



Louisiana

Thermography

Policy # 00115

Original Effective Date: 03/1995

Current Effective Date: 05/11/2020

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, lower 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.

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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 plaques, 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)

A number of thermographic devices have been cleared for marketing by the Food and Drug Administration through the 510(k) process. Food and Drug Administration product codes: LHQ, FXN. Devices with product code LHQ may only be marketed for adjunct use. Devices with product code FXN do not provide a diagnosis or therapy. 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.
Infrared Sciences Breastscan IR System	Infrared Sciences	Feb 2004	K032350
Telethermographic Camera, Series A, E, S, and P	FLIR Systems	Mar 2004	K033967
Notouch Breastscan	UE Lifesciences	Feb 2012	K113259
WoundVision Scout	WoundVision	Dec 2013	K131596

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Current Effective Date: 05/11/2020

Archived Date: 08/21/2013

Returned to Active Status: 11/21/2018

Device Name	Manufacturer	Clearance Date	510(K) No.
AlfaSight 9000 Thermographic System	Alfa Thermodiagnosics	Apr 2015	K150457
FirstSense Breast Exam [®]	First Sense Medical	Jun 2016	K160573
Sentinel BreastScan II System	First Sense Medical	Jan 2017	K162767
InTouchThermal Camera	InTouch Technologies	Feb 2019	K181716

Rationale/Source

Thermography is a noninvasive imaging technique that measures 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.

For individuals who have an indication for breast cancer screening or diagnosis who receive thermography, the evidence includes diagnostic accuracy studies and systematic reviews. The relevant outcomes are overall survival, disease-specific survival, and test validity. Using histopathologic findings as to 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

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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, a longitudinal prospective study, and a systematic review. The 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 high-quality or randomized 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 temporomandibular joint disorder who receive thermography, the evidence includes a systematic review. The relevant outcomes are test validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing temporomandibular joint disorder found a wide variation in accuracy compared to other diagnostics. There is a lack of a consistent reference standard. The 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 the temporomandibular joint disorder. 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, diabetic foot) who receive thermography, the evidence includes diagnostic accuracy studies. The relevant outcomes are test validity, symptoms, and functional outcomes. There are one or two 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.

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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.

Supplemental Information **Practice Guidelines and Position Statements**

European Society of Breast Imaging

A position paper by the European Society of Breast Imaging (2017) and 30 other national breast radiology bodies on screening for breast cancer stated that "screening with thermography or other optical tools as alternatives to mammography is discouraged."

American College of Physicians

The American College of Physicians (2019) issued a guidance statement for breast cancer screening in average-risk women that reviews existing screening guidelines. While the use of thermography was not mentioned in this statement, the authors conclude that evidence is insufficient to understand the benefits and harms of primary or adjunctive screening strategies in women who are found to have dense breasts on screening mammography.

American College of Radiology

The American College of Radiology guidelines for breast cancer screening (revised 2017) do not mention the use of thermography for breast cancer screening.

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on breast cancer screening and diagnosis (v.1.2019) states that: "Current evidence does not support the routine use of thermography or ductal lavage as screening procedures."

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2016) recommendations on breast cancer screening do not mention thermography. Additionally, there is insufficient evidence for the use of adjunctive

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screening methods for breast cancer (ultrasonography, magnetic resonance imaging, digital breast tomosynthesis, or other methods) in women identified to have dense breasts on a negative screening mammogram.

Medicare National Coverage

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..."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02705443	Early Identification of Suspected Deep Tissue Injury (sDTI) Utilizing Long-Wave Thermographic Imaging (LWIT)	60	Jun 2017 (unknown)
NCT03089463	Foot Assessment in People with Diabetes: A Quantitative Diagnostic Approach	153	Apr 2020 (recruiting)

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Returned to Active Status: 11/21/2018

NCT03735550	Investigation of the Effectiveness of Liquid Crystal Contact Thermography in Detecting Pathological Changes in Female Breasts Compared to Standard Diagnostic Methods of Breast Cancer	3000	Jan 2019 (ongoing)
NCT03217214	Investigation of Contact Based Method for Diagnosis of Cardiovascular Disease	100	Sep 2019 (recruiting)
NCT02776995	Tumor Monitoring Using Thermography During Radiation Therapy	80	Dec 2020 (recruiting)
NCT04013711	Quantitative Thermal Imaging to Evaluate Skin Toxicity from Radiation Treatment	200	Aug 2021 (recruiting)
<i>Unpublished</i>			
NCT03254095	Thermal and Biomechanical Characterization of Diabetic Foot Patients, Predictors of Skin Temperature, Barefoot Plantar Pressure and Ulceration	100	Sep 2018 (completed)

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NCT: national clinical trial.

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Louisiana

Thermography

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- 08/16/2001 Medical Policy Committee review
- 09/17/2001 Managed Care Advisory Council approval
- 06/24/2002 Format revision. Coverage eligibility unchanged.
- 09/16/2003 Medical Policy Committee review.
- 09/29/2003 Managed Care Advisory Council approval
- 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.

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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.
11/07/2019 Medical Policy Committee review
11/13/2019 Medical Policy Implementation Committee approval. No change to coverage.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2021

Coding

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Louisiana

Thermography

Policy # 00115

Original Effective Date: 03/1995

Current Effective Date: 05/11/2020

Archived Date: 08/21/2013

Returned to Active Status: 11/21/2018

CPT is a registered trademark of the American Medical Association.

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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Louisiana

Thermography

Policy # 00115

Original Effective Date: 03/1995

Current Effective Date: 05/11/2020

Archived Date: 08/21/2013

Returned to Active Status: 11/21/2018

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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