

Subject: Thermography for the Detection of Breast Lesions		Original Effective Date: 12/11/13
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PREFACE

This Medical Guidance 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 exclusions 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 following website: <http://www.cms.hhs.gov/center/coverage.asp>.

FDA INDICATIONS

The Food and Drug Administration (FDA) regulates thermographic systems such as those used for breast cancer detection as Class II devices and numerous systems have been approved via the FDA 510(k) process. These devices have been classified by the FDA as suitable for stand-alone use or as adjuncts to other methods for the detection of breast cancer.³

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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 medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS has established a non-coverage policy in its National Coverage Determination (NCD) #220.11 for thermography, which specifically mentions breast lesions. This NCD, which was last updated in February 1994, excludes thermography from Medicare coverage for any indication since it is considered ineffective as an aid to diagnosis or treatment.²

INITIAL COVERAGE CRITERIA

Thermography also referred to as digital infrared thermal imaging (DITI) and temperature gradient studies for the diagnosis of breast lesions is considered investigational as 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.

CONTINUATION OF THERAPY

Thermography for the diagnosis of breast lesions is considered investigational as the technology is unproven.

COVERAGE EXCLUSIONS

Thermography for the diagnosis of breast lesions is considered investigational as the technology is unproven.

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.

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.

GENERAL INFORMATION

Summary of Medical Evidence

There is no evidence that breast thermography alters patient management or that it impacts long-term outcomes including breast cancer mortality.

Vreugdenburg et al. (2013) performed a systematic review to identify and evaluate all the available evidence of safety, effectiveness and diagnostic accuracy for three emerging classes of technology promoted for breast cancer screening and diagnosis: Digital infrared thermal imaging (DITI), electrical impedance scanning (EIS) and elastography. The principal outcome measures were safety, effectiveness, and diagnostic accuracy. From

6,808 search results, 267 full-text articles were assessed, of which 60 satisfied the inclusion criteria. No effectiveness studies were identified. Only one EIS screening accuracy study was identified, while all other studies involved symptomatic populations. Significant heterogeneity was present among all device classes, limiting the potential for meta-analyses. Sensitivity and specificity varied greatly for DITI (Sens 0.25-0.97, Spec 0.12-0.85), EIS (Sens 0.26-0.98, Spec 0.08-0.81) and ultrasound elastography (Sens 0.35-1.00, Spec 0.21-0.99). The authors concluded that there is currently insufficient evidence to recommend the use of these technologies for breast cancer screening. Moreover, the high level of heterogeneity among studies of symptomatic women limits inferences that may be drawn regarding their use as diagnostic tools. Future research employing standardized imaging, research and reporting methods is required.¹⁸

Fitzgerald and associates (2011) performed a systematic review to determine the effectiveness of digital infrared thermography for the detection of breast cancer in a screening population, and as a diagnostic tool in women with suspected breast cancer. A comprehensive search of electronic databases together with a search of international websites was conducted. Diagnostic studies comparing thermography with mammography for screening in asymptomatic populations; or comparing thermography with histology in women with suspected breast cancer; were eligible for inclusion. Quality of included studies was appraised using the QUADAS criteria. One study reported results for thermography in screening population and five studies reported diagnostic accuracy of thermography in women with suspected breast cancer. Overall, studies were of average quality. Sensitivity for thermography as a screening tool was 25% (specificity 74%) compared to mammography. Sensitivity for thermography as a diagnostic tool ranged from 25% (specificity 85%) to 97% (specificity 12%) compared to histology. The authors concluded that currently there is insufficient evidence to support the use of thermography in breast cancer screening, nor is there sufficient evidence to show that thermography provides benefit to patients as an adjunctive tool to mammography or to suspicious clinical findings in diagnosing breast cancer.¹⁶

Kontos and colleagues (2011) sought to determine the sensitivity and specificity of digital infrared thermal imaging (DITI) in 63 women who underwent surgical excision or core biopsy of benign and malignant breast lesions presenting through the symptomatic clinic. Thermography had 90 true-negative, 16 false-positive, 15 false-negative and 5 true-positive results. The sensitivity was 25%, specificity 85%, positive predictive value 24%, and negative predictive value 86%. The authors concluded that despite being non-invasive and painless, because of the low sensitivity for breast cancer, DITI is not indicated for the primary evaluation of symptomatic patients nor should it be used on a routine basis as a screening test for breast cancer.¹³

Arora and colleagues (2008) reported on the role of digital infrared thermal imaging (DITI) in the detection of breast cancer. In this prospective clinical trial, 92 patients for whom a breast biopsy was recommended based on prior mammogram or ultrasound underwent DITI. Three scores were generated: an overall risk score in the screening mode, a clinical score based on patient information and a third assessment by artificial neural network. Sixty of 94 biopsies were malignant and 34 were benign. DITI identified 58 of 60 malignancies, with 97% sensitivity, 44% specificity, and 82% negative predictive value depending on the mode used. Compared to an overall risk score of 0, a score of 3 or greater was significantly more likely to be associated with malignancy (30% vs 90%, $P < .03$).¹⁴

Amalu (2004) presented unpublished results of a smaller study of DIRI at the 2004 EMBS meeting. For this study, 23 women with known breast cancer underwent DIRI with the cold challenge performed by submersion of their hands in ice water for 1 minute. The sensitivity of DIRI was only 52%, much lower than the sensitivity reported in the other available studies of DIRI but this may be due to differences in the type of cold challenge used. This study did not report the sensitivity or specificity of mammography alone or in combination with DIRI.¹²

Parisky and colleagues (2003) performed the largest available peer-reviewed study of DIRI for breast cancer detection. 1293 patients were recruited who underwent infrared thermography in an exam that included a cold air challenge provided by a Breast Cancer System 2100 (Computerized Thermal Imaging (CTI), Ogden, UT). Due to technical problems that degraded image quality, DIRI did not provide evaluable results for 229 (18%) patients. For another 295 (23%) patients, DIRI results could not be used because of protocol violations or problems with the mammogram. In the remaining 769 patients, there were 875 suspicious lesions that underwent biopsy. Based on mammograms and other clinical information, three radiologists who were blinded to the biopsy results identified regions of interest on the DIRI scans. The system software then calculated an index of suspicion or probability of malignancy for the area of interest, using an algorithm based on biopsy data from the early stages of the study. Although the results showed that DIRI had a 97% sensitivity and 95% NPV due to a small number of false-positive readings, these high values may be inaccurate due to the exclusion of DIRI scans that were not evaluable due to poor image quality. The reported sensitivity and specificity may also be inaccurate because image interpretations were excluded when the region of interest selected by the radiologist fell outside the region indicated by the case report. In addition to potential errors in the sensitivity and NPV reported, DIRI had only 14% specificity and 24% PPV. These poor outcomes were due to a large number of false-positive results.⁹

In an unpublished study presented at the 2003 Annual International Conference of the Engineering in Medicine and Biology Society (EMBS), Arena et al. (2003) reported the following diagnostic values for digital DIRI with automated interpretation: 98% sensitivity, 55% specificity, 62% PPV, and 99% NPV. This study did not report comparable outcomes for mammography alone or combined with DIRI. The patient population consisted of 238 women with no known cancer and 67 women with newly detected, biopsy-proven breast cancer (prevalence 22%).¹¹

Keyserlingk and colleagues (1998) conducted a peer-reviewed study of static IRI for breast cancer detection. For this study, 100 women with known Stage I or II breast cancer were enrolled to assess the sensitivity of thermography versus other methods. Results of this study indicated that IRI has 83% sensitivity, as does mammography combined with a clinical exam. When IRI, mammography, and clinical exam were combined, sensitivity increased to 98% but the investigators did not report whether this increase was statistically significant. Similarly, 100 women who were shown to have benign lesions were enrolled to determine specificity of breast cancer detection, which was 81% for IRI versus 70% for mammography; however, the

investigators did not report whether this difference was statistically significant nor did they report if IRI combined with mammography improved specificity.¹⁰

Hayes, Cochrane, UpToDate, MD Consult etc.

Hayes:

There is a Hayes Health Technology Brief for Digital Infrared (Thermography) for the Detection of Breast Cancer last updated July 2008. This report outlines that the results of the reviewed studies suggest that dynamic infrared imaging (DIRI) has high sensitivity and poor to moderate specificity for detection of breast cancer. DIRI incorrectly identifies many benign masses as being malignant. None of the available studies determined whether the sensitivity and/or specificity of diagnosis improved when DIRI was combined with mammography. There is no evidence that breast thermography alters patient management or that it impacts long-term outcomes including breast cancer mortality.¹

UpToDate:

In a report called Breast Cancer Screening a section on thermography outlines that the use of thermography to detect occult breast cancer was based on the observation that patients have elevated breast skin temperatures over their breast cancers. It was first investigated for screening in the Breast Cancer Detection Demonstration Project in the 1970s and was found to have poor test characteristics, with a false positive rate of 25 percent and a false negative rate of more than 60 percent. In 2004 a breast thermography device received approval from the US Food and Drug Administration (FDA) on the basis of prior approval for infrared imaging technology, because of demonstrated safety but not necessarily efficacy. The specificity of thermography remains very low, even with modern equipment. Despite this, a number of thermography centers have been established in several US cities. No major organization making screening recommendations recommends thermography. The US FDA issued a safety communication in June 2011 notifying consumers that thermography is not a replacement for screening mammography and that thermography on its own is not an effective screening tool Patients should be advised that thermography is not recommended as a modality for breast cancer screening.^{6 17}

Professional Organizations

American College of Obstetricians and Gynecologists (ACOG)⁷

The updated (2011) breast cancer screening guidelines from ACOG do not mention thermography as a screening technique. The following techniques were considered but not recommended: ultrasonography, magnetic resonance imaging, color Doppler ultrasonography, computer-aided detection, positron emission tomography, scintimammography, and breast digital tomosynthesis.

American College of Radiology (ACR)¹⁵

The ACR breast cancer screening appropriateness criteria (2012) indicate that there is insufficient evidence to support the use of other imaging modalities such as thermography, breast specific gamma imaging (BSGI), positron emission mammography (PEM), or optical imaging for breast cancer screening. Radiation dose from BSGI and PEM are 15-30 times higher than the dose of a digital mammogram, and they are not indicated for screening in their present form.

American Medical Association (AMA)⁸

The American Medical Association has issued the following policy statement called H-175.988 Thermography Update:

- “(1) In view of the lack of sufficient proof of effectiveness, it is the policy of the AMA that the use of thermography for diagnostic purposes cannot be recommended at this time. It should be noted that research protocols using thermography are continuing and data derived from these studies will require careful evaluation.
- (2) The AMA will continue to monitor the published literature on thermography, with periodic reports as appropriate.
- (3) The AMA affirms the principle that proponents of a test, procedure, or treatment should bear the burden of proving that it is safe and effective for the proposed purpose through well-designed and well-controlled clinical trials. The results of these trials should be critically reviewed, preferably through reports submitted to peer-reviewed journals. “

The Society of Breast Imaging (SBI)¹⁹

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	
CPT	Description
93740	Temperature gradient studies

ICD-9	Description
174- 174.9	Malignant neoplasm of female breast
175.9	Malignant neoplasm of male breast

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

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