

Regence

Medical Policy Manual

Radiology, Policy No. 17

Thermography

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Thermography is a noninvasive imaging technique that is intended to measure temperature distribution of organs and tissues.

MEDICAL POLICY CRITERIA

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

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

This technique is commonly called infrared, thermal imaging, digital infrared thermal imaging (DITI), and temperature gradient studies. The visual display of this temperature information is known as a thermogram and it consists of brightly colored patterns on a liquid crystal display. It is thought that temperature differences associated with changes in metabolic activity (such as

metabolic increases seen in regions with cancer) can be identified through color differences on a visual display, leading some to propose thermography as a diagnostic tool for a variety of conditions, including but not limited to:

- Breast cancer
- Complex regional pain syndrome ([CRPS], previously known as reflex sympathetic dystrophy)
- Temporomandibular Joint Disorder
- Musculoskeletal injuries
- Raynaud's phenomenon
- Digital artery vasospasm in hand-arm vibration syndrome
- Peripheral nerve damage following trauma
- Impaired spermatogenesis in infertile men
- Skin burns
- Deep vein thrombosis
- Gastric cancer
- Tear-film layer stability in dry-eye syndrome
- Frey's syndrome
- Headaches
- Low-back pain
- Vertebral subluxation

Thermography is also hypothesized 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.

REGULATORY STATUS

More than 20 devices have received 510(k) approval by the U.S. Food and Drug Administration (FDA). The FDA determined that these devices were substantially equivalent to existing devices for use in thermographic analysis. Examples of some recent devices, approved for use in detecting skin surface temperature differences as an adjunct to current clinical diagnostic procedures, include:

- The FirstSense Breast Exam® by First Sense Medical™
- The AG Thermographic Camera by AG Digital Technology Corporation™
- The EMD Thermography System by EM Diagnostics™
- The ICI P and S Series IR Cameras by Infrared Cameras Inc.
- The Med-Hot MTI 2000 Thermal Imaging System by Med-Hot Thermal Imaging®
- The Sentinel BreastScan II System by First Sense Medical™
- The InTouch Thermal Camera by InTouch Health™
- The Smile-100 System by Niramai Health Analytix Private Limited
- Therma Pix™ Thermovisual Camera by USA Therm, Inc

EVIDENCE SUMMARY

The main indication under consideration for the use of thermography is the screening or diagnosis of breast cancer. Currently, mammography and needle biopsy are the gold standard for the screening and diagnosis, respectively.

Within this context, and that of other indications where gold standard tests exist, the validation of a thermographic diagnostic test must include direct comparisons with the existing standard of care in order to:

- Demonstrate diagnostic accuracy (sensitivity, specificity, positive and negative predictive values) compared with that of the test or tests it purports to replace; and
- Determine whether thermography leads to differential treatment and improved health outcomes beyond that conferred by the standard of care (in other words, demonstrate clinical utility).

Clinical trials directly comparing health outcomes of patients diagnosed using thermography, versus the standard of care, are needed to evaluate the effectiveness of this technology. To determine efficacy outcomes, high-quality systematic reviews (SRs) and published randomized controlled trials (RCTs) were considered. When the availability of SRs and RCTs is limited, single-arm or non-controlled studies also were considered for assessment of clinical utility.

BREAST CANCER

In 2019, the FDA issued the following alert regarding the use of thermography for breast cancer screening:^[1]

“The FDA is alerting women, health care providers, and people getting breast cancer screening, that thermography is not an effective alternative to mammography and should not be used in place of mammography for breast cancer screening or diagnosis. There is no valid scientific data to demonstrate that thermography devices, when used on their own or with another diagnostic test, are an effective screening tool for any medical condition including the early detection of breast cancer or other diseases and health conditions.”

Breast cancer is the potential application of thermography with the most published literature. The literature on the use of thermography for breast cancer screening is confined to case series testing the diagnostic accuracy of this procedure. Clinical utility is not addressed in these studies, nor is there a consensus on diagnostic accuracy.

Systematic Reviews

A 2013 SR identified eight studies on thermography for the diagnosis of breast cancer that included a valid reference standard.^[2] Six of the eight studies, with sample sizes between 29 and 769 patients, included women scheduled for biopsy. The sensitivity of thermography in the individual studies ranged from 25% to 97% and specificity ranged from 12% to 85%. Study findings were not pooled. For example, in a study by Arora and colleagues included in the review, results from 92 patients presenting for breast biopsy were reviewed.^[3] When used in a screening mode (any positive reading was considered abnormal) for breast cancer, the sensitivity of thermography was 97% and specificity was 12%; when evaluated in a clinical mode (the lesion in question was used to determine an abnormal score), sensitivity was 90% and specificity was 44%. Further, in an additional study identified in the review, Kontos (2011) reported an estimated sensitivity of 25% and specificity of 85% for the use of thermography in

the detection of breast cancer among 63 patients in a breast clinic.^[4] Thus, the sensitivity and specificity varies significantly between individual studies.

A 2012 SR 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.^[5] In the screening study, more than 10,000 women were invited to participate, and sample sizes in the diagnosis studies ranged from 63 to 2,625 participants. The screening study found that, compared to 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%.

Nonrandomized Studies

Morales-Cervantes (2018) retrospectively analyzed 206 thermograms of patients with suspected breast cancer to evaluate the accuracy of an automated assessment of thermography images to detect breast cancer.^[6] The reference standard was biopsy with histopathologic confirmation. The authors report their method achieved test sensitivity of 100%, specificity of 68.68%, a positive predictive value of 11.42 % and negative predictive value of 100%. They assert these results exceed the reliability of the qualitative evaluation by an oncologist of the same patient data. However, double-blinding is indicated for assessment of thermograms by the oncologist and blinding of the biopsy assessor was not described. These limitations in blinding, as well as the lack of data reported for mammography despite inclusion as comparator, limit the reliability of the study outcomes.

A retrospective study conducted published by Neal (2018) assessed outcomes in 38 women referred for further breast imaging following abnormal thermography testing.^[7] Records were reviewed for clinical history, thermography results, mammogram and/or ultrasound findings, and pathology. Mammograms and ultrasounds were prospectively interpreted by one of 14 Mammography Quality Standards Act-certified breast imaging radiologists with 3-30 years of experience. Patient outcomes were determined by biopsy or at least 1 year of follow-up. Patient ages ranged from 23 to 70 years (mean = 50 years). Thirty six of the 38 of patients did not have breast cancer. The two patients diagnosed with breast cancer had suspicious clinical symptoms including palpable mass and erythema. No asymptomatic woman had breast cancer. Negative predictive value was 100%. Two of six patients with biopsy recommendations were diagnosed with breast cancer (positive predictive value 2 = 33.3%). This study is limited by not describing appropriate blinding, reference testing not being uniform for all patients, having a small sample size and a retrospective design. In addition, long-term health outcomes are not described.

Omranipour (2016) compared the accuracy of thermography and mammography in 132 patients in Iran who had breast lesions and were candidates for breast biopsy.^[8] 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 two 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.

Rassiwala (2014) published a diagnostic accuracy study.^[9] The study included 1008 women who were being screened for breast cancer. Following infrared breast thermography, 959 women were classified as normal (temperature gradient, <2.5), eight as abnormal (temperature gradient between 2.5 and three) and 41 as potentially having breast cancer (temperature gradient, $\geq$ three). 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 study was limited because women who had normal thermograms did not undergo radiologic reference tests, only clinical examination, and thus the false negative rate cannot be accurately calculated.

OTHER INDICATIONS

Temporomandibular Joint Disorder

A SR by de Melo (2019) evaluated the diagnostic accuracy of infrared thermography (IT) in temporomandibular joint disorder (TMD).^[10] Nine studies were identified utilizing a variety of comparators. Four studies concluded that IT presents low accuracy or is not an accurate instrument for TMD diagnosis, but there was substantial variation in sensitivity, specificity, and receiver operating characteristic curve values. Five studies concluded that IT appears to be promising or may be a complementary diagnostic aid in the evaluation of TMDs. These studies presented sensitivity values ranging from 70% to 90% and specificity values ranging from 62% to 92%. All studies were judged as being "at risk of bias" and as having "concerns regarding applicability." The authors conclude that there are insufficient studies regarding the reliability of IT for the diagnosis of TMDs.

Musculoskeletal Injuries

A SR by Vardasca (2019) evaluated the literature on musculoskeletal applications of thermography specific to the arm and forearm.^[11] The review mainly focused on correlations between skin surface temperatures and physical condition or health recovery monitoring. As diagnostic accuracy data was not extracted or pooled from included studies, this review was not assessed for evidence of clinical validity.

A SR by Sanchis-Sanchez (2014) evaluated the evidence for thermography in diagnosing musculoskeletal injuries.^[12] 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 (N=416); three included patients with suspected stress fractures (N=119) and the remainder addressed other musculoskeletal injuries. Sample sizes of individual studies ranged from 17 to 164 patients. In the three 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. High heterogeneity in thermography index test methodologies and diagnostic accuracy assessment by the authors indicates moderate-to-high risk of bias in studies on stress fractures.

Thermography also has been investigated as a diagnostic tool for a number of other indications. Examples of other studies on thermography include evaluating the association between thermographic findings and post-herpetic neuralgia in patients with herpes zoster^[13, 14], surgical site healing in patients who underwent knee replacements^[15, 16], ulcer healing in patients with pressure ulcers,^[17] predicting pressure ulcers,^[18] post-treatment pain in patients

with coccygodynia,^[19] diagnosis of regional pain syndrome,^[20] early diagnosis of diabetic neuropathy^[21] or diabetic foot infection,^[22, 23] diagnosis of cutaneous lesions,^[24] and evaluation of burn depth.^[25] None of the identified studies investigated the impact of thermography on patient management decisions or health outcomes. In addition, evidence from case series is considered unreliable due to methodological limitations, including but not limited to non-random allocation of treatment and lack of an adequate comparison group.

SUMMARY OF EVIDENCE

For individuals who have an indication for breast cancer screening or diagnosis who receive thermography, the evidence includes systematic reviews and diagnostic accuracy studies. Using histopathologic findings as to the reference standard, a series of systematic reviews of studies 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 thermography is sufficiently accurate to replace or supplement mammography for breast cancer diagnosis. For all other indications for which research is available, including but not limited to use in diagnosis of temporomandibular joint disorder and musculoskeletal injury, the 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 any of these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

PRACTICE GUIDELINE SUMMARY

There are currently no evidence-based clinical practice guidelines that recommend or endorse the use of thermography as a diagnostic technology, including the following:

NATIONAL COMPREHENSIVE CANCER NETWORK

National Comprehensive Cancer Network guidelines on breast cancer screening and diagnosis (v.3.2023) states that: "Current evidence does not support the routine use of thermography or ductal lavage as screening procedures."^[21]

EUROPEAN SOCIETY OF BREAST IMAGING

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."^[26]

AMERICAN COLLEGE OF RADIOLOGY

The American College of Radiology guidelines for breast cancer screening do not mention the use of thermography for breast cancer screening.^[27]

SUMMARY

There is not enough research to support the use of thermography, also known as thermal imaging, for screening, diagnosis, treatment planning or treatment monitoring. In addition, there are no clinical guidelines based on research that recommend the use of thermography

for the screening, diagnosis, or treatment of any condition. Therefore, the use of thermography is considered investigational for all indications.

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Codes	Number	Description
CPT	93799	Unlisted cardiovascular service or procedure
HCPCS	None	

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