



**Kansas City**

An Independent Licensee of the Blue Cross and Blue Shield Association

# Thermography and Temperature Gradient Studies

**Policy Number:** 6.01.12  
**Origination:** 11/2002

**Last Review:** 11/2018  
**Next Review:** 11/2019

## Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for thermography or temperature gradient studies. These are considered investigational.

## When Policy Topic is covered

Not Applicable

## When Policy Topic is not covered

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

The use of temperature gradient studies is considered **investigational**.

## Description of Procedure or Service

<b>Populations</b>	<b>Interventions</b>	<b>Comparators</b>	<b>Outcomes</b>
Individuals: <ul style="list-style-type: none"> <li>With an indication for breast cancer screening or diagnosis</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Thermography</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Mammography</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Disease-specific survival</li> <li>Test accuracy</li> <li>Test validity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With musculoskeletal injuries</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Thermography</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Radiography</li> <li>Magnetic resonance imaging</li> <li>Standard care without imaging</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Test accuracy</li> <li>Test validity</li> <li>Symptoms</li> <li>Functional outcomes</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With miscellaneous condition (eg, herpes zoster, pressure ulcers, temporomandibular joint disorder)</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Thermography</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Radiography</li> <li>Magnetic resonance imaging</li> <li>Standard care without imaging</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Test accuracy</li> <li>Test validity</li> <li>Symptoms</li> <li>Functional outcomes</li> </ul>

Thermography is a noninvasive imaging technique 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 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. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and test validity. Systematic reviews of studies evaluating the accuracy of thermography to screen and/or to diagnose breast cancer found wide ranges of sensitivities and specificities. Studies to date have not 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 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 accuracy and validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing musculoskeletal injuries have 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 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) who receive thermography, the evidence includes diagnostic accuracy studies and a systematic review. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. There are 1 or 2 preliminary studies each from outside of the United States on various miscellaneous potential indications for thermography. Most studies assessed temperature gradients or the association between temperature differences and the clinical condition. Studies have not adequately evaluated the diagnostic accuracy or clinical utility of thermography for any of these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Background**

Thermography involves use of an infrared scanning device. 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 is also thought to 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.

The American Chiropractic Association suggests that high-resolution infrared imaging is of value in the diagnostic evaluation of patients when the clinical history suggests the presence of one of the following situations:

- To obtain early diagnosis and monitor reflex sympathetic dystrophy syndromes.
- To evaluate spinal nerve root fiber irritation and distal peripheral nerve fiber pathology for detection of sensory/autonomic dysfunction.
- To evaluate and monitor soft tissue injuries, including segmental dysfunction/subluxation, sprain, and myofascial conditions (sprains and myofascial pain syndromes) not responding to clinical treatment.
- To evaluate the physiological significance of equivocal or minor anatomical findings seen on myelogram, computed tomography (CT) scan, and/or magnetic resonance imaging (MRI).
- To evaluate for feigned disorders.

Thermography can include various types of telethermographic infrared detector images and heat-sensitive cholesteric liquid crystal systems.

### **Regulatory Status**

In 2002, the Dorex Spectrum 9000 MD Thermography System (DOREX, Inc.; Orange, CA) was cleared for marketing by the U. S. Food and Drug Administration (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 management, neurology, and diabetic foot care. This type of device is also known as a telethermographic system.

In 2003, several telethermographic 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.

In contrast to the skin surface thermography techniques used by some chiropractors and other providers, a newer invasive test called a temperature gradient study involves an intravenous catheter. The catheter is threaded into the coronary arteries to directly measure temperature differences on the inner artery walls.

## **Rationale**

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### **Literature Review**

This evidence review was created in March 1996 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through July 21, 2017. The following is a summary of the key literature to date.

### **BREAST CANCER**

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

The question addressed in this portion of the evidence review is whether there is sufficient evidence that thermography used to screen or diagnose breast cancer improves 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 degree of increased accuracy likely to improve health outcomes via earlier diagnosis and treatment?

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

#### ***Patients***

The relevant population of interest is asymptomatic individuals being screened for breast cancer or individuals undergoing breast cancer diagnosis.

#### ***Interventions***

The intervention of interest is thermography.

#### ***Comparators***

The comparator of interest is mammography.

#### ***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 overall survival and breast cancer-specific survival.

#### ***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 the office of a trained provider.

## **Technical Reliability**

Several thermography devices have been cleared by the U.S. Food and Drug Administration (FDA); FDA has evaluated technical reliability.

## **Clinical Validity**

Several systematic reviews of the published literature on diagnostic accuracy were identified. A 2013 systematic review by Vreugdenburg et al identified eight studies on thermography for diagnosis of breast cancer that included a valid reference standard (eg, biopsy with histopathologic confirmation).(1) Six of the 8 studies, with sample sizes between 29 and 769 patients, included women scheduled for biopsy. The accuracy of thermography was highly variable. Sensitivity in the individual studies ranged from 25% to 97%, and specificity ranged from 12% to 85%. Study findings were not pooled.

Previously, a 2012 systematic review by Fitzgerald et al identified six studies, one study using thermography for breast cancer screening and five using thermography to diagnose breast cancer among symptomatic women or those with a positive mammogram.(2) In the screening study, more than 10000 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 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%.

Several studies were published after the systematic reviews. In 2016, Omranipour et al compared the accuracy of thermography and mammography in 132 patients in Iran who had breast lesions and were candidates for breast biopsy.(3) 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 thermography (57.8%). Both the positive and negative predictive values were lower with thermography than mammography. The positive and negative predictive values were 85.4% and 66.0% for mammography, and 78.9% and 61.9% for thermography, respectively.

In 2014, Rissiwala et al (2014) in India reported on 1008 women being screened for breast cancer.(4) Following infrared 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, ≥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 women who had normal thermograms did not undergo radiologic reference tests, only clinical examination.

## **Clinical Utility**

### ***Direct Evidence***

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Preferred evidence comes from randomized controlled trials. No studies have demonstrated how the results of thermography can be used to enhance management of breast cancer patients in a manner that would improve patient health outcomes in breast cancer.

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

It is not possible to construct an indirect 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

## **MUSCULOSKELETAL INJURIES**

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

The question addressed in this portion of the evidence review is whether there is sufficient evidence that thermography, when used to diagnose musculoskeletal injuries, improves 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 via 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 comparators of interest are 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 pain symptoms and functional ability.

### **Timing**

The timing would be following musculoskeletal injury.

### **Setting**

The test would be performed in the office of a trained provider.

### **Technical Reliability**

Several thermography devices are FDA-cleared; FDA has evaluated technical reliability.

### **Clinical Validity**

A 2014 systematic review by Sanchis-Sanchez evaluated the literature on thermography for diagnosis of musculoskeletal injuries.<sup>(5)</sup> 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; three included patients with suspected stress fractures and the remainder addressed other musculoskeletal conditions. 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.

### **Clinical Utility**

#### **Direct Evidence**

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Preferred evidence comes 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**

It is not possible to construct an indirect 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 applications of thermography. 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 evaluating the association between thermographic findings and postherpetic neuralgia in patients with herpes zoster,(6,7) surgical site healing in patients who underwent knee replacements,(8) predicting pressure ulcers,(9) ulcer healing in patients with pressure ulcers,(10) posttreatment pain in patients with coccygodynia,(11) evaluation of allergic conjunctivitis,(12) early diagnosis of diabetic neuropathy(13) or diabetic foot infection,(14) evaluation of burn depth,(15) and identifying patients with temporomandibular disorder.(16)

## **Section Summary: Miscellaneous Conditions**

There are one or two preliminary studies each on various potential indications for thermography. Most studies were on temperature gradients or the association between temperature differences and the clinical condition. Studies did not adequately evaluate the diagnostic accuracy or clinical utility of thermography for any of these miscellaneous 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, test accuracy, and test validity. Using histopathological 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 discovered wide ranges of sensitivities and specificities. To date, no study has been able to demonstrate 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 accuracy and validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing musculoskeletal injuries have found moderate levels of accuracy compared with other diagnostic

imaging tests. There is a lack of a consistent reference standard. This evidence does not allow for 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) who receive thermography, the evidence includes diagnostic accuracy studies and a systematic review. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. There are one or two preliminary studies each on various potential indications for thermography. Most studies assessed temperature gradients or the association between temperature differences and the clinical condition. Studies have not adequately evaluated the diagnostic accuracy or clinical utility of thermography for any of these conditions. 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 et al**

A 2017 position paper by the European Society of Breast Imaging and 30 national breast radiology bodies on screening for breast cancer stated, "screening with thermography or other optical tools as alternatives to mammography is discouraged."(17)

#### **American College of Radiology**

A 2013 (republished 2016) American College of Radiology statement concluded that there is insufficient evidence to support the use of thermography for breast cancer screening.(18)

### **U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

The 2016 U.S. Preventive Services Task Force recommendations on breast cancer screening do not mention thermography.(19)

### **MEDICARE NATIONAL COVERAGE**

Medicare does not consider thermography to be eligible for coverage. The Medicare coverage policy, current as of August 2017 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."(20)

## **ONGOING AND UNPUBLISHED CLINICAL TRIALS**

A search of ClinicalTrials.gov in July 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

### References:

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## **Billing Coding/Physician Documentation Information**

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- 93740** Temperature gradient studies  
**93799** Unlisted cardiovascular service or procedure

### **ICD-10 Codes**

- G56.40-** Causalgia of upper limb code range  
**G56.42**  
**G57.70-** Causalgia of lower limb code range  
**G57.72**  
**G89.0-** Pain, not elsewhere classified code range  
**G89.4**  
**G90.50-** Complex regional pain syndrome I code range  
**G90.59**  
**M25.50-** Pain in joint code range  
**M25.579**  
**M54.00-** Dorsalgia code range  
**M54.9**  
**M79.60-** Pain in limb, hand, foot, fingers and toes code range  
**M79.676**  
**R52** Pain, unspecified

CPT codes 93760 and 93762 for thermography were deleted effective 12/31/2008. These services would now be reported using the unlisted code 93799.

## **Additional Policy Key Words**

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N/A

## **Policy Implementation/Update Information**

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- 11/1/02 New policy added to the Medical section.  
 11/1/03 No policy statement changes. Added to the radiology section.  
 11/1/04 No policy statement changes.  
 11/1/05 No policy statement changes.  
 5/1/06 No policy statement changes.  
 11/1/06 No policy statement changes.  
 5/1/07 No policy statement changes.  
 11/1/07 No policy statement changes.  
 5/1/08 No policy statement changes.  
 8/1/08 Policy updated to include discussion regarding Temperature Gradient

Studies. Policy statement revised to indicate this is considered investigational. Policy title updated to include Temperature Gradient Studies.

- 11/1/08 No policy statement changes.
- 5/1/09 No policy statement changes.
- 11/1/09 No policy statement changes.
- 5/1/10 No policy statement changes.
- 11/1/10 No policy statement changes.
- 5/1/11 No policy statement changes.
- 11/1/12 No policy statement changes.
- 11/1/13 No policy statement changes.
- 11/1/14 No policy statement changes.
- 11/1/15 No policy statement changes.
- 11/1/16 No policy statement changes.
- 11/1/17 No policy statement changes.
- 11/1/18 No policy statement changes.

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State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.