# Molina Clinical Policy
# Thermography and Breast Specific Gamma Imaging for the Detection of Breast Lesions: Policy No. 127

**Last Approval: 8/10/2022**
**Next Review Due By: August 2023**

## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## OVERVIEW

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. (Elmore & Lee, 2021 & 2020; Slantez, 2021).

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; some evidence suggests that thermography can identify patients at risk for breast cancer. (Elmore & Lee, 2021 & 2020; Slantez, 2021).

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. (Elmore & Lee, 2021 & 2020; Slantez, 2021).

## COVERAGE POLICY

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. (AMR, 2013; CMS, 1992).

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. (AMR, 2013; CMS, 1992).

**DOCUMENTATION REQUIREMENTS.** Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

## SUMMARY OF MEDICAL EVIDENCE

**Breast Thermography.** 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 (Elmore & Lee, 2021) and 55% in a second study which suggests that, like mammography, DIRI incorrectly identifies many benign masses as being malignant (Arena et al., 2013). Only one study evaluated the diagnostic efficacy of IRI, finding that it had 83% sensitivity and 81% specificity (Kontos et al., 2011). 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. (Brem et al., 2009, 2008, 2005; [1-2] Brem et al., 2007).

### National and Specialty Organizations

The following 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* (2022) describing 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.
- **The American College of Obstetricians-Gynecologists (ACOG)** (2021) have not published any bulletins regarding tests for breast cancer screening.

- **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. ([1-2] ACR, 2017; ACR, 2016).
- **The Food and Drug Administration (FDA) Center for Devices and Radiological Health** did not yield information when using the Searchable 510(k) database.
- **The National Comprehensive Cancer Network (NCCN)** (2022) guidelines for Breast Cancer Screening and Diagnosis did not yield specific information.
- **The Society of Breast Imaging** (2012) 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.
- **The United States Preventive Services Task Force (USPSTF)** (2016) recommendations do not address thermography.

## SUPPLEMENTAL INFORMATION

None.

## CODING & BILLING INFORMATION

**CPT Codes***

| 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 Codes***

| 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 Code**

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

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

## APPROVAL HISTORY

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| **8/10/2022** | Policy reviewed, no changes to coverage criteria. Updated Reference section. |
| **8/11/2021** | Policy reviewed, no changes to criteria, updated references. |
| **6/17/2020** | Policy reviewed, no changes to criteria, updated references. |
| **6/19/2019** | Policy reviewed, no changes to criteria. |
| **3/8/2018** | Policy reviewed, no changes to criteria. |
| **1/1/2016** | Policy reviewed, revised to include breast-specific gamma imaging (BSGI) – another test used for breast cancer screening. Both |

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|---|---|
| | thermography and BSGI are outlined as experimental, investigational breast cancer screening tests. |
| **12/16/2015** | Policy reviewed, no changes. |
| **12/11/2013** | New policy. |

## REFERENCES

**Government Agencies**

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National Coverage Determination (NCD) – Thermography (220.11). Available from CMS. Published December 21, 1992. Accessed July 11, 2022.
2. United States Food and Drug Administration (FDA) Center for Devices and Radiological Health. 510(k) premarket notification (search product code "IYM" [telethermographic system], "LHQ" (telethermographic system for adjunctive use). Available from FDA. Accessed July 11, 2022.
3. United States Preventive Services Task Force (USPSTF). Breast cancer: Screening (update in progress). Available from USPSTF. Published 2016. Updated April 29, 2021. Accessed July 11, 2022.

**Evidence Based Reviews and Publications**

1. AMR Peer Review. Policy reviewed on November 13, 2013 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Radiology.
2. Elmore JG, Lee CI. Screening for breast cancer: Strategies and recommendations. Available from UpToDate. Updated April 20, 2021. Accessed July 11, 2022. Registration and login required.
3. Elmore JG, Lee CI. Screening for breast cancer: Evidence for effectiveness and harms. Available from UpToDate. Updated December 8, 2020. Accessed July 11, 2022. Registration and login required.
4. Slantez PJ. MRI of the breast and emerging technologies. Available from UpToDate. Updated November 29, 2021. Accessed July 11, 2022. Registration and login required.

**Peer Reviewed Publications**

1. Arena F, Barone C, DiCicco T. Use of digital infrared imaging in enhanced breast cancer detection and monitoring of the clinical response to treatment. Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (IEEE Cat. No.03CH37439), 2013, 2, 1129-1132 Vol.2. doi: 10.1109/IEMBS.2003.1279447. Accessed July 11, 2022.
2. Brem RF, Ioffe M, Rapelyea JA, et al. Invasive lobular carcinoma: Detection with mammography, sonography, MRI, and breast-specific gamma imaging. AJR Am J Roentgenol. 2009 Feb;192(2):379-83. doi: 10.2214/AJR.07.3827. Accessed July 11, 2022.
3. Brem RF, Floerke AC, Rapelyea JA, Teal C, Kelly T, Mathur V. Breast-specific gamma imaging as an adjunct imaging modality for the diagnosis of breast cancer. Radiology. 2008 Jun;247(3):651-7. doi: 10.1148/radiol.2473061678. Accessed July 11, 2022.
4. [1] Brem RF, Fishman M, Rapelyea JA. Detection of ductal carcinoma in situ with mammography, breast specific gamma imaging, and magnetic resonance imaging: A comparative study. Acad Radiol. 2007 Aug;14(8):945-50. doi: 10.1016/j.acra.2007.04.004. Accessed July 11, 2022.
5. [2] Brem RF, Petrovitch I, Rapelyea JA, Young H, Teal C, Kelly T. Breast-specific gamma imaging with 99mTc-Sestamibi and magnetic resonance imaging in the diagnosis of breast cancer – a comparative study. Breast J. Sep-Oct 2007;13(5):465-9. doi: 10.1111/j.1524-4741.2007.00466.x. Accessed July 11, 2022.
6. Brem RF, Rapelyea JA, Zisman G, et al. Occult breast cancer: Scintimammography with high-resolution breast-specific gamma camera in women at high risk for breast cancer. Radiology. 2005 Oct;237(1):274-80. doi: 10.1148/radiol.2371040758. Accessed July 11, 2022.
7. Kontos M, Wilson R, Fentiman I. Digital infrared thermal imaging (DITI) of breast lesions: sensitivity and specificity of detection of primary breast cancers. Clin Radiol. 2011 Jun;66(6):536-9. doi: 10.1016/j.crad.2011.01.009. Accessed July 11, 2022.

**National and Specialty Organizations**

1. American Cancer Society (ACS). Newer and experimental breast imaging tests. Available from ACS. Updated January 14, 2022. Accessed July 11, 2022.
2. American College of Obstetricians-Gynecologists (ACOG). Practice bulletin: Breast cancer risk assessment and screening in average-risk women (no. 179). Available from ACOG. Published July 2017. Reaffirmed 2021. Accessed July 11, 2022.
3. [1] American College of Radiology (ACR). Appropriateness criteria: Breast cancer screening. Available from ACR. Revised 2017. Accessed July 11, 2022.
4. [2] American College of Radiology (ACR). Practice parameter for the performance of Molecular Breast Imaging (MBI) using a dedicated gamma camera (resolution 38). Available from ACR. Adopted 2017. Accessed July 11, 2022.
5. American College of Radiology (ACR). Appropriateness criteria: Palpable breast masses. Available from ACR. Published 2016. Accessed July 11, 2022.
6. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: Breast cancer screening and diagnosis (version 4.2022). Available from NCCN. Published June 21, 2022. Accessed July 11, 2022. Registration and login required (free).
7. Society of Breast Imaging. Position statement: Breast thermography. Available from SBI. Published 2012. Accessed July 11, 2022.

**Other Peer Reviewed and National Organization Publications (used in the development of this policy)**

1. Alikhassi A, Hamidpour SF, et al. Prospective comparative study assessing role of ultrasound versus thermography in breast cancer detection. Breast Dis. 2018;37(4):191-196. doi: 10.3233/BD-180321. Accessed July 11, 2022.
2. Choi EK, Im JJ, et al. Usefulness of feature analysis of breast-specific gamma imaging for predicting malignancy. Eur Radiol. 2018 Jun 12. doi: 10.1007/s00330-018-5563-3. Accessed July 11, 2022.
3. ECRI Institute. Evidence report: Breast-specific gamma imaging for breast cancer. Available from ECRI. Published March 22, 2013. Accessed July 11, 2022.
4. Huppe AI, et al. Molecular breast imaging: a comprehensive review. Semin Ultrasound CT MR 2018 Feb;39(1):60-69. doi: 10.1053/j.sult.2017.10.001. Accessed July 11, 2022.

5. Neal CH, Flynt KA, et al. Breast imaging outcomes following abnormal thermography. Acad Radiol. 2018 Mar;25(3):273-278. doi: 10.1016/j.acra.2017.10.015. Accessed July 11, 2022.
6. Omranipour R, Kazemian A, et al. Comparison of the accuracy of thermography and mammography in the detection of breast cancer. Breast Care (Basel). 2016 Aug;11(4):260-264. doi: 10.1159/000448347. Accessed July 11, 2022.
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8. Zare I, Ghafarpour A, et al. Evaluating the thermal imaging system in detecting certain types of breast tissue masses. Biomedical Research. 2016;27(3):670-675. Accessed July 11, 2022.
9. Zhang XH, Xiao C, et al. Diagnostic value of nineteen different imaging methods for patients with breast cancer: A network meta-analysis. Cell Physiol Biochem. 2018;46(5):2041-2055. doi: 10.1159/000489443. Accessed July 11, 2022.

## APPENDIX

***Reserved for State specific information.*** *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*