



# Louisiana

## Thermography

**Policy #** 00115  
**Original Effective Date:** 03/1995  
**Current Effective Date:** 11/21/2018  
**Archived Date:** 08/21/2013  
**Returned to Active Status:** 11/21/2018

*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.*

*Note: Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer is addressed separately in medical policy 00084.*

*Note: Scintimammography and Gamma Imaging of the Breast and Axilla is addressed separately in medical policy 00438.*

### **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**

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.

Infrared radiation from the skin or organ tissue reveals temperature variations by producing brightly colored patterns on a liquid crystal display. 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.

Thermography may also assist in treatment planning and procedure guidance by accomplishing the following tasks: 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.

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### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

A number of thermographic devices have been cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process. Examples of these devices are shown in Table 1.

**Table 1. Thermography Devices Cleared by the Food and Drug Administration**

Device Name	Manufacturer	Clearance Date	510(K) No.
Dorex Spectrum 9000MB Thermography System	Dorex	Nov 2002	K023434
Infrared Sciences Breastscan IR System	Infrared Sciences	Feb 2004	K032350
Notouch Breastscan	Lifesciences	Feb 2012	K113259
WoundVision Scout	WoundVision	Dec 2013	K131596
FirstSense Breast Exam®	First Sense Medical	Jun 2016	K160573

#### **Centers for Medicare and Medicaid Services (CMS)**

Medicare does not cover thermography. Current Medicare coverage policy states: “Thermography for any indication (including breast lesions which were excluded from Medicare coverage ...) 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....”

#### **Rationale/Source**

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

### **BREAST CANCER**

#### **Clinical Context and Test Purpose**

The purpose of using thermography in patients who are suspected of having breast cancer is to inform a decision whether to proceed to appropriate treatment or not.

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The question addressed in this portion of the evidence review is: Does thermography when used to screen or diagnose breast cancer improve the net health outcome compared with standard mammographic techniques? Specifically, does the use of thermography improve diagnostic accuracy compared with standard screening mammography methods and is this increase in accuracy likely to improve health outcomes by leading to earlier diagnosis and treatment?

The following PICOTS were used to select literature to inform this review.

### **Patients**

The relevant populations of interest are asymptomatic individuals being screened for breast cancer or individuals undergoing testing to diagnose breast cancer.

### **Interventions**

The intervention of interest is thermography.

### **Comparators**

The following test is currently being used to make decisions about breast cancer diagnosis: mammography.

### **Outcomes**

The outcome of interest for diagnostic accuracy is test validity (ie, sensitivity, specificity). The primary outcomes of interest for clinical utility are overall survival and breast cancer–specific survival rates.

The potential beneficial outcomes of primary interest in the case of a true-negative would be the avoidance of unnecessary surgery and its associated consequences (eg, morbidity, mortality, resource utilization, patient anxiety). The potential harms from a false-positive could be inappropriate assessment and improper management of patients with breast malignancies, which could result in the following: inappropriate surgical decisions, high frequency of unnecessary further testing, and unnecessary patient anxiety. The potential harms from a false-negative could be a determination that the patient does not have malignancy, which would lead to a delay in surgery and tumor diagnosis.

### **Timing**

The timing for routine screening can be guided by national guidelines on breast cancer screening. The timing for diagnosis would be after an initial screening test or clinical examination.

### **Setting**

The test would be performed in an outpatient setting.

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### ***Technically Reliable***

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

### ***Clinically Valid***

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

### **Systematic Reviews**

Several systematic reviews of the published literature on the diagnostic accuracy of thermography were identified. A systematic review by Vreugdenburg et al (2013) identified 8 studies on thermography for diagnosis of breast cancer that included a valid reference standard (eg, biopsy with histopathologic confirmation). Six of the 8 studies, with sample sizes between 29 and 769 patients, included women scheduled for a biopsy. Thermography accuracy varied highly. Sensitivity in the individual studies ranged from 25% to 97%, and specificity ranged from 12% to 85%. Study findings were not pooled.

Previously, a systematic review by Fitzgerald and Berentson-Shaw (2012) identified 6 studies, one using thermography for breast cancer screening and the others 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 a 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%.

### **Diagnostic Studies**

Several studies have been published since the systematic reviews. Omranipour et al (2016) compared the accuracy of thermography and mammography in 132 patients in Iran who had breast lesions and were candidates for breast biopsy. The final pathologic result, which was used as the reference standard, indicated that there were 45 benign lesions and 87 malignant lesions. The diagnostic accuracy of thermography (67.7%) was lower than for mammography (76.9%; p values not reported). While the sensitivities of the 2 tests were similar (80.5% for mammography vs 81.6% for thermography), the specificity was higher for mammography (73.3%) than for thermography (57.8%). Both the positive and negative predictive values were lower with thermography than with mammography. The positive and negative predictive values were 85.4% and 66.0% for mammography, and 78.9% and 61.9% for thermography, respectively.

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Rassiwala et al (2014) in India reported on 1008 women being screened for breast cancer. Following 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,  $\geq 3$ ). 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 only women who had normal thermograms had a clinical examination and did not undergo radiologic reference tests.

### ***Clinically Useful***

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

### **Direct Evidence**

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

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

### **Chain of Evidence**

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

It is not possible to construct a chain of evidence for clinical utility due to the lack of sufficient evidence that the diagnostic accuracy of thermography is at least as high as mammographic techniques for breast cancer screening and diagnosis.

### ***Section Summary: Breast Cancer***

Systematic reviews of studies evaluating the accuracy of thermography for diagnosing breast cancer found wide ranges of sensitivities and specificities and, where data are available, relatively low diagnostic accuracy compared with mammography. To date, no study has 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.

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### **MUSCULOSKELETAL INJURIES**

#### **Clinical Context and Test Purpose**

The purpose of using thermography in patients who have a musculoskeletal injury is to inform a decision whether to proceed to appropriate treatment or not.

The question addressed in this portion of the evidence review is: Does thermography when used to diagnose musculoskeletal injuries, improve the net health outcome compared with standard approaches. Specifically, does the use of thermography improve diagnostic accuracy compared with standard approaches (eg, clinical examination, imaging with radiography or magnetic resonance imaging), and is this degree of increased accuracy likely to improve health outcomes by leading to earlier diagnosis and treatment?

The following PICOTS were used to select literature to inform this review.

#### **Patients**

The relevant population of interest is individuals with musculoskeletal pain.

#### **Interventions**

The intervention of interest is thermography.

#### **Comparators**

The following tests and practices are currently being used to make decisions about musculoskeletal injuries: standard care without imaging and other forms of imaging (eg, with radiography, magnetic resonance imaging).

#### **Outcomes**

The outcomes of interest for diagnostic accuracy include test accuracy and test validity (ie, sensitivity, specificity). The primary outcomes of interest for clinical utility are a reduction in pain symptoms and improvement in functional ability.

#### **Timing**

The timing would be following a musculoskeletal injury.

#### **Setting**

The test would be performed in an outpatient setting.

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### ***Technically Reliable***

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

### ***Clinically Valid***

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

A systematic review by Sanchis-Sanchez et al (2014) evaluated the literature on thermography for diagnosing 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 injuries. 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.

### ***Clinically Useful***

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

### ***Direct Evidence***

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No studies have been published that evaluate health outcomes in patients with musculoskeletal injuries who were managed with and without thermography.

### ***Chain of Evidence***

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

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It is not possible to construct a chain of evidence for clinical utility due to the lack of sufficient evidence that the diagnostic accuracy of thermography is at least as high as standard techniques for diagnosing musculoskeletal injuries.

### **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. There was a lack of a consistent reference standard. This evidence does not permit conclusions as to 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 thermography applications. To date, no study has examined the impact of thermography on patient management decisions or health outcomes.

Examples of other studies on thermography, mainly conducted outside of the United States, include those evaluating the association between thermographic findings and post-herpetic neuralgia in patients with herpes zoster, surgical site healing in patients who underwent knee replacements, predicting pressure ulcers and pressure ulcer healing, posttreatment pain in patients with coccygodynia, evaluation of allergic conjunctivitis, evaluation of burn depth, identifying patients with temporomandibular disorder, detecting cervical lymph node metastasis from oral cavity cancer, monitoring lesions in patients with juvenile localized scleroderma, and measuring disease activity in patients with rheumatoid arthritis.

Several studies evaluating the clinical validity of thermography to assess potential complications of the diabetic foot have been conducted. Thermographic images of nondiabetic feet, nonulcerated diabetic feet and ulcerated diabetic feet have been compared. Another study used thermography to diagnose infections in patients admitted with diabetic foot complications. While these studies reported temperature differences between the different feet, none investigated clinical utility, in which health outcomes were compared in patients who were managed with and without thermography results.

### **Section Summary: Miscellaneous Conditions**

For most of these potential indications, there are 1 or 2 preliminary studies on each of the indications. Several studies evaluated the clinical validity of thermography in assessing diabetic foot and related complications. For all indications, the studies described temperature gradients or the association between temperature differences and the clinical condition. Due to the small number of studies for each indication, the diagnostic accuracy could not adequately be evaluated. The clinical utility of thermography for these miscellaneous conditions was not investigated in any study.

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### **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, and test validity. Using histopathologic findings as the reference standard, a series of systematic reviews of studies have evaluated the accuracy of thermography to screen and/or diagnose breast cancer and reported wide ranges of sensitivities and specificities. To date, no study has demonstrated whether 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 validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing musculoskeletal injuries found moderate levels of accuracy compared with other diagnostic imaging tests. There is a lack of a consistent reference standard. This evidence does not permit conclusions as to 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, diabetic foot) who receive thermography, the evidence includes diagnostic accuracy studies. Relevant outcomes are test validity, symptoms, and functional outcomes. There are 1 or 2 preliminary studies on each of these potential indications for thermography. Most studies assessed temperature gradients or the association between temperature differences and the clinical condition. Due to the small number of studies for each indication, diagnostic accuracy could not adequately be evaluated. The clinical utility of thermography for any of these miscellaneous conditions has not been investigated in studies considered. The evidence is insufficient to determine the effects of the technology on health outcomes.

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08/16/2001	Medical Policy Committee review
09/17/2001	Managed Care Advisory Council approval
09/16/2003	Medical Policy Committee review.
09/29/2003	Managed Care Advisory Council approval
06/24/2002	Format revision. Coverage eligibility unchanged.
09/16/2003	Format revision. Coverage eligibility unchanged.
09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review. Format revision. FDA approval information added.
09/22/2005	Quality Care Advisory Council approval
08/01/2007	Medical Director review
08/15/2007	Medical Policy Committee approval. No change to coverage eligibility.
08/06/2009	Medical Policy Committee approval
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/05/2010	Medical Policy Committee review
08/01/2010	Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/04/2011	Medical Policy Committee review
08/17/2011	Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/01/2013	Medical Policy Committee review. Recommend archiving policy.
08/21/2013	Medical Policy Implementation Committee approval. Archived
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. Returned to active status.

Next Scheduled Review Date: 11/2019

### **Coding**

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# Louisiana

## Thermography

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

Code Type	Code
CPT	93740, 93799
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

\*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:

- 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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