



FEP Medical Policy Manual

FEP 6.01.12 Thermography

Annual Effective Policy Date: January 1, 2024

Original Policy Date: December 2011

Related Policies:

- 2.01.21 - Temporomandibular Joint Disorder
- 6.01.06 - Miscellaneous (Noncardiac, Nononcologic) Applications of Fluorine 18 Fluorodeoxyglucose Positron Emission Tomography
- 6.01.20 - Cardiac Applications of Positron Emission Tomography Scanning
- 6.01.26 - Oncologic Applications of Positron Emission Tomography Scanning (Genitourinary)
- 6.01.29 - Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer
- 6.01.51 - Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment

Thermography

Description

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.

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.

OBJECTIVE

The objective of this evidence review is to determine whether thermography improves the net health outcome for a variety of indications including but not limited to the diagnosis of breast cancer, musculoskeletal injuries, and temporomandibular joint disorder.

POLICY STATEMENT

The use of all forms of thermography is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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
Smile-100 System	Niramai Health Analytix Private Limited	Mar 2022	K212965
ThermPix™ Thermovisual Camera	USA Therm	Apr 2022	K213650

RATIONALE

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.

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.

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."⁴³

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.⁴⁴ 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.⁴⁵

National Comprehensive Cancer Network

National Comprehensive Cancer Network guideline on breast cancer screening and diagnosis (v.1.2023) states that: "Current evidence does not support the routine use of thermography as screening procedures."⁴⁶

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.⁴⁷

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..."⁴⁸

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy statement changed to read not medically necessary.
September 2013	Replace policy	Policy updated with literature search through April 2, 2013. References added; other references renumbered/removed. No change in policy statement.
September 2014	Replace policy	Policy updated with literature search, adding references 5, 4, 13. No changes to policy statement.
September 2015	Replace policy	Policy updated with literature review; reference 3, 11, and 13 added. Policy statement unchanged.
December 2016	Replace policy	Policy updated with literature review through July 21, 2016; references 13-14, 17, and 19 added. Policy statement unchanged.
December 2017	Replace policy	Policy updated with literature review through July 21, 2017; references 3, 9, and 17-18 added. Policy statement unchanged but "not medically necessary, corrected to "investigational,.
December 2018	Replace policy	Policy updated with literature review through July 9, 2018; references 15-19 and 24 added. Policy statement unchanged.
December 2019	Replace policy	Policy updated with literature review through June 26, 2019; references added. Regulatory Status and Supplemental Information sections updated. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through August 4, 2020; references added. Policy statement unchanged.
December 2021	Replace policy	Policy updated with literature review through August 8, 2021; references added. Policy statement unchanged.
December 2022	Replace policy	Policy updated with literature review through July 12, 2022; references added. Policy statement unchanged.
December 2023	Replace policy	Policy updated with literature review through July 11, 2023; no references added. Policy statement unchanged.

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