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Medical Policy Manual

Topic: Thermography

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Section: Radiology

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Thermography is a noninvasive imaging technique that is intended to measure temperature distribution of organs and tissues. This technique is commonly called infrared, thermal imaging, digital infrared thermal imaging (DITI), and temperature gradient studies. The visual display of this temperature information is known as a thermogram and it consists of brightly colored patterns on a liquid crystal display. It is thought that temperature differences associated with changes in metabolic activity (such as metabolic increases seen in regions with cancer) can be identified through color differences on a visual display, leading some to propose thermography as a diagnostic tool for a variety of conditions, including but not limited to:

- Complex regional pain syndrome ([CRPS] previously known as reflex sympathetic dystrophy)
- Breast cancer
- Raynaud's phenomenon
- Digital artery vasospasm in hand-arm vibration syndrome
- Peripheral nerve damage following trauma
- Impaired spermatogenesis in infertile men
- Skin burns
- Deep vein thrombosis
- Gastric cancer

- Tear-film layer stability in dry-eye syndrome
- Frey's syndrome
- Headaches
- Low-back pain
- Vertebral subluxation

Thermography is also hypothesized to 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

More than 20 devices have received 510(k) approval by the U.S. Food and Drug Administration (FDA). The FDA determined that these devices were substantially equivalent to existing devices for use in thermographic analysis. Examples of some recent devices, approved for use in detecting skin surface temperature differences as an adjunct to current clinical diagnostic procedures, include:

- The AG Thermographic Camera by AG Digital Technology Corporation;
- The EMD Thermography System by EM Diagnostics;
- ICI P and S Series IR Cameras by Infrared Cameras Inc.; and
- The Medhot MTI 2000 Thermal Imaging System by Medhot Thermal Imaging.

MEDICAL POLICY CRITERIA

The use of all forms of thermography is considered **investigational** for all indications.

SCIENTIFIC EVIDENCE

The two main indications under consideration for the use of thermography are the diagnosis of complex regional pain syndrome (CRPS) and breast cancer. Currently, clinical findings are the gold standard for the diagnosis of CRPS and mammography and needle biopsy are the gold standard for the screening and diagnosis, respectively, of breast cancer.

Within this context, and that of other indications where gold standard tests exist, the validation of a thermographic diagnostic test must include direct comparisons with the existing standard of care in order to:

- Demonstrate diagnostic accuracy (sensitivity, specificity, positive and negative predictive values) compared with that of the test or tests it purports to replace; and
- Determine whether thermography leads to differential treatment and improved health outcomes beyond that conferred by the standard of care (in other words, demonstrate clinical utility).

Clinical trials directly comparing health outcomes of patients diagnosed using thermography, versus the standard of care, are needed to evaluate the effectiveness of this technology.

Literature Appraisal

Complex Regional Pain Syndrome (CRPS)

The literature for diagnosis of CRPS using thermography is limited to nonrandomized studies. No studies have examined the impact of thermography on patient management decisions or health outcomes for the treatment of CPRA.

- In a study by Krumova and colleagues reported on skin temperature measurements in 22 patients with complex regional pain syndrome (CPRS), 18 with non-CRPS pain, and 23 healthy controls.[1] Using long-term thermography, there was asymmetry in limb temperature in the CRPS group and, to some extent, in non-CRPS pain patients that was not seen in healthy controls. However, the significance of these results is uncertain. Some of the differences could be due to effects of medication, e.g., antiseizure or antidepressant medications. In addition, the similarity of some findings between those with CRPS and non-CRPS pain limits applicability for use in diagnosis.
- Another example is a study published by Shada and colleagues that addressed the use of infrared thermography for differentiating between a melanoma metastasis and benign cutaneous lesions.[2] The study included 74 individuals with 251 palpable skin lesions. Thermographic images were taken of the lesions and diagnosis was confirmed by biopsy or clinical diagnosis. The sensitivity and specificity of thermography varied by lesion size. For lesions between 0 and 5 mm (n=40), the sensitivity was 39% and specificity was 100%. For lesions between 5 and 15 mm (n=46), the sensitivity was 0.58% and the specificity was 98%. Sensitivity and specificity were 95% and 100%, respectively, for lesions between 15 and 30 mm and 78% and 89%, respectively, for lesions above 30 mm.

Breast Cancer

Breast cancer is the potential application of thermography with the most published literature. The literature on the use of thermography for breast cancer screening is confined to case series testing the diagnostic accuracy of this procedure. Clinical utility is not addressed in these studies, nor is there a consensus on diagnostic accuracy.

Systematic reviews

- 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.[3] In the screening study, more than 10,000 women were invited to participate, and sample sizes in the diagnosis studies ranged from 63 and 2,625 participants. The screening study found that, compared to 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 the diagnosis of breast cancer that included a valid reference standard.[4] Six of the 8 studies, with sample sizes between 29 and 769 patients, included women scheduled for biopsy. The sensitivity of

thermography in the individual studies ranged from 25% to 97% and specificity ranged from 12% to 85%. Study findings were not pooled. For example, in a study by Arora and colleagues included in the review, results from 92 patients presenting for breast biopsy were reviewed. [5] When used in a screening mode (any positive reading was considered abnormal) for breast cancer, the sensitivity of thermography was 97% and specificity was 12%; when evaluated in a clinical mode (the lesion in question was used to determine an abnormal score), sensitivity was 90% and specificity was 44%. Further, in an additional study identified in the review, Kontos and colleagues reported an estimated sensitivity of 25% and specificity of 85% for the use of thermography in the detection of breast cancer among 63 patients in a breast clinic.[6] Thus, the sensitivity and specificity varies significantly between individual studies.

In 2011, the FDA issued the following alert regarding the use of thermography for breast cancer screening:[7]

> "The FDA is issuing this communication to alert the public, including women and health care providers, that thermography is not a replacement for screening mammography and should not be used by itself to diagnose breast cancer. The FDA is not aware of any valid scientific data to show that thermographic devices, when used on their own, are an effective screening tool for any medical condition including the early detection of breast cancer or other breast disease."

Other Indications

Thermography has also been investigated as a diagnostic tool for a number of other indications. Examples of other studies on thermography, all conducted outside of the United States, include evaluating the association between thermographic findings and post-herpetic neuralgia in patients with herpes zoster[8,9], surgical site healing in patients who underwent knee replacements[10], ulcer healing in patients with pressure ulcers[11], post-treatment pain in patients with coccygodynia[12], and early diagnosis of diabetic neuropathy.[13]None of the identified case series investigated the impact of thermography on patient management decisions or health outcomes. In addition, evidence from case series is considered unreliable due to methodological limitations, including but not limited to non-random allocation of treatment and lack of an adequate comparison group.

Clinical Practice Guidelines

There are currently no evidence-based clinical practice guidelines that recommend or endorse the use of thermography as a diagnostic technology, including the following:

American College of Radiology (ACR)

- In the 2011 ACR statement on myelopathy, ACR states that there is no high-quality evidence in support of thermography.[14]
- In the 2012 ACR statement on breast imaging, ACR states that there is insufficient evidence to support the use of thermography for breast cancer screening.[15]

American College of Obstetricians and Gynecologists (ACOG)

- The ACOG 2011 practice bulletin on breast cancer did not address thermography as a screening option.[16]

American Cancer Society (ASC)

- The 2012 ASC guidelines recommended mammogram and clinical breast exam for breast cancer screening.[17] The ASC informational statement on mammograms and other breast imaging procedures specifically addressed thermography.[18] It noted that, though thermography has been studied for many years, "no study has yet shown that it is an effective screening tool for finding breast cancer early."
- The ASC describes thermography in their 2013 report on experimental and other breast imaging methods, "Thermography has been around for many years, but studies have shown that it's not an effective screening tool for finding breast cancer early. Although it has been promoted as helping detect breast cancer early, a 2012 research review found that thermography detected only a quarter of the breast cancers found by mammography. Thermography should not be used as a substitute for mammograms."[19]

National Comprehensive Cancer Network (NCCN)

- NCCN guidelines did not include thermography in their list of recommended screening techniques for breast cancer[20] or for the evaluation of deep or superficial vein thrombosis.[21]

National Cancer Institute (NCI)

- NCI's recommendation on breast cancer screening does not address the addition of thermography to mammography.[22] NCI states the following, "Mammography is the most widely used screening modality, with solid evidence of benefit for women aged 40 to 74 years. Clinical breast examination and breast self-exam have also been evaluated but are of uncertain benefit. Technologies such as ultrasound, magnetic resonance imaging, tomosynthesis, and molecular breast imaging are being evaluated, usually as adjuncts to mammography."

U.S. Preventive Services Task Force (USPSTF)

- U.S. Preventive Services Task Force (USPSTF) guidelines recommended only screening mammography for breast cancer screening.[23]

American Academy of Neurology (AAN)

- A 1990 technology assessment from the American Academy of Neurology (AAN) concluded that, "Based on the present medical literature, infrared thermography is of limited value in the characterization of neurologic dysfunction or deficit. If it is to be used, it should only be in conjunction with established neurodiagnostic evaluation procedures."[24] There has been no update of the technology assessment.

Council on Chiropractic Practice

- In 2008, the Council on Chiropractic Practice issued an updated clinical practice guideline which included the following recommendation on skin temperature instrumentation, "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."[25] The

recommendation was based on expert opinion and literature support in the form of observational, pre-post, and/or case studies but not controlled studies.

Work Loss Institute

- 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.[26,27]

Summary

There is insufficient evidence to support the use of thermography, a noninvasive infrared scanning device, for screening, diagnosis, treatment planning or treatment monitoring. Studies are lacking that thermography can accurately diagnose any condition or improve the accuracy of another diagnostic tool. Moreover, there are no published studies evaluating whether use of thermography in patient management, such as to select a treatment or determine treatment effectiveness, improves health outcomes. In addition, published evidence-based clinical practice guidelines either recommend against the use of thermography or do not include thermography in their recommendations for the screening, diagnosis, or treatment of any condition. Therefore, the use of thermography is considered investigational for all indications.

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CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	93799	Unlisted cardiovascular service or procedure
HCPCS	None	