Thermography
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00115
Original Effective Date: 03/1995
Archived Date: 08/21/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of all forms of thermography to be investigational.*

Background/Overview
Thermography is a noninvasive imaging technique that is 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 to use with a variety of conditions as a diagnostic tool, for treatment planning and to evaluate the effects of treatment.

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 (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 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
In 2002, the Dorex Spectrum 9000 MD Thermography System (DOREX, Inc.; Orange, CA) was cleared for marketing by the U. S. 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
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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.

Centers for Medicare and Medicaid Services (CMS)
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.”

Rationale/Source
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. 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. 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. 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
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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 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, 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. 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, surgical site healing in patients who underwent knee replacements, ulcer healing in patients with pressure ulcers, post-treatment pain in patients with coccygodynia and early diagnosis of diabetic neuropathy.

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.

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Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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Policy History

Original Effective Date: 03/1995
08/16/2001 Medical Policy Committee review
08/26/2009 Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/05/2010 Medical Policy Committee review
08/04/2011 Medical Policy Committee review
08/01/2013 Medical Policy Committee review. Recommend archiving policy.
08/17/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/21/2013 Medical Policy Implementation Committee approval. Archived

Next Scheduled Review Date: Archived medical policy.

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:
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A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

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