Name of Policy: Thermography

Policy #: 436       Latest Review Date: June 2014
Category: Radiology       Policy Grade: B

Background:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**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, for treatment planning and to evaluate the effects of treatment.

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 (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.

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

**Policy:**
The use of all forms of thermography does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
The American Medical Association, the American College of Radiology, the American Academy of Neurology, the American College of Obstetricians and Gynecologists (ACOG) and the Work Loss Data Institute have issued policy statements or other documents that specifically do not recommend or endorse thermography as a diagnostic technology. The most recent literature review was conducted through April 1, 2014. The 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 six studies, one study using thermography for breast cancer screening and five using thermography to diagnose breast cancer among symptomatic women or those with a positive mammogram. 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 eight studies on thermography for diagnosis of breast cancer that included a valid reference standard. Six of the eight 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 2008 study by Arora et al included 92 patients presenting for breast biopsy. 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 more recent example is a 2013 study from Croatia by Kolaric et al in which 26 patients were evaluated with mammography and thermography before breast cancer surgery. The sensitivity and specificity of mammography were 85% and 84%, respectively, and of thermography were 100% and 79%, respectively. Limitations of the Kolaric study include its small sample size, unclear patient selection criteria, and unblinded analysis of test findings.

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 et al reported on skin temperature measurements in 22 patients with complex regional pain syndrome (CRPS), 18 with non-CRPS pain, and 23 healthy controls. 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, eg, 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 et al that addressed the use of infrared thermography for differentiating between a melanoma metastasis and benign cutaneous lesions. The study included 74 subjects 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 greater than 30 mm.

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...

Summary
There is insufficient evidence to support the use of thermography for diagnosis. Studies are lacking that thermography can accurately diagnosis 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.

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.

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

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, tele-thermography, multiple IR detectors, etc.) may be used to detect temperature changes in spinal and paraspinal tissues related to vertebral subluxation.” 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.

Key Words:
Thermography, rolling thermal scan, Insight™ thermal scanner,

Approved by Governing Bodies:
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. FDA product code: LHQ.
In 2003, several telethermographic cameras (Series A, E, P and S) by Flir Systems (McCordsville, IN) was 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 FDA based on demonstrating substantial equivalence to existing products. FDA product code: LHQ.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Coding:**
CPT Codes:

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
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**References:**


Policy History:
Medical Policy Group, June 2010 (3)
Medical Policy Administration Committee, July 2010
Available for comment July 2-August 16, 2010
Medial Policy Group, December 2010 (2)
Medical Policy Group, June 2011 (3) Updated Key Points & References
Medical Policy Group, May 2012 (3): Updated Key Points & References
Medical Policy Panel, May 2013
Medical Policy Group, May 2013 (3): 2013 Updates to Key points & References; no change in policy statement
Medical Policy Panel, May 2014
Medical Policy Group, June 2014 (3): 2014 Updates to Key Points, Governing Bodies & References; no change in policy statement

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.