Kansas City

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Thermography and Temperature Gradient Studies

Policy Number: 6.01.12
Origination: 11/2002
Last Review: 11/2013
Next Review: 11/2014

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for thermography or temperature gradient studies. These are considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

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

The use of temperature gradient studies is considered **investigational**.

Description of Procedure or Service

Thermography is a noninvasive imaging technique that is intended to measure temperature distribution of 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, e.g., complex regional pain syndrome (CRPS), for treatment planning and to evaluate the effects of treatment.

Background

Thermography involves use of an infrared scanning device. 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 ([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, degree of burns, deep vein thrombosis, gastric cancer, tear-film layer stability in dry-eye syndrome, Frey's syndrome, headaches, low-back pain, and vertebral subluxation. Thermography is also thought 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.

The American Chiropractic Association suggests that high-resolution infrared imaging is of value in the diagnostic evaluation of patients when the clinical history suggests the presence of one of the following situations:

- To obtain early diagnosis and monitor reflex sympathetic dystrophy syndromes.
- To evaluate spinal nerve root fiber irritation and distal peripheral nerve fiber pathology for detection of sensory/autonomic dysfunction.
- To evaluate and monitor soft tissue injuries, including segmental dysfunction/subluxation, sprain, and myofascial conditions (strains and myofascial pain syndromes) not responding to clinical treatment.
- To evaluate the physiological significance of equivocal or minor anatomical findings seen on myelogram, computed tomography (CT) scan, and/or magnetic resonance imaging (MRI).

- To evaluate for feigned disorders.

Thermography can include various types of telethermographic infrared detector images and heat-sensitive cholesteric liquid crystal systems.

Regulatory Status
In 2002, the Dorex Spectrum 9000 MD Thermography System (DOREX, Inc.; Orange, CA) was cleared for marketing by the U. S. Food and Drug Administration (FDA) through the 510(k) process. The 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.

In 2003, several teletheromographic cameras (Series A, E, P, and S) by Flir Systems (McCordsville, IN) were cleared for marketing by the 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, three new or updated thermography devices received 510(k) marketing clearance from the FDA based on demonstrating substantial equivalence to existing products.

In contrast to the skin surface thermography techniques used by some chiropractors and other providers, a newer invasive test called a temperature gradient study involves an intravenous catheter. The catheter is threaded into the coronary arteries to directly measure temperature differences on the inner artery walls.

Rationale

Temperature Gradient Studies, References:

1. Madjid M, Willerson JT, Casscells SW. Intracoronary thermography for detection of high-risk vulnerable plaques. J Am Coll Cardiol. 2006;47(8 Suppl):C80-C85.
2. Schaar JA, Mastik F, Regar E, et al. Current diagnostic modalities for vulnerable plaque detection. Curr Pharm Des. 2007;13(10):995-1001.

Literature Review
This policy was originally created in 1996 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period March 2012 through April 2, 2013. Following is a summary of the key literature to date:

No published studies have demonstrated how the results of thermography can be used to enhance patient management and/or improve patient health outcomes Breast cancer is the potential application of thermography with the most published literature. Two systematic reviews of the published literature 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 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 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 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, a study by Arora and colleagues included 92 patients presenting for breast biopsy. (3) 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%.

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. For example, 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. (4) 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. (5) 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.

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, (6, 7), surgical site healing in patients who underwent knee replacements, (8) ulcer healing in patients with pressure ulcers, (9) post-treatment pain in patients with coccygodynia (10) and early diagnosis of diabetic neuropathy. (11)

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. Thus, thermography is considered investigational.

Practice Guidelines and Position Statements

American College of Radiology (ACR): Their 2011 statement on myelopathy states that there is no high-quality evidence in support of thermography. (12)

American College of Radiology (ACR): Their 2012 statement on breast imaging states that there is insufficient evidence to support the use of thermography for breast cancer screening. (13)

American College of Obstetricians and Gynecologists (ACOG): Their 2011 practice bulletin on breast cancer did not address thermography as a screening option. (14)

Council on Chiropractic Practice: In 2008, they issued an updated clinical practice guideline which includes 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.” (15) 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: Their 2011 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. (16, 17)

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

1. Fitzgerald A, Berentson-Shaw J. Thermography as a screening and diagnostic tool: a systematic review. N Z Med J 2012; 125(1351):80-91.
2. Vreugdenburg TD, Willis CD, Mundy L et al. A systematic review of elastography, electrical impedance scanning, and digital infrared thermography for breast cancer screening and diagnosis. Breast Cancer Res Treat 2013; 137(3):665-76.
3. Arora N, Martins D, Ruggerio D et al. Effectiveness of a noninvasive digital infrared thermal imaging system in the detection of breast cancer. Am J Surg 2008; 196(4):523-6.
4. Krumova EK, Frettlöh J, Klauenberg S et al. Long-term skin temperature measurements - a practical diagnostic tool in complex regional pain syndrome. Pain 2008; 140(1-Jan):8-22.
5. Shada AL, Dengel LT, Petroni GR et al. Infrared thermography of cutaneous melanoma metastases. J Surg Res 2012 [Epub ahead of print].
6. Han SS, Jung CH, Lee SC et al. Does skin temperature difference as measured by infrared thermography within 6 months of acute herpes zoster infection correlate with pain level? Skin Res Technol 2010; 16(2):198-201.
7. Park J, Jang WS, Park KY et al. Thermography as a predictor of postherpetic neuralgia in acute herpes zoster patients: a preliminary study. Skin Res Technol 2012; 18(1):88-93.
8. Romano CL, Logoluso N, Dell'Oro F et al. Telethermographic findings after uncomplicated and septic total knee replacement. Knee 2012; 19(3):193-7.
9. Nakagami G, Sanada H, Iizaka S et al. Predicting delayed pressure ulcer healing using thermography: a prospective cohort study. J Wound Care 2010; 19(11):465-72.
10. Wu CL, Yu KL, Chuang HY et al. The application of infrared thermography in the assessment of patients with coccygodynia before and after manual therapy combined with diathermy. J Manipulative Physiol Ther 2009; 32(4):287-93.
11. Balbinot LF, Canani LH, Robinson CC et al. Plantar thermography is useful in the early diagnosis of diabetic neuropathy. Clinics (Sao Paulo) 2012; 67(12):1419-25.
12. ACR Appropriateness Criteria®. ACR Appropriateness Criteria® myelopathy: 2011. Available online at: www.guideline.gov
13. ACR Appropriateness Criteria®. ACR Appropriateness Criteria® breast cancer screening: 2012. Available online at: www.guideline.gov
14. American College of Obstetricians and Gynecologists (ACOG). Breast cancer screening: ACOG practice bulletin; no. 122. Available online at: www.guideline.gov
15. Council on Chiropractic Practice. Vertebral subluxation in chiropractic practice: 2008. Available online at: www.clinicaltrials.gov
16. Work Loss Data Institute. Neck and upper back (acute & chronic): 2011. Available online at: www.guideline.gov
17. Work Loss Data Institute. Low back - lumbar & thoracic (acute & chronic): 2011. Available online at: www.guideline.gov

Billing Coding/Physician Documentation Information

93740 Temperature gradient studies

CPT codes 93760 and 93762 for thermography were deleted effective 12/31/2008. These services would now be reported using the unlisted code 93799.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

11/1/02	New policy added to the Medical section.
11/1/03	No policy statement changes. Added to the radiology section.
11/1/04	No policy statement changes.
11/1/05	No policy statement changes.
5/1/06	No policy statement changes.
11/1/06	No policy statement changes.
5/1/07	No policy statement changes.
11/1/07	No policy statement changes.
5/1/08	No policy statement changes.
8/1/08	Policy updated to include discussion regarding Temperature Gradient Studies. Policy statement revised to indicate this is considered investigational. Policy title updated to include Temperature Gradient Studies.
11/1/08	No policy statement changes.
5/1/09	No policy statement changes.
11/1/09	No policy statement changes.
5/1/10	No policy statement changes.
11/1/10	No policy statement changes.
5/1/11	No policy statement changes.
11/1/12	No policy statement changes.
11/1/13	No policy statement changes.