Thermography

Description

Thermography is a noninvasive imaging technique intended to measure temperature distribution in organs and tissues. The visual display of this temperature information is known as a thermogram. Thermography has been proposed as a diagnostic tool, for treatment planning, and for evaluation of treatment effects for a variety of conditions.

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 descended 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

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
No studies have demonstrated how the results of thermography can be used to enhance management of breast cancer patients in a manner that would improve patient health outcomes in breast cancer.

Systematic Reviews
Several systematic reviews of the published literature on diagnostic accuracy were identified. A 2013 systematic review by Vreugdenburg et al identified 8 studies on thermography for diagnosis of breast cancer that included a valid reference standard.¹ 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.

Previously, a 2012 systematic review by Fitzgerald et al 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.² 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%.

Prospective Studies
Subsequent to the systematic reviews, a diagnostic accuracy study was published by Rissiwala et al (2014) in India.³ The study included 1008 women being screened for breast cancer. Following infrared breast thermography, 959 women were classified as normal (temperature gradient, <2.5), 8 as abnormal (temperature gradient range, 2.5-3), 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 false-negative rate could not be accurately calculated because women who had normal thermograms did not undergo radiologic reference tests, only clinical examination.

**Section Summary: Breast Cancer**
Systematic reviews of studies evaluating the accuracy of thermography for diagnosing breast cancer found wide ranges of sensitivities and specificities. In 1 large screening study included in a systematic review, the sensitivity and specificity of thermography were relatively low compared with mammography. Studies to date have not demonstrated that thermography is sufficiently accurate to replace or supplement mammography for breast cancer diagnosis. Moreover, there are no studies on the impact of thermography on patient management or health outcomes for patients with breast cancer.

**Musculoskeletal Injuries**
A 2014 systematic review by Sanchis-Sanchez evaluated the literature on thermography for diagnosis of musculoskeletal injuries. To be included in the review, studies had 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 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 69% (95% confidence interval, 49% to 85%); data on sensitivity were not pooled.

**Section Summary: Musculoskeletal Injuries**
A systematic review of studies on thermography for diagnosing musculoskeletal injuries found moderate levels of accuracy compared with other diagnostic imaging tests. This evidence does not permit conclusions whether thermography is sufficiently accurate to replace or supplement standard testing. Moreover, there are no studies on the impact of thermography on patient management or health outcomes for patients with musculoskeletal injuries.

**Miscellaneous Conditions**
A number of studies have assessed a range of potential applications of thermography. None has 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, surgical site healing in patients who underwent knee replacements, ulcer healing in patients with pressure ulcers, posttreatment pain in patients with coccygodynia, evaluation of allergic conjunctivitis, early diagnosis of diabetic neuropathy or diabetic foot infection, evaluation of burn depth, and identifying patients with temporomandibular disorder.

**Section Summary: Miscellaneous Potential Conditions**
There are 1 or 2 preliminary studies each from outside of the United States on various miscellaneous potential indications for thermography. Most studies were on temperature gradients or the association between temperature differences and the clinical condition. Studies did not adequately evaluate the diagnostic accuracy or clinical utility of thermography for any of these miscellaneous conditions.
Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in August 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements

American College of Radiology
The 2012 American College of Radiology (ACR) statement on breast imaging concluded that there is insufficient evidence to support the use of thermography for breast cancer screening.\(^\text{15}\)

The 2015 ACR statement on imaging for myelopathy concluded that there is no high quality evidence to support the use of thermography in the evaluation of myelopathy.\(^\text{16}\)

American College of Obstetricians and Gynecologists
The 2015 American College of Obstetricians and Gynecologists breast cancer screening recommendations did not address thermography as a screening option.\(^\text{17}\)

Council on Chiropractic Practice
The 2013 Council on Chiropractic Practice clinical practice guideline included the following recommendation on skin temperature instrumentation\(^\text{18}\): “Temperature reading devices employing thermocouples, infrared [IR] 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.”

U.S. Preventive Services Task Force Recommendations
The 2016 U.S. Preventive Services Task Force recommendations on breast cancer screening do not mention thermography.\(^\text{19}\)

Summary of Evidence
For individuals who have an indication for breast cancer screening or diagnosis who receive thermography, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and test validity. Systematic reviews of studies evaluating the accuracy of thermography to screen and/or to diagnose breast cancer found wide ranges of sensitivities and specificities. Studies to date have not demonstrated that thermography is sufficiently accurate to replace or supplement mammography for breast cancer diagnosis. Moreover, there are no studies on the impact of thermography on patient management or health outcomes for patients with breast cancer. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have musculoskeletal injuries who receive thermography, the evidence includes diagnostic accuracy studies and a systematic review. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing musculoskeletal injuries have found moderate levels of accuracy compared with other diagnostic imaging tests. This evidence does not permit conclusions whether thermography is
sufficiently accurate to replace or supplement standard testing. Moreover, there are no studies on the impact of thermography on patient management or health outcomes for patients with musculoskeletal injuries. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have miscellaneous conditions (eg, herpes zoster, pressure ulcers, temporomandibular joint disorder) who receive thermography, the evidence includes diagnostic accuracy studies and a systematic review. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. There are 1 or 2 preliminary studies each from outside of the United States on various miscellaneous potential indications for thermography. Most studies assessed temperature gradients or the association between temperature differences and the clinical condition. Studies have not adequately evaluated the diagnostic accuracy or clinical utility of thermography for any of these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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**

Policy History

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<tr>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
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<tr>
<td>June 2012</td>
<td>Update Policy</td>
<td>Policy statement changed to read not medically necessary.</td>
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<tr>
<td>September 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature search through April 2, 2013. References added; other references renumbered/removed. No change in policy statement.</td>
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<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature search, adding references 5, 4, 13. No changes to policy statement.</td>
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Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2016 and is effective January 15, 2017.

Signature on file

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