Subject: Thermography and Breast Specific Gamma Imaging for the Detection of Breast Lesions		Original Effective Date: 12/11/13
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

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.[5-7]

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.[5-7]

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** due to 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.[2]

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** as the available evidence has not conclusively demonstrated that BSGI is more effective than ultrasound (US) or MRI for evaluation of suspicious breast lesions detected by mammography or clinical breast examination.[2]

SUMMARY OF MEDICAL EVIDENCE

Breast Thermography [8-15]

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[8] and 55% in a second study[14] 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.[10] 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) [16-27]

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%.[16-20] 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

Several professional organizations have not endorsed or have not mentioned thermography and/or BSGI as standard diagnostic tests for the detection of breast lesions.

- The **American Cancer Society (ACS)** published an article on *Newer and Experimental Breast Imaging Tests* including breast tomosynthesis (3D mammography); molecular breast imaging (MBI) – also known as scintimammography or breast-specific gamma imaging (BSGI); positron emission mammography (PEM); contrast-enhanced mammography (CEM) or contrast-enhanced spectral mammography (CESM); optical imaging tests; electrical impedance imaging (EIT); and elastography.[28]
- The **American College of Obstetricians-Gynecologists (ACOG)** have not published any bulletins regarding tests for breast cancer screening.[29]
- The **American College of Radiology (ACR)** mentions that there have been no large population studies of molecular breast imaging (MBI) for screening. There was also concern with the whole-body radiation dose with this technique.[30-32]
- The **Food and Drug Administration (FDA) Center for Devices and Radiological Health** did not yield information when using the Searchable 510(k) database (keywords: IYM, telethermographic system, LHQ, Telethermographic system for adjunctive use).[3]
- The **National Comprehensive Cancer Network (NCCN)** guidelines for Breast Cancer Screening and Diagnosis did not yield specific information.[33]
- The **Society of Breast Imaging** 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.[34]
- The **United States Preventive Services Task Force (USPSTF)** recommendations do not address thermography.[4]

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.

CPT*	Description
78800	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area (when used for BSGI)
78801	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas (when used for BSGI)
93740	Temperature gradient studies (when used for breast thermography)

HCPCS*	Description
A9500	Imaging agent; Technetium TC 99M sodium gluceptate, diagnostic, per study dose up to 25 millicurie (when used for BSGI)
S8080	Scintimammography (radioimmunoscintigraphy of the breast, unilateral), including supply of Radiopharmaceutical (when used for BSGI)

NOTE: There are no CPT or HCPCS codes that specifically describe BSGI or breast thermography

ICD-10	Description
C50-C50.929	Malignant neoplasm of the breast

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Revision/Review History

12/11/2013 New policy.

12/16/2015	Policy reviewed, no changes.
1/1/2016	Policy reviewed, revised to include breast-specific gamma imaging (BSGI) – another test used for breast cancer screening. Both thermography and BSGI are outlined as experimental, investigational breast cancer screening tests.
3/8/2018	Policy reviewed, no changes to criteria.
6/19/2019	Policy reviewed, no changes to criteria.
6/17/2020	Policy reviewed, no changes to criteria, updated references.
8/11/2021	Policy reviewed, no changes to criteria, updated references.