breast. After injection of a radiopharmaceutical, the breast is evaluated with planar imaging. 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. Interest in scintimammography has increased in recent years with the development of breast-specific gamma imaging (BSGI) techniques that resemble those utilized in conventional mammography, allowing more detailed visualization of the breasts. 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 systems can 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 they lightly compress the breast. The maximum distance between the detector and the breast is therefore from the surface to the midpoint of the breast. The radiotracer usually utilized is technetium Tc99m sestamibi. MBI imaging takes approximately 40 minutes.

Several scintillation cameras (gamma camera) have received general 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) (e.g., Dilon 6800, LumaGEM™, Sentinella 102).

Localization of Sentinel Lymph Nodes Using Radiopharmaceutical and Gamma Detection

Breast cancer staging requires evaluation of draining lymph node groups and primarily axillary lymph nodes. Sentinel lymph node identification can be performed using a simple procedure to inject into the skin and under the skin a radiotracer that travels within the lymphatic channels of the breast and accumulates in draining lymph nodes. The first appearing lymph nodes or the lymph nodes with the greatest uptake of radiotracer are identified as sentinel nodes.

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 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

Summary and Analysis of Evidence: Data are limited regarding the use of sestamibi molecular breast imaging (MBI) for screening women at average risk. Most studies have focused upon women with dense breasts and variable risk profiles. One of the larger studies published to date of 1,696 women with recent negative or benign mammographic examinations showed that sestamibi MBI yielded an incremental CDR of 7.7 cancers per 1,000 examinations; however, all 13 cancers were detected in women with dense breasts. Although 92% of the women within the study had < 20% estimated lifetime risk, the estimates ranged from 6.1% to 17.2%. Additional retrospective and prospective studies have demonstrated similar incremental CDR for sestamibi MBI of 6.5 to 9 per 1,000 over mammography. Sestamibi MBI demonstrates similar sensitivity, better specificity, and lower recall rate compared to supplemental screening US in women with dense breasts (ACR, 2023).

To investigate the effectiveness of 3D freehand SPECT (fhSPECT) in sentinel lymph node (SLN) mapping in breast cancer, compared with the use of a conventional gamma probe. The authors retrospectively compared the fhSPECT lymph node mapping modality, with gamma probe detection in early-stage, clinically node-negative breast cancer patients, with biopsy-confirmed malignancy. The two techniques were compared based on the average number of LNs excised per axilla. The duration of SLN mapping was also compared between the two groups. The performance of the two methods on obese and post-systemic therapy patients was evaluated. FhSPECT was used in 150 cases, while the gamma probe was employed in 50 cases. FhSPECT detected at least 3 nodes in 83.3% of the patients vs. 72.0% with the γ-probe ($p = 0.107$). The mean number of SLNs excised per axilla was 3.66 using the γ-probe and 4.18 with fhSPECT ($p = 0.03$). The average surgical time was 39 ±7 min with the γ-probe and 37.54 ±17 min with fhSPECT ($p = 0.228$). Sentinel lymph node biopsy (SLNB) mean surgical time evolved from 40.2 ±20.77 min to 32.35 ±10.46 min ($p = 0.033$). In obese patients, a reduction in surgical times was noted from 45.5 ±3.09 min to 44.04 ±20.9 ($p = 0.27$), in addition to a significant increase in average LN detection in the fhSPECT group (4.26 ±1.44) compared to the γ-probe group (3.2 ±1.65) ($p = 0.043$).The authors concluded that the use of the fhSPECT modality is effective and safe, and, when compared to the γ-probe, has significant advantages in SLN mapping (Argentou et al 2022).

POSITION STATEMENT:

Scintimammography, breast- specific gamma imaging, and molecular breast imaging is considered **experimental or investigational** in all applications, including but not limited to use as an adjunct to

mammography or in staging the axillary lymph nodes. The evidence is insufficient to determine that scintimammography, breast- specific gamma imaging, or molecular breast imaging results in an improvement in the net health outcome.

Use of gamma detection following radiopharmaceutical administration for localization of sentinel lymph nodes in members with breast cancer **meets the definition of medical necessity**.

BILLING/CODING INFORMATION:

There is no specific CPT code that describes breast -specific gamma imaging, molecular breast imaging.

CPT code 78800 and 78801 does not specifically describe scintimammography, breast-specific gamma imaging, or molecular breast imaging. CPT code 78800 and 78801 is considered experimental or investigational when used to describe scintimammography, breast -specific gamma imaging, or molecular breast imaging.

There is no specific HCPCS code that describes breast-specific gamma imaging or molecular breast imaging. HCPCS code A9500 does not specifically describe the radiopharmaceutical for scintimammography, breast-specific gamma imaging, or molecular breast imaging. HCPCS code A9500 is considered experimental or investigational when used to describe scintimammography, breast -specific gamma imaging, or molecular breast imaging.

Sentinel lymph node detection

There is no specific CPT or HCPCS code that describes gamma detection for localization of sentinel lymph nodes. HCPCS code A9520 may be used to describe gamma detection for localization of sentinel lymph nodes.

HCPCS Coding:

S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical (**experimental or investigational**)

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

DEFINITIONS:

Molecular breast imaging (MBI): a variant on scintimammography that uses gamma cameras and a radioactive tracer to obtain images of metabolic patterns.

Scintimammography: a method of imaging metabolic patterns of tissues by tracking the metabolism of a radioactive tracer with gamma cameras.

RELATED GUIDELINES:

None applicable.

OTHER:

Other names used to report scintimammography:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Breast scintigraphy
Breast specific-gamma imaging (BSGI)
Gammagram
Mammoscintigraphy
Molecular breast imaging (MBI)
Radionclide scanning, breast
Radiopharmaceutical localization of tumor(s), breast
Scintimammography (SMM)
Technetium sestamibi scan
Technetium-99m sestamibi (MIBI)
Tumor localization, breast
Tumor specific imaging, breast
99m Tc-methoxyisobutyl isonitrile (MIBI)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/24/24.

GUIDELINE UPDATE INFORMATION:

09/15/01	Original policy – investigational.
09/15/02	Reviewed and revised – continue investigational.
10/15/03	Annual review; remains investigational.
07/15/04	Scheduled review. No change in coverage statement.
08/15/05	Scheduled review. Updated references. Maintain investigational statement.
07/15/06	Scheduled review. No change in coverage statement (investigational). Updated references.
07/15/07	Scheduled review; no change in investigational status; reformatted guideline; updated references.
05/15/08	Scheduled review. No change in position statement. Updated references.
06/15/09	Annual review. Added specific gamma imaging to the guideline title and description section. Added specific gamma imaging to position statement (experimental or investigational).
12/15/10	Annual review: Revised guideline title; added “breast scintigraphy” and “molecular breast imaging”. Revised description. Revised position statement; added molecular breast imaging (experimental or investigational). Updated references.
04/15/11	Reviewed; no change in position statement. Updated references.
08/15/12	Annual review. Updated description. Maintain position statement, added in all applications, including but not limited to its use as an adjunct to mammography or in staging the axillary lymph nodes. Added 78800, 78801 and A9500. Updated references.
12/15/13	Scheduled review. No change in position statement. Added Medicare Advantage products program exception. Updated references.
11/15/14	Annual review. No change in position statement. Updated references.

12/15/15	Review; updated description, added position statement for preoperative or intraoperative sentinel lymph node detection using handheld or mounted mobile gamma cameras. Updated references.
11/15/16	Revision; added statement for gamma detection. Updated description and references.
11/15/17	Review; no change in position statement. Updated references.
10/15/19	Review; no change in position statement. Deleted code A9541. Updated references.
10/15/21	Review; no change in position statement. Updated references.
11/15/23	Review; no change in position statement. Updated references.
11/15/24	Review; no change in position statement. Updated references.