Thermography

Policy # 00115
Original Effective Date: 03/1995
Current Effective Date: 05/13/2024
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: Scintimammography and Gamma Imaging of the Breast and Axilla is addressed separately in medical policy 00438.

Note: Temporomandibular Joint Dysfunction is addressed separately in medical policy 00583.

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

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.

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.

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 U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA 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 U.S. 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
AlfaSight 9000 Thermographic System™‡	Alfa Thermodiagnostics	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

Device Name	Manufacturer	Clearance Date	510(K) No.
Smile-100 System	Niramai Health Analytix Private Limited	Mar 2022	K212965
ThermPix™‡ Thermovisual Camera	USA Therm	Apr 2022	K213650

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

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.

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 compared 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 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 that the technology results in an improvement in the net health outcome.

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For individuals who have musculoskeletal injuries who receive thermography, the evidence includes diagnostic accuracy studies, a longitudinal prospective study, 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 no 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 that the technology results in an improvement in the net health outcome.

For individuals who have temporomandibular joint (TMJ) disorder who receive thermography, the evidence includes a systematic review. Relevant outcomes are test validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing TMJ disorder found a wide variation in accuracy compared to other diagnostics. There is no 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 TMJ disorder. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have miscellaneous conditions (eg, herpes zoster, pressure ulcers, diabetic foot) who receive thermography, the evidence primarily includes diagnostic accuracy studies. Outcomes in these studies are test validity, symptoms, and functional outcomes. 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 has only been considered in a single study of diabetic foot ulcers. For other miscellaneous conditions, the clinical utility of thermography has not been investigated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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Supplemental Information

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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 concluded 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 guideline on breast cancer screening and diagnosis (v.2.2024) states that: "Current evidence does not support the routine use of thermography as screening procedures."

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U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (2016) recommendations on breast cancer screening (currently undergoing an update) do not mention thermography. Additionally, there is insufficient evidence for the use of adjunctive 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
Unpublished			
NCT04013711	Quantitative Thermal Imaging to Evaluate Skin Toxicity from Radiation Treatment	200	Jul 2022
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
NCT03217214	Investigation of Contact Based Method for Diagnosis of Cardiovascular Disease (INDICES)	67	Sep 2019

NCT02776995	Tumor Monitoring Using Thermography During Radiation Therapy	80	Dec 2020

NCT: national clinical trial.

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Policy History

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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.

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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.
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.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2022	Medical Policy Committee review

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04/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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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 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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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.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.