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

Last Approval: 08/12/2026
Next Review Due By: August 2027

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OVERVIEW

Thermography, also referred to as digital infrared thermal imaging, measures emanating heat signatures from the surface of the skin using infrared technology and displays the temperature signatures as a colored heat graph. Warmer regions of skin may indicate the presence of precancerous tissue or tumors, as tumor development is associated with increased heat due to angiogenesis, increased metabolism, and other physiological changes. While thermography has been marketed for use in breast cancer screening, it is not a standalone screening or diagnostic tool, and a diagnosis of breast cancer must be confirmed with a biopsy (Slanetz 2025). Thermographic devices have only been FDA-cleared for adjunctive use alongside primary screening methods, such as mammography, and not as an alternative or replacement. According to the U.S. Food and Drug Administration, “there is no valid scientific data to show that thermographic devices, when used on their own or with another diagnostic test, are an effective screening tool for any medical condition, including the early detection of breast cancer or other diseases and conditions.” The FDA has released multiple warning letters and consumer updates related to thermography and has stressed that mammography is the only screening method proven to reduce deaths from breast cancer through early detection (FDA 2019, 2023).

Breast-specific gamma imaging (BSGI), also referred to as molecular breast imaging (MBI) or scintimammography, is a nuclear medicine imaging technique that utilizes a dedicated scintillation (gamma) camera to evaluate differential uptake of the injected radioactive tracer technetium-99 (Tc-99m) sestamibi, which tends to accumulate in malignant breast tissue due to increased vascularity and mitochondrial activity. The sensitivity of BSGI is not affected by breast tissue density, breast implants, or scars, unlike mammography. Some observational studies suggest that BSGI has equal sensitivity and even greater specificity than magnetic resonance imaging (MRI) in the detection of breast lesions and may serve as an alternative when MRI is indicated but not possible. However, the radiation dose associated with BSGI is 15 to 30 times greater than the dose of a digital mammogram. BSGI is primarily used in conjunction with standard imaging methods, such as mammography, to further evaluate suspicious lesions or assist in surgical planning after breast cancer diagnosis (Hayes 2014; Slanetz 2025).

Regulatory Status

Thermography

The FDA has cleared thermographic devices for medical use since the late 1970s through the 510(k) premarket notification process. Devices intended for use in breast cancer screening are only cleared as an adjunctive tool to be used alongside a primary diagnostic test like mammography. There are several FDA-cleared thermographic devices on the market, such as the FirstSense Breast Exam (First Sense Medical) and NoTouch Breastscan (UE LifeSciences Inc). For more information, search product code LHQ in the FDA 510(k) Premarket Notification Database.

Breast-Specific Gamma Imaging (BSGI)

Numerous scintillation (gamma) cameras have been cleared through the FDA 510(k) premarket notification process under product code IYX for measuring and imaging the distribution of radionuclides by means of photon detection in order to aid in the evaluation of lesions in the treat tissues and other small body parts, such as with BSGI. Notable examples of devices include the Dilon 6800 (Dilon Technologies) and LumaGEM (Gamma Medical).

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COVERAGE POLICY

Thermography, or digital infrared thermal imaging, for the imaging of breast lesions, is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

Breast specific gamma imaging (BSGI), or molecular breast imaging (MBI), for the imaging of breast lesions, is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

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

Systematic Reviews and Meta-Analyses

Goñi-Arana et al. (2024) performed a systematic review and meta-analysis to evaluate the diagnostic accuracy of digital, long-wave infrared breast thermography as a tool for breast cancer screening and diagnosis. Although breast thermography originated in the 1950s and has largely been abandoned due to contradictory results, recent advances in infrared technology and image processing algorithms have led to renewed interest in the technology. The review included 22 studies published between 2001 and 2023, with sample sizes ranging from 25 to 3,000 participants per study. Most studies involved patients undergoing diagnostic workups for suspicious findings, though some more recent studies included asymptomatic women. The meta-analysis reported a pooled sensitivity of 88.5 to 88.67% and a pooled specificity of 71.8%, although specificity varied significantly across studies. I^2 was 79.3% for sensitivity and 99.1% for specificity, indicating extremely high variability in how well thermography avoids detecting false positives. A bivariate meta-analysis confirmed these pooled values and highlighted a 95% predictive region, indicating high heterogeneity and variability, especially in specificity. Studies used both static and dynamic imaging protocol, various thermal camera technologies with thermal sensitivities ranging from 0.02K to 0.1K, and different interpretation strategies (e.g., visual analysis, proprietary software, and machine learning algorithms. Lack of standardized protocols, interpretation criteria, and a variable patient selection contributed to significant heterogeneity. 10 of the 22 studies had potential conflicts of interest, being supported by manufacturers of thermographic equipment or analysis software. The authors concluded that breast thermography shows promise as a high-sensitivity imaging modality and may be particularly useful as an adjunct to mammography, especially in women with dense breasts. In low-resources settings, it may serve as a cost-effective companion to ultrasound. The authors emphasized that large, high-quality prospective studies and cost-effective analyses are needed to establish clinical utility and to determine optimal imaging strategies across different populations.

Aboagye et al. (2024) performed a systematic review to evaluate the recent advances in portable, non-invasive technologies for early breast cancer detection, including infrared thermography, microwave imaging, electrical impedance tomography, bioimpedance spectroscopy, and pressure sensing. Most studies were early-stage and heterogeneous in design, with about 60% relying on phantom models or small-scale human trials, with sample sizes ranging from 1 to 478 participants. Thermography paired with artificial intelligence (AI) achieved 89% sensitivity and 83% specificity in the largest study (n = 478). In another study of 201 participants, a thermography device, the Cyrcadia Breast Monitor, achieved 83.6% sensitivity, 71.5% specificity, and 78% overall accuracy in differentiating benign from malignant lesions. Overall, thermography, particularly when paired with smartphone-technology and AI-integration, offers significant accuracy and accessibility in some studies, though specificity remains a concern and imaging protocols vary widely. Microwave imaging and electrical impedance tomography were found to be the most promising for early detection of small tumors (≤5-10mm), especially because of their ability to differentiate tissue dielectric or

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conductivity properties without ionizing radiation. However, microwave imaging requires complex signal processing and electrical impedance tomography suffers from limited spatial resolution and sensitivity to electrode placement. For limitations, most of the studies had small participant numbers, lack of standardization, or overreliance on simulated data, leading to a high potential for bias. The authors concluded that while portable, non-invasive technologies show promise for breast cancer screening, especially in underserved areas, further research is needed to validate their clinical efficacy, address implementation challenges, and assess impact on patient outcomes before widespread adoption can be recommended.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Harish et al. (2026) conducted a single-center, comparative study to compare the diagnostic accuracy of infrared thermography to standard mammography for the detection of breast cancer. A total of 30 participants between the ages of 20 and 60 years were included. Exclusion criteria included male patients, females outside of the specified age range, participants receiving chemotherapy or radiotherapy for the same pathology, and those with clinically apparent inflammatory breast conditions. A total of 34 participants were included with a mean age of 51.8±7.07 years. Each participant completed thermographic imaging with frontal, superior, and lateral imaging views obtained in a similar temperature-controlled setting. A difference of 2.5-3°C was considered benign pathology and differences > 3°C were considered suggestive of malignant pathology. Lesions were classified according to BI-RADS categories and BI-RADS 4 or 5 were considered malignant. Following imaging, each participant completed mammography and appropriate histopathology (fine-needle aspiration, core needle biopsy, etc.). Histopathological testing served as the gold standard for validation. Ten benign cases and 24 malignant cases were identified among participants. Breast density was significantly associated with malignancy ($p < 0.001$) and malignant cases were predominantly type B (n = 13, 54.2%) and type C (n = 9, 37.5%). Mammography demonstrated a higher sensitivity (95.8%, 95% CI 78.9-99.9%) compared to infrared thermography (75.0%, 95% CI 53.3-90.2%). The overall diagnostic accuracy of mammography was 92.3% (95% CI 74.9-99.1%) compared to 82.4% (95% CI 65.5-93.2%) for infrared thermography. Researchers noted that infrared thermography does not have the diagnostic performance to replace mammography but can serve as a valuable adjunct for the diagnosis of breast cancer.

Wang et al. (2023) conducted a prospective, multicenter, cohort study to evaluate the diagnostic accuracy of a novel, portable AI assisted infrared thermography system (AI-IRT) for pre-clinical breast cancer screening. The clinical trial aimed to address the global lack of access to conventional breast cancer screening by developing a mobile phone-based system using a wearable infrared camera and AI algorithm that classifies breast cancer risk based on thermal imaging. The study enrolled 2,202 participants, with 2,100 used for model development, internal validation, and testing (Dataset A), while 102 were used for external validation and reader comparison (Dataset B). Two different AI models were developed, a binary model and multinomial model. Both models were trained with thermal images, model performance was evaluated against standard imaging modalities (e.g., ultrasound, mammography, MRI) and pathological findings and results were validated against clinician assessments in a reader comparison. Six clinicians (three radiologists and three surgeons with 6-28 years of experience) assessed 102 cases from Dataset B. The AI-IRT binary model outperformed average clinician accuracy (86.27% vs. 80.88%), showed higher specificity (83.87% vs. 63.44%), and positive predictive value (92.31% vs. 84.74%). A major limitation of the study is that clinicians had limited experience with infrared thermography interpretation, and there were constraints related to image quality control and guideline standardization. The authors concluded that the AI-IRT system is a promising, noninvasive, radiation-free, and cost-effective tool for large-scale, home-based breast cancer pre-clinical screening. This technology could improve early detection rates and access to screening, particularly in under-resourced areas. (ClinicalTrials.gov NCT04761211).

Kakileti et al. (2020) conducted a cross-sectional, observational study to evaluate the clinical efficacy of Thermalytix, an AI-based computer-aided diagnostic tool (CADx) that analyzes thermal images to detect malignancies. The study enrolled 470 (n = 470) women aged 18 to 82 years who presented for breast health evaluation, with 238 being symptomatic (e.g., breast lump, pain, nipple discharge) and 232 being asymptomatic. All participants underwent a Thermalytix test and one or more standard of care tests for breast cancer screening, such as mammography, ultrasonography, elastography, fine needle aspiration cytology, and/or biopsy. Results were evaluated in a blind manner. Thermalytix demonstrated an overall sensitivity of 91.02% and specificity of 82.39% in detecting breast malignancies. Of the asymptomatic population, performance was higher, where sensitivity reached 100% and specificity reached 92.41%. Thermalytix showed an overall area under the curve of 0.90 (0.82 for symptomatic women and 0.98 for asymptomatic women. In comparison, mammography showed higher specificity (94.05%) but lower

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sensitivity (85.96%). Among 24 malignant tumors < 2 cm (T1 stage) in asymptomatic women < 40 years old, Thermalytix identified 71% of lesions while mammography identified 68% of lesions. The authors concluded that Thermalytix offers a promising, affordable, portable, and scalable option for breast cancer screening, especially in low to middle income countries where access to mammography is limited. The authors also highlight its potential for early detection, particularly in younger women and those with dense breast tissue.

Omranipour et al. (2016) conducted a prospective study comparing mammographic versus thermographic images in 132 women found to be candidates for breast biopsy based on clinical examination and medical history. The median age of the participants was 49.5 ± 10.3 years, and the final pathological result yielded 87 malignancies and 45 benign lesions. The images were analyzed blind to biopsy results. Mammography revealed an 80.5% sensitivity rate, a 73.3% specificity rate, 85.4% positive predictive value rate, and a 66% negative predictive value rate. Thermography yielded an 81.6% sensitivity rate, a 57.8% specificity rate, a 78.9% positive predictive value rate, and a 61.9% negative predictive value rate. The results revealed thermography cannot substitute mammography in early diagnosis of breast cancer, however it shows promise as an adjunctive screening and diagnostic tool.

Wishart et al. (2010) conducted a study on 100 women comparing differing thermographic analysis tools prior to the participants undergoing biopsy. One hundred and six biopsies were performed on 100 participants resulting in 65 malignancies and 41 benign lesions. The participants were scanned prior to the biopsy using a digital infrared breast scan (Sentinel BreastScan) and the images were analyzed in four ways, blind to biopsy results. The highest accuracy rate of a single method was via expert manual review with a sensitivity of 78%, followed by novel AI program, NoTouch BreastScan, with a 70% sensitivity. The Sentinel screening report yielded a low 53% sensitivity rate, and Sentinel AI only had a 48% sensitivity. NoTouch BreastScan exhibited a higher sensitivity and specificity of 78% and 75% respectively, in women under 50 years old. The combination of thermography analyzed with NoTouch BreastScan technology paired with a mammogram exhibited an 89% sensitivity, showing that thermography as an adjunct to be an effective screening tool, especially in younger women.

Breast Specific Gamma Imaging (BSGI)

Systematic Reviews and Meta-Analyses

De Feo et al. (2022) conducted a systematic review that analyzed studies that compared at least one anatomical imaging modality - ultrasound (US), mammography (MMG), and/or MRI - with BSGI. A total of 15 studies met inclusion criteria, all of which were determined to have low risk of bias and applicability concerns. The results were as follows: BSGI had a similar sensitivity and a higher specificity than MRI. BSGI had a higher specificity, positive predictive value, and negative predictive value compared to US and MMG. When utilized in the evaluation for suspected breast lesions, sensitivity was higher with BSGI than without. The authors concluded BSGI is a valuable imaging modality, however the increased radiation burden associated with BSGI must be considered when determining best clinical use.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Zhang et al. (2020) conducted a retrospective comparative study on the diagnostic accuracy of MMG and US versus MMG and BSGI. Three hundred and sixty-four women with both mammographically dense breasts and a final surgical/biopsy pathological diagnosis were included in the study. BSGI in conjunction with MMG had a higher specificity rate (Sp-Difference 10.3%, p = 0.003) than MMG and US; however, there was no difference in the enhancement of MMG diagnostic sensitivity between BSGI and US. The area under the ROC curve showed that MMG and BSGI had better diagnostic accuracy than MMG and US (0.90 vs. 0.83, p = 0.0019).

Liu et al. (2020) conducted a retrospective review of 390 patients who had undergone diagnosis and treatment at a single breast surgery center. All patients were imaged with BSGI, mammography, ultrasound, and MRI; and the resulting diagnostic accuracy data between the differing imaging techniques was compared. BSGI, MRI, mammography, and ultrasound yielded respective sensitivity values of 91.7, 92.5, 77.3, and 82.1%, while the respective specificity values for these imaging modalities were 80.7, 69.7, 74.5, and 70.8%. For lesions > 1 cm, BSGI offered a sensitivity of 92.5%. For mammographic breast density A, B, C, and D, BSGI offered a sensitivity of 93.3, 94.0, 91.5, and 89.3%, respectively; and yielded a significantly higher lesion-to-normal lesion ratio (LNR) for malignant lesions relative to benign lesions (2.76 ± 1.32 vs 1.46 ± 0.49).

Zhan et al. (2020) conducted a retrospective review of 177 women diagnosed with BI-RADS4 category lesions via ultrasound/mammography who then underwent BSGI for confirmation. The specificity and positive predictive values of

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BSGI were 78.3% (47/60) and 89.5% (111/124) respectively, versus mammography at 48.3% (29/60) and 77.5% (107/138), and ultrasound at 53.3% (32/60) and 79.6% (109/137). The sensitivity and specificity of BSGI for the detection of lesions ≤1 cm in size were 90.9% (10/11) and 88.0% (22/25), respectively, while for breast lesions >1 cm in size these values were 94.3% (100/106) and 71.4% (25/35). In addition, BSGI sensitivity and specificity values for dense breast tissue were 94.0% (79/84) and 78.0% (39/50), respectively, whereas for non-dense breast tissue these values were 97.0% (32/33) and 80.0% (8/10). The sensitivity of BSGI for invasive ductal carcinomas and ductal carcinomas in situ (DCIS) was 98.9% (95/96) and 75.0% (9/12), respectively; and the tumor to normal tissue ratio of BSGI for malignant lesions was significantly higher than for benign lesions (2.18 ± 1.17 vs 1.66 ± 0.40, t = 7.56, P<0.05). The authors concluded that BSGI is a highly sensitive detection tool, especially in invasive ductal carcinoma cases.

National and Specialty Organizations

The **U.S. Preventive Services Task Force (USPSTF)** (2024) recommends biennial screening mammography for all women aged 40 to 74 years. This is a Grade B recommendation, which means the USPSTF recommends this service as there is high certainty of a moderate net benefit. For women with dense breasts who have a negative mammogram screening, the USPSTF states that current evidence is insufficient to assess the balance of benefits and harms of supplemental screening using ultrasonography or MRI. Evidence is lacking, conflicting, or of poor quality. The USPSTF also notes that both digital mammography and digital breast tomosynthesis are effective mammographic screening modalities.

The **American College of Radiology (ACR)** (2025) published appropriateness criteria for female breast cancer screening. The document indicates that BSGI is usually not appropriate and has a high relative radiation level. According to the ACR, evidence supporting the use of BSGI for screening females is limited, including those with average, intermediate, and high risk. Most studies have focused on females with dense breasts and variable risk profiles.

Additionally, the **ACR** (2024) published appropriateness criteria for supplemental breast cancer screening based on breast density. The document indicates that BSGI is usually not appropriate and has a high relative radiation level. According to the ACR, there is insufficient evidence to support the use of Tc-99m sestamibi molecular breast imaging as a supplemental screening exam in average-risk, intermediate-risk, and high-risk women with heterogeneously dense tissue.

The **ACR** (2022) also published a practice parameter for the performance of BSGI using a dedicated gamma camera. According to the ACR, in general, BSGI may be indicated for breast cancer screening when MRI is not feasible. While mammography is the first-line tool for breast cancer screening for all women, additional MRI screening is recommended for high-risk women. However, approximately 15% of patients cannot undergo MRI for reasons such as claustrophobia, kidney disease, non-compatible metallic implants, and body size. BSGI may serve as a supplemental screening option for these high-risk patients who cannot undergo MRI. Additionally, BSGI may also be an alternative to MRI to evaluate the extent of disease in newly diagnosed breast cancer patients, to evaluate response to neoadjuvant chemotherapy, evaluating tumor recurrence, lesion characterization, and metastatic axillary lymphadenopathy without evidence of a primary malignancy. Contraindications to BSGI include pregnancy due to full body ionizing radiation, and allergy to technetium.

The **Society of Breast Imaging (SBI)**, in collaboration with the **ACR**, released updated recommendations on breast cancer screening in 2021 for women at average risk (Monticciolo et al. 2021). The guidelines recommend annual mammography screening beginning at age 40. The guidelines also recognize the growing evidence of supplemental screening technologies, including MRI, whole breast ultrasound, contrast-enhanced mammography, and molecular breast imaging to detect lesions after a negative mammographic screening. However, there is insufficient evidence to support supplemental screening in average-risk women. Digital mammography, digital breast tomosynthesis, ultrasound, and MRI, were the supplemental screening modalities most reviewed.

The **SBI**, in a position statement about breast cancer screening for women at higher-than-average risk, recommends annual screening beginning at age 40 for women of average risk, and earlier or more intensive screening for women at higher-than-average risk. The SBI notes that MRI is the supplemental screening method of choice for most women. The SBI also recommends women with personal history of breast cancer and with dense breasts, or who are diagnosed

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with breast cancer before the age of 50, should undergo supplemental MRI screening annually. For women with dense breasts who desire supplemental screening, the SBI recommends breast MRI. For those who cannot undergo MRI when indicated, the SBI recommends contrast-enhanced mammography or ultrasound (Monticciolo et al. 2023).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
78800	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (e.g., head, neck, chest, pelvis), single day imaging
78801	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, 2 or more areas (e.g., abdomen and pelvis, head and chest), 1 or more days imaging or single area imaging over 2 or more days
93740	Temperature gradient studies (when used for breast thermography)

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
A9500	Technetium Tc-99m sestamibi, diagnostic, per study dose (when used for BSGI)
S8080	Scintimammography (radioimmunoscintigraphy of the breast, unilateral), including supply of radiopharmaceutical

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

08/12/2026	Policy reviewed, no changes to criteria.
08/13/2025	Policy reviewed. No change to coverage criteria.
08/14/2024	Policy reviewed, no changes to criteria. Updated Summary of Medical Evidence and References.
08/09/2023	Policy reviewed, no changes to criteria. IRO Peer Review on July 24, 2023, by a practicing physician board-certified in Diagnostic Radiology.
08/10/2022	Policy reviewed, no changes to criteria.
08/11/2021	Policy reviewed, no changes to criteria.
06/17/2020	Policy reviewed, no changes to criteria.
06/19/2019	Policy reviewed, no changes to criteria.
03/08/2018	Policy reviewed, no changes to criteria.
01/01/2016	Policy reviewed, revised to include breast-specific gamma imaging (BSGI) – another test used for breast cancer screening.
12/16/2015	Policy reviewed, no changes.
12/11/2013	New policy.

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