Thermography

**Description**

Thermography is a noninvasive imaging technique that is intended to measure temperature distribution of skin temperature based on dermal blood flow. In turn, this temperature distribution is postulated to reflect the physiologic status of deeper organs and tissues. The visual display of this temperature information is known as a thermogram. Thermography has been proposed as a diagnostic tool for a variety of conditions as a diagnostic, for treatment planning and to evaluate the effects of treatment.

**Background**

Thermography involves the use of an infrared scanning device and can include various types of telethermographic infrared detector images and heat-sensitive cholesteric liquid crystal systems. Infrared radiation from the skin or organ tissue reveals temperature variations by producing brightly colored patterns on a liquid crystal display. Interpretation of the color patterns is thought to assist in the diagnosis of many disorders such as complex regional pain syndrome (previously known as reflex sympathetic dystrophy), breast cancer, Raynaud phenomenon, digital artery vasospasm in hand-arm vibration syndrome, peripheral nerve damage following trauma, impaired spermatogenesis in infertile men, degree of burns, deep vein thrombosis, gastric cancer, tear-film layer stability in dry-eye syndrome, Frey syndrome, headaches, low-back pain, and vertebral subluxation.

Thermography may also assist in treatment planning and procedure guidance such as identifying restricted areas of perfusion in coronary artery bypass grafting, identifying unstable atherosclerotic plaque, assessing response to methylprednisone in rheumatoid arthritis, and locating high undescended testicles.

**Regulatory Status**

In 2002, the Dorex Spectrum 9000 MD Thermography System (Dorex Inc.; Orange, CA) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in quantifying and visualizing skin temperature changes. Its indicated use is as an aid in diagnosis and follow-up therapy in areas such as orthopedics, pain management, neurology, and diabetic foot care. This type of device is also known as a telethermographic system. FDA product code: LHQ.
In 2003, several telethermographic cameras (series A, E, P, S) by Flir Systems (McCordsville, IN) were cleared for marketing by FDA through the 510(k) process. Their intended use is as an adjunct to other clinical diagnostic procedures when there is a need for quantifying differences in skin surface temperature. Between 2006 and 2009, 3 new or updated thermography devices received 510(k) marketing clearance from FDA based on demonstrating substantial equivalence to existing products. FDA product code: LHQ.

**Related policies**

6.01.18 Scintimammography and Gamma Imaging of the Breast and Axilla  
6.01.29 Magnetic Resonance Imaging of the Breast  
6.01.53 Digital Breast Tomosynthesis

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

The use of all forms of thermography is considered **not medically necessary.**

**Rationale**

**Breast Cancer**

Breast cancer is the potential application of thermography with the most published literature. No studies have demonstrated how the results of thermography can be used to enhance patient management and/or improve patient health outcomes in breast cancer. Several systematic reviews of the published literature on diagnostic accuracy were identified. A 2012 systematic review identified 6 studies, 1 study using thermography for breast cancer screening and 5 using thermography to diagnose breast cancer among symptomatic women or those with a positive mammogram. (1) In the screening study, more than 10,000 women were invited to participate, and sample sizes in the diagnosis studies ranged from 63 to 2625 subjects. The screening study found that, compared with mammography, thermography had a sensitivity of 25% and specificity of 74%. In the diagnostic studies, which all used histology as the reference standard, sensitivity ranged from 25% to 97% and specificity ranged from 12% to 85%.

In addition, a 2013 systematic review identified 8 studies on thermography for diagnosis of breast cancer that included a valid reference standard. (2) Six of the 8 studies, with sample sizes between 29 and 769 patients, included women scheduled for biopsy. The accuracy of thermography was highly variable. Sensitivity in the individual studies ranged from 25% to 97% and specificity ranged from 12% to 85%. Study findings were not pooled.

In addition to the systematic reviews, in 2014 a diagnostic accuracy study was published by Rissiwala et al in India. (3) The study included 1008 women who were being screened for breast cancer. Following infrared breast thermography, 959 women were classified as normal (temperature gradient, <2.5), 8 as abnormal (temperature gradient between 2.5 and 3) and 41 as potentially having breast cancer (temperature gradient, ≥3). Women who tested positive on thermography (n=49) underwent clinical, radiologic, and histopathologic examination. Forty-one of 49 women with positive thermograms
were found to have breast cancer. The authors calculated the sensitivity of thermography to be 97.6% and the specificity to be 99.17%. The study was limited because women who had normal thermograms did not undergo radiologic reference tests, only clinical examination, and thus the false-negative rate cannot be accurately calculated.

**Other Potential Indications**

A number of other studies have been published on a range of potential applications of thermography. None of these studies have examined the impact of thermography on patient management decisions or health outcomes. Examples of other studies on thermography, all conducted outside of the United States, include evaluating the association between thermographic findings and postherpetic neuralgia in patients with herpes zoster, (4, 5) surgical site healing in patients who underwent knee replacements, (6) ulcer healing in patients with pressure ulcers, (7) posttreatment pain in patients with coccygodynia, (8) evaluation of allergic conjunctivitis, (9) early diagnosis of diabetic neuropathy (10) or diabetic foot infection (11) and differentiating between melanoma and benign cutaneous lesions. (12)

A 2014 systematic review by Sanchis-Sanchez evaluated the literature on thermography for diagnosis of musculoskeletal injuries. (13) To be included in the review, studies needed to report on diagnostic accuracy and use findings from diagnostic imaging tests (eg, radiographs, computed tomography, magnetic resonance imaging, or ultrasound) as the reference standard. Six studies met the eligibility criteria; 3 included patients with suspected stress fractures, and the remainder addressed various other musculoskeletal conditions. Sample sizes of individual studies ranged from 17 to 164 patients. In the 3 studies on stress fracture, sensitivity ranged from 45% to 82% and specificity from 83% to 100%. Pooled specificity was 0.69 (95% confidence interval, 0.49 to 0.85); data on sensitivity were not pooled.

**Practice Guidelines and Position Statements**

The 2011 American College of Radiology statement on myelopathy states that there is no high-quality evidence in support of thermography. (14)

The 2012 American College of Radiology statement on breast imaging states that there is insufficient evidence to support the use of thermography for breast cancer screening. (15)

The 2011 American College of Obstetricians and Gynecologists practice bulletin on breast cancer did not address thermography as a screening option. (16)

The 2013 Council on Chiropractic Practice updated clinical practice guideline includes the following recommendation on skin temperature instrumentation (17): “Temperature reading devices employing thermocouples, infrared thermometry or thermography (liquid crystal, telethermography, multiple IR detectors, etc.) may be used to detect temperature changes in spinal and paraspinal tissues related to vertebral subluxation.” The recommendation remains unchanged from 2008. (18) It was based on expert opinion and literature support in the form of observational, pre-post, and/or case studies but not controlled studies.
The 2011 Work Loss Institute guidelines include statements that thermography is not recommended for acute and chronic neck and upper back pain and that thermography is not recommended for treating chronic pain. (19, 20)

U.S. Preventive Services Task Force Recommendations

Not applicable

Summary

There is insufficient evidence to support the use of thermography. Sufficient data are lacking that thermography can accurately diagnose any condition or improve the accuracy of another diagnostic tool. Moreover, there are no published studies evaluating the impact of thermography on patient management or health outcomes. Thus, thermography is considered not medically necessary.

Medicare National Coverage

Medicare considers thermography as ineligible for coverage. The Medicare coverage policy, current as of April 2011 states, “Thermography for any indication (including breast lesions which were excluded from Medicare coverage on July 20, 1984) is excluded from Medicare coverage because the available evidence does not support this test as a useful aid in the diagnosis or treatment of illness or injury. Therefore, it is not considered effective. This exclusion was published as a CMS Final Notice in the "Federal Register" on November 20, 1992.”

References


This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 18, 2015 and is effective October 15, 2015.

Signature on file
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