Mammography is considered the gold standard for breast cancer screening and the most effective means for detecting breast cancer when combined with breast self-examination. Approximately three fourths of lesions identified on mammograms have a benign biopsy outcome therefore thermography in general, and infrared imaging (IRI) in particular, have been developed as a safe, noninvasive adjunct to, rather than a replacement for, mammography to improve early detection and avoid unnecessary biopsy. Since thermography provides results more quickly than biopsy, it has the potential to prevent unnecessary concern after a positive mammogram. Another feature of thermography is that, unlike mammography and some other adjunctive tests, it detects physiological rather than anatomical changes.

Thermographic devices measure infrared energy emanating from the surface of the skin and display heat or temperature in the form of a colored pattern. Warmer regions of skin may indicate the presence of precancerous tissue or tumors since tissue temperature rises due to angiogenesis and other physiological changes associated with tumor development. Like other imaging modalities, thermography is a screening rather than a diagnostic test. A diagnosis of breast cancer must be confirmed with a biopsy. Since thermography is designed to detect
physiological changes that occur in very early-stage breast cancer, it may detect tumors that other modalities would miss and some evidence suggests that thermography can identify patients at risk for breast cancer.

Breast-specific gamma imaging (BSGI) was developed as a confirmatory test to be used in conjunction with mammography and a clinical breast examination. Unlike mammography, the sensitivity of BSGI is not affected by breast tissue density, breast implants, or scars. BSGI differentiates normal and abnormal breast tissue based on the differential uptake of technetium-99m (99mTc) sestamibi, a radioactive agent that accumulates in malignant breast tissue due to increased vascularity and mitochondrial activity. BSGI was initially performed using general nuclear medicine gamma cameras which had large fields of view and resultant low sensitivity. The Dilon 6800 Gamma Camera, with high resolution and a small field of view, was specially designed for this imaging. BSGI is typically performed on an outpatient basis by a nuclear medicine technician who has been trained in breast positioning. It takes between 45 and 60 minutes. Approximately 5 to 10 minutes after intravenous injection of 25 to 30 mCi (millicuries) of 99mTc-sestamibi, each breast undergoes two 10-minute imaging sessions. One image is taken in the mediolateral plane and the other in the craniocaudal plane. During each 10-minute period of imaging, the gamma camera is continuously pressed against one side of the breast, which is mildly compressed. Additional views may be ordered as needed. Results are interpreted by a radiologist or a nuclear medicine physician.

RECOMMENDATION

- Thermography also referred to as digital infrared thermal imaging (DITI) and temperature gradient studies for the diagnosis of breast lesions is considered experimental, investigational and unproven because there is insufficient clinical evidence to determine whether the sensitivity and/or specificity of diagnosis improved when thermography was combined with mammography, or whether breast thermography improves health outcomes.

- Breast specific gamma imaging (BSGI) also known as molecular breast imaging or scintimammography for the diagnosis of breast lesions is considered experimental, investigational and unproven because the available evidence has not conclusively demonstrated that BSGI is more effective than US or MRI for evaluation of suspicious breast lesions detected by mammography or clinical breast examination.

SUMMARY OF MEDICAL EVIDENCE

*Breast Thermography* 10-17

The published evidence includes comparative studies that evaluated the diagnostic accuracy of dynamic infrared imaging (DIRI) or infrared imaging (IRI) with diagnoses confirmed by biopsy and uncontrolled studies. The study results suggest that DIRI has high sensitivity and poor to moderate specificity for detection of breast cancer. In the largest studies, DIRI had 97% to 98% sensitivity, indicating that it detected almost all of the breast cancers. However, the specificity was 14% in the largest study 10 and 55% in a second study, 16 which suggests that, like mammography, DIRI incorrectly identifies many benign masses as being malignant. Only one study evaluated the diagnostic efficacy of IRI, finding that it had 83% sensitivity and 81% specificity.12 Although this study found that IRI combined with mammography and clinical breast examination had 98%
sensitivity, the investigators did not report whether this outcome was statistically significant. Moreover, the specificity of this combination of tests was not reported. None of the available studies determined whether the sensitivity and/or specificity of diagnosis improved when DIRI was combined with mammography, or whether breast thermography improves health outcomes. Therefore, there is insufficient clinical evidence to determine whether the sensitivity and/or specificity of diagnosis improved when thermography was combined with mammography, or whether breast thermography improves health outcomes.

**Breast specific gamma imaging (BSGI)**

The published evidence includes comparative studies that evaluated BSGI for detection of breast cancer and uncontrolled studies that evaluated its influence on post biopsy patient management. Sensitivity ranged from 89% to 100% and specificity ranged from 60% to 90%. Results of the available studies do not provide conclusive evidence that BSGI should be relied on as a replacement for biopsy, US, or MRI in women who have suspicious breast lesions on mammograms. In several of the studies, BSGI detected some cancerous lesions that were not detected by mammography; however, these studies did not report whether the increased detection corresponded to a statistically significant increase in the sensitivity of BSGI compared with mammography. In the studies that provided data on patient management, BSGI was not rigorously compared with MRI or US to determine whether it was more effective. Only two studies reported the statistical significance of results, both of which indicated that BSGI was more specific than MRI. The available evidence has not conclusively demonstrated that BSGI is more effective than US or MRI for evaluation of suspicious breast lesions detected by mammography or clinical breast examination.

**Professional Organizations**

**American College of Radiology (ACR):** The ACR breast cancer screening appropriateness criteria (2013) state that there is insufficient evidence to support the use of other imaging modalities, such as thermography, breast-specific gamma imaging, positron emission mammography, and optical imaging for breast cancer screening.

**Society of Nuclear Medicine (SNM):** A Society of Nuclear Medicine (SNM) guideline on scintigraphy with breast-specific gamma cameras mentions that BSGI is commonly used for presurgical planning and recommends that, if possible, this technique be performed before interventional procedures and between days 2 and 12 of the menstrual cycle.

**The Society of Breast Imaging (SBI):** The SBI does not currently support the use of thermography/infrared imaging of the breast as either a screening tool in the detection of breast cancer or as an adjunctive diagnostic tool.

**CODING INFORMATION:** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT, THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

<p>| CPT | Description: There are no CPT codes which specifically describe BSGI or breast thermography |</p>
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>78800</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area (when used for BSGI)</td>
</tr>
<tr>
<td>78801</td>
<td>Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas (when used for BSGI)</td>
</tr>
<tr>
<td>93740</td>
<td>Temperature gradient studies (when used for breast thermography)</td>
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</table>

**HCPCS**

**Description:** There are no HCPCS codes which specifically describe BSGI or breast thermography.

<table>
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<tr>
<td>A9500</td>
<td>Imaging agent; Technetium TC 99M sodium gluceptate, diagnostic, per study dose up to 25 millicurie (when used for BSGI)</td>
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<tr>
<td>S8080</td>
<td>Scintimammography (radioimmunoscintigraphy of the breast, unilateral), including supply of Radiopharmaceutical (when used for BSGI)</td>
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**ICD-9**

**Description:** [For dates of service prior to 10/01/2015]

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<td>174-174.9</td>
<td>Malignant neoplasm of female breast</td>
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<tr>
<td>175.9</td>
<td>Malignant neoplasm of male breast</td>
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**ICD-10**

**Description:** [For dates of service on or after 10/01/2015]

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<tr>
<td>C50-C50.929</td>
<td>Malignant neoplasm of the breast</td>
</tr>
</tbody>
</table>

**Resource References**

**Government Agency**


**Professional Society Guidelines**


Peer Reviewed Literature


Other Resources
33. UpToDate: Slantez P. MRI of the breast and emerging technologies. 2016.