Policy Statement

The use of all forms of thermography is considered investigational.

Policy Guidelines

These services are reported using the following unlisted code:
- 93799: Unlisted cardiovascular service or procedure

The following CPT code is specific for temperature gradient studies:
- 93740: Temperature gradient studies

Description

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.

Related Policies

- Digital Breast Tomosynthesis
- Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer
- Scintimammography and Gamma Imaging of the Breast and Axilla

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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

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

Background
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. 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 (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.

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.

Literature Review
Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical reliability (test-retest reliability or interrater reliability); (2) clinical validity (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) clinical utility demonstrating that the diagnostic information can be used to improve patient outcomes.

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 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 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 (i.e., sensitivity, specificity). The primary outcomes of interest for clinical utility are overall survival and breast cancer-specific survival rates.

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.
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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); the FDA has evaluated device 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 8 studies on thermography for diagnosis of breast cancer that included a valid reference standard (e.g., biopsy with histopathologic confirmation). 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 6 studies, one using thermography for breast cancer screening and five 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%.

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. 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.

In 2014, Rissiwala et al in India reported on 1008 women being screened for breast cancer. 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 only had clinical examination and did not undergo radiologic reference tests.

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 their health outcomes.
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 (e.g., 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 comparators of interest are standard care without imaging and other forms of imaging (e.g., with radiography, magnetic resonance imaging).

Outcomes
The outcomes of interest for diagnostic accuracy include test accuracy and test validity (i.e., 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; the FDA has evaluated technical reliability.

Clinical Validity
A 2014 systematic review by Sanchis-Sanchez evaluated the literature on thermography for diagnosis of musculoskeletal injuries. To be included in the review, studies had to report on diagnostic accuracy and use findings from diagnostic imaging tests (e.g., 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 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 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, 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, early diagnosis of diabetic neuropathy or diabetic foot infection, evaluation of burn depth, and identifying patients with temporomandibular disorder.

**Section Summary: Miscellaneous Conditions**

There are 1 or 2 preliminary studies on each of these potential indications for thermography. Most studies were on temperature gradients or the association between temperature differences and the clinical condition. Studies were not adequately evaluated 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 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 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 has 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 (e.g., 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 on each of these 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.”

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

**U.S. Preventive Services Task Force Recommendations**
The 2016 U.S. Preventive Services Task Force recommendations on breast cancer screening do not mention thermography.

**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.”

**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**


17. Sardanelli F, Aase HS, Alvarez M, et al. Position paper on screening for breast cancer by the European Society of Breast Imaging (EUSOBI) and 30 national breast radiology bodies from Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Israel, Lithuania, Moldova, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, Switzerland and Turkey. Eur Radiol. Jul 2017;27(7):2737-2743. PMID 27807699


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**Documentation for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services may be considered investigational.

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<th>Type</th>
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<td>93740</td>
<td>Temperature gradient studies</td>
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<td>Measurement of Temperature, External Approach</td>
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**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<tr>
<td>01/11/2008</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
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<tr>
<td>08/23/2013</td>
<td>Policy revision without position change. Policy placed on No Further Routine Literature Review and Update status.</td>
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<tr>
<td>06/30/2015</td>
<td>Coding update</td>
<td>Administrative Review</td>
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<td>11/01/2016</td>
<td>Policy title change from Thermography/ Temperature Gradient Studies</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>11/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
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</tbody>
</table>

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.
Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.