Clinical Policy Bulletin:
Thermography

Revised February 2015

Number: 0029

Policy

Aetna considers thermography (including digital infrared thermal imaging, magnetic resonance (MR) thermography studies) experimental and investigational because available medical literature indicates thermography to be an ineffective and investigational because of a lack of evidence to support its utility.

Aetna considers dynamic infrared blood perfusion imaging (DIRI) experimental and investigational because of a lack of evidence to support its utility.

Background

Thermography

Thermography is the measurement of temperature variations at the body surface. The scientific evidence suggests confirming the presence of a temperature difference, and that other procedures are needed to reach a specific diagnosis, which is little to what doctors already know based on history, physical examination, and other studies.

Thermography studies are non-invasive imaging techniques that are intended to measure the skin surface temperature of organs and tissues. The infrared radiation from the tissues reveals temperature variations by producing brightly colored images. Interpretation of the color pattern is thought to contribute to the diagnosis of many disorders including breast tissue abnormalities, digital artery vasospasm, impaired spermatogenesis in infertile men, deep vein thrombosis, reflex sympathetic dystrophy, regional pain syndrome, vertebral subluxation, and others.

In contrast to the skin surface thermography techniques used by some chiropractors and other providers, a newer temperature gradient study involves an intravenous catheter. The catheter is threaded into the coronary arteries to measure temperature differences on the inner artery walls. Researchers believe this information may be related to the presence of unstable plaques that could be useful in diagnosing vulnerable patients. Madjid et al (2006) have shown that inflamed atherosclerotic plaques have an increased temperature compared to normal plaques, which correlates with an increased number of macrophages and decreased fibrous-cap thickness. Multiple studies have shown that temperature heterogeneity correlates with arterial inflammation in vivo. Several coronary temperature gradient studies are currently being developed and studied. These thermography methods can be used in the future to detect vulnerable plaques, determine patients' prognosis, and to study the plaque-stabilizing effects of different medications.
A number of medical authorities have concluded that thermography has no proven medical value, including the American Office of Health Technology Assessment (OHTA), and the American Academy of Neurology. Based on a study by the Financing Administration (now the Center for Medicare and Medicaid Services) withdrew Medicare coverage of the device.

Devices that have been used for thermography skin temperature differential analysis include the Nervoscope, the Neurolometer.

There is insufficient evidence for the use of thermography for detection of breast cancer. A structured evidence review conducted by the A. Kerr (2004) reached the following conclusions: "The evidence that is currently available does not provide evidence of effectiveness for either population screening or adjuvant diagnostic testing of breast cancer. The major gaps are only be addressed by large-scale, prospective randomised trials. More robust research on the effectiveness and cost-effectiveness of infrared thermography devices for population screening and diagnostic testing of breast cancer is needed, and the technology should be revisited in the face of additional reliable evidence".

Other reviews have also found a need for additional research on thermography. Kennedy et al (2009) noted that thermography was used as a screening tool for breast cancer in mid-1950s. However, after a 1977 study found thermography to lag behind mammography, the medical community lost interest in this diagnostic approach. These researchers discussed each screening tool with thermography. They stated that no single diagnostic tool provides excellent predictability; however, a combination of thermography and mammography may boost both sensitivity as well as specificity. The authors concluded that in light of technological advances and the thermographical industry, more research is needed to confirm the potential of thermography in providing an effective adjunctive tool for the early detection of breast cancer.

Mammography is currently the gold standard for breast cancer screening. Thus, sensitivities, specificities, as well predictives values of thermography need to be compared with those of mammography in order to ascertain if thermography can be substituted for mammography. Presently, there is a lack of scientific data comparing the 2 screening techniques. In addition, there are no practice guidelines and/or position statements that recommend thermography as the appropriate method of breast cancer screening.

Arora et al (2008) examined the effectiveness of a non-invasive digital infrared thermal imaging (DITI) system in the total of 92 patients for whom a breast biopsy was recommended based on prior mammogram or ultrasound under generated: (i) an overall risk score in the screening mode, (ii) a clinical score based on patient information, and (iii) the network. Sixty of 94 biopsies were malignant and 34 were benign. Digital infrared thermal imaging identified 58 of 92 patients as having cancer, 88 % specificity, and 82 % negative predictive value depending on the mode used. Compared to an overall percentage of 80 % greater was significantly more likely to be associated with malignancy (30 % versus 90 %, p < 0.03). The authors concluded that the potential for thermography in providing an effective adjunctive tool for the early detection of breast cancer.

Mammography is currently the gold standard for breast cancer screening. Thus, sensitivities, specificities, as well predictives values of thermography need to be compared with those of mammography in order to ascertain if thermography can be substituted for mammography. Presently, there is a lack of scientific data comparing the 2 screening techniques. In addition, there are no practice guidelines and/or position statements that recommend thermography as the appropriate method of breast cancer screening.

An American Cancer Society report Mammograms and Other Breast Imaging Procedures (2010) stated that "[t]hermography and map the heat on the surface of the breast using a special heat-sensing camera. It is based on the idea that the increased blood flow and metabolism, which could be a sign of a tumor. Thermography has been around for many years, but there is still trying to improve the technology to use it in breast imaging. But no study has ever shown that it is an effective cancer early. It should not be used as a substitute for mammograms. Newer versions of this test are better able to detect differences. They may prove to be more accurate than older versions, and are now being studied to find out if they are effective". Thermography is listed under "newer and experimental breast imaging methods" in this report.
Additionally, the United Kingdom's NHS Cancer Screening Programmes (2010) stated that "thermography is not a reliable new test and isn't reliable enough to use either to diagnose or screen for cancer. Mammography is a world wide standard for breast screening in women over 50".

The Food and Drug Administration (FDA, 2011) stated that breast thermography should not be used instead of mammography. It has not been approved as a stand-alone tool for breast cancer screening or diagnosis. Telethermography images and do not require exposure to radiation or breast compression, which some healthcare providers claim makes mammographic devices. However, the FDA stated that "there is simply no evidence" that breast thermography can be used instead of mammography. The agency has sent warning letters to manufacturers and practitioners who have made misleading claims about thermography use.

Currently, there is insufficient evidence to support the use of thermography for the diagnosis of complex regional pain syndrome (CRPS). Thermography in the diagnosis of CRPS type 1 (CRPS1) is based on the presence of temperature asymmetries. However, the interpretation of thermographical images has not been validated for routine use. Huygen et al (2004) developed a sensitive, specific and reproducible arithmetical model to analyze thermographical images and do not require exposure to radiation or breast compression, which some healthcare providers claim makes mammographic devices. However, the FDA stated that "there is simply no evidence" that breast thermography can be used instead of mammography. The agency has sent warning letters to manufacturers and practitioners who have made misleading claims about thermography use.

Gradl and colleagues (2003) stated that CRPS1 represents a frequent complication following distal radial fractures. A total of 158 patients followed-up for 16 weeks after trauma. Apart from a detailed clinical examination 8 and 16 weeks after trauma, the radiographs of both hands were carried out. At the end of the observation period 18 patients (11 %) were clinically severe of the preceding trauma and the chosen therapy did not influence the process of the disease. Sixteen weeks after distal radial fracture, differentiation between normal fracture patients and CRPS1 patients was possible. Eight weeks after distal radial fracture, the sensitivity of clinical evaluation, radiography and thermography in the early diagnosis of CRPS1 was determined by means of pain questionnaire, [pain and McGill Pain Questionnaire], measurements of mobility (active range of motion) and edema volume. Asymmetry factor was calculated by means of the asymmetry factor, the ratio and the average temperature discrimination power of the 3 methods was determined by the receiver-operating curve (ROC). The regression between the temperature distributions of both extremities was plotted. Subsequently the correlation of the data was calculated. The area under the ROC curve was excellent. The area under the curve was 0.97 (p < 0.001), the sensitivity and specificity respectively. Furthermore, the temperature asymmetry factor was correlated with the duration of the disease and severity of the disease.

Arterial wall thermography has also been used to identify rupture-prone vulnerable coronary plaque. However, the thermography in interventional cardiology has not been established.

Schaar and colleagues (2007) noted that rupture of vulnerable plaques is the principal cause of acute coronary syninfarction. Identification of vulnerable plaques is therefore essential to enable the development of treatment modalities. Thermography is one of the several novel methods being examined for detecting vulnerable plaques. It evaluates the arterial wall of the plaque. The authors concluded that while several invasive and non-invasive methods are being collected with the use of this catheter with either thermography capability or additional imaging, such as optical coherence tomography (OCT) and intravascular ultrasound (IVUS), the data suggest that these methods have potential for the early detection and treatment of vulnerable plaques.

García-García and colleagues (2008) stated that thin-capped fibroatheroma is the morphology that most resembles these vulnerable plaques in-vivo is essential to being able to study their natural history and evaluate potential treat may ultimately have an important impact on the prevention of acute myocardial infarction and death. The investigators used conventional grayscale intra-vascular ultrasound, virtual histology and palpography data are being collected with the same pullback. A combination of this catheter with either thermography capability or additional imaging, such as optical coherence tomography (OCT) and intravascular ultrasound (IVUS), the data suggest that these methods have potential for the early detection and treatment of vulnerable plaques.

http://qawww.aetna.com/cpb/medical/data/1_99/0029_draft.html 02/18/2015
spectroscopy, would be an exciting development. Intra-vascular magnetic resonance imaging also holds much pro-
that, to date, none of the techniques described above has been sufficiently validated and, most importantly, their p-
cardiac events remains elusive. The investigators concluded that very rigorous and well-designed studies are need-
diagnostic modality. Until researchers are able to detect in-vivo vulnerable plaques accurately, no specific treat-
Madjid and colleagues (2006) stated that up to 2/3 of acute myocardial infarctions develop at sites of culprit lesions.
New imaging techniques are needed to identify those lesions with an increased risk of developing an acute compl-
Inflammation is a hallmark feature of these vulnerable/high-risk plaques. These investigators have demonstrated t-
noted that animal and human studies have reported that temperature heterogeneity correlates with arterial inflam-
temperature mapping catheters are currently being developed. These thermographic methods can be used in the-
plaques, potentially to ascertain patients' prognosis, and to examine the plaque-stabilizing effects of various pharm-
Sharif and Murphy (2010) noted that critical coronary stenoses have been shown to contribute to only a minority of-
sudden cardiac death. Autopsy studies have identified a subgroup of high-risk patients with disrupted vulnerable p-
Consequently, a clinical need exists to develop methods to identify these plaques prospectively before disruption a-
The anatomical characteristics of the vulnerable plaque such as thin cap fibro-atheroma and lipid pool can be ident-
frequency intra-vascular ultrasound, intra-vascular magnetic resonance imaging (MRI), and optical coherence tom-
to recognize active inflammation in high-risk plaques using intra-vascular thermography. Plaque chemical co-
magnetic radiation using spectroscopy is also an emerging technology to detect vulnerable plaques. Non-invasive-
tomography, and positron emission tomography also holds the potential to differentiate between low-risk and high-
present none of these imaging modalities is able to detect vulnerable plaque nor have they been shown to definit-
Nevertheless in contrast, there has been a parallel development in the physiological assessment of advanced athe-
disease. Thus, recent trials using fractional flow reserve in patients with modest non flow-limiting stenoses have s-
percutaneous coronary intervention with optimal medical therapy in these patients is superior to coronary intervent-
Further trials are needed to provide more information regarding the natural history of high-risk but non flow-limiting p-
specific targeted therapy and to refine plaque stabilizing strategies in the future.

There is insufficient evidence to support the use of thermography in post-herpetic neuralgia. Han and associates (-
of infrared thermography as a predictor of post-herpetic neuralgia (PHN). Infrared thermography was performed o-
110 patients who had been diagnosed with acute herpes zoster (HZ). Demographical data collected included age,-
onset, development of PHN, and co-morbidities. The temperature differences between the unaffected and affected-
Differences greater than 0.6 degrees C for the mean temperature across the face and trunk were considered abno-
warmer in 35 patients and cooler in 33 patients than the contralateral side. A patient's age and disease duration a-
However, the temperature differences were not correlated with pain severity, disease duration, alldynia, developm-
agents (p > 0.05). The authors concluded that a patient's age and disease duration are the most important factors-
irrespective of thermal findings, and PHN can not be predicted by infrared thermal imaging.

An Agency for Healthcare Research and Quality's report on non-invasive diagnostic techniques for the detection o-
2011) listed thermography as one of the investigational diagnostic techniques for the detection of skin cancers.

Kontos et al (2011) determined the sensitivity and specificity of DITI in a series of women who underwent surgical e-
and malignant breast lesions presenting through the symptomatic clinic. Digital infrared thermal imaging was eval-
attending a 1-stop diagnostic breast clinic. Thermography had 90 true-negative, 16 false-positive, 15 false-negativ-
The sensitivity was 25 %, specificity 85 %, positive-predictive value 24 %, and negative-predictive value 86 %. Th-
being non-invasive and painless, because of the low sensitivity for breast cancer, DITI is not indicated for the prima-
patients nor should it be used on a routine basis as a screening test for breast cancer.

The Canadian Agency for Drugs and Technologies in Health's technology assessment on "Infrared thermography f-
diagnostic testing for breast cancer" (Morrison, 2012) states that "No randomized controlled trials have been condu-
effectiveness of thermography with mammography for screening in well women, and there is no evidence regardin
Thermography used for screening. Prospective cohort studies of symptomatic patients or patients with abnormal m
not provide the type of evidence needed to justify the use of thermography for breast screening. Results indicate t
worse than mammography in terms of sensitivity, specificity, and predictive values; however, some of the studies’
may be a role for thermography as an adjunct diagnostic test in some cases”.

Kim et al (2012) evaluated the accuracy of the size and location of the ablation zone produced by volumetric MRI-g
ultrasound (HIFU) ablation of uterine fibroids on the basis of MR thermometric analysis and assessed the effects o
A total of 33 women with 38 uterine fibroids were treated with an MR imaging-guided HIFU system capable of volu
(diameter times length) and location (3-D displacements) of each ablation zone induced by 527 sonifications (with [n
feedback) were analyzed according to the thermal dose obtained with MR thermometry. Prospectively defined acc
accuracy were ± 5 mm in left-right (LR) and cranio-caudal (CC) directions and ± 12 mm in antero-posterior (AP) dir
control in 8- and 12-mm treatment cells were evaluated by using a mixed model with repeated observations within
ablation zones produced by 4-, 8-, 12-, and 16-mm treatment cells (with and without feedback) were 4.6 mm ± 1.4
4.8 (n = 13), 8.9 mm ± 1.9 × 20.2 mm ± 6.5 (n = 248), 13.0 mm ± 1.2 × 29.1 mm ± 5.6 (n = 234), and 18.1 mm ± 1.
respectively. Targeting accuracy values (displacements in absolute values) were 0.9 mm ± 0.7, 1.2 mm ± 0.9, and
directions, respectively. Of 527 sonifications, 99.8 % (526 of 527) were within acceptance ranges. Feedback contro
effect on targeting accuracy or ablation zone size. However, variations in ablation zone size were smaller in the fe
authors concluded that sonication accuracy of volumetric MRI-guided HIFU ablation of uterine fibroids appears clin
further improved by feedback control to produce more consistent ablation zones.

Brkljacic et al (2013) noted that breast cancer is a common malignancy causing high mortality in women especially
the contribution of mammographic screening and improvements in therapy, the mortality rate from breast cancer ha
also as screening tool, while breast ultrasound plays a major role in the diagnostic setting in distinguishing solid les
tissue sampling. Several indications are established for contrast-enhanced MRI. Thermography was not validated
study performed long ago for evaluating this technology in the screening setting demonstrated very poor results. T
might be feasible for screening cannot be derived from studies with small sample size, unclear selection of patients
and thermography were not blindly compared as screening modalities. Thermography cannot be used to aspirate,
operatively since no method so far was described to accurately transpose the thermographic location of the lesion
ultrasound and to surgical specimen. The authors concluded that thermography cannot be proclaimed as a screen
evidence whatsoever.

The Work Loss Data Institute’s guideline on “Low back -- lumbar & thoracic (acute & chronic)” (2013) listed thermo
thermography) as one of the interventions/procedures that was considered, but is not recommended.

Dynamic Infrared Blood Perfusion Imaging

Dynamic infrared blood perfusion imaging (DIRI) is a new infrared imaging technique that is intended to detect cha
organs by sensing passively emitted infrared radiation from tissues. Potential clinical applications of DIRI include:
tool for breast cancer and other cancers; evaluation of response to cancer chemotherapy; monitoring response to t
vascular disease; identifying perforator vessels during pre-surgical planning; assessing post-operative perfusion of
reconstructive surgery (i.e., of the breast); mapping of functional cortex in patients undergoing tumor surgery; and d
patency and perfusion of the myocardium in cardiac surgery. Agostini and colleagues (2009) stated that dynamic i
technique in breast oncology. Currently available evidence, however, is limited to evaluations of DIRI’s technical f
evidence of the impact of DIRI on health outcomes. The BioScanIR System (OmniCorder Technologies, Inc., Bohe
DIRI device that is commercially available.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes not covered for indications listed in the CPB:
ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

- 140.0 - 208.91 Malignant neoplasm
- 250.70 - 250.73 Diabetes with peripheral circulatory disorders
- 414.00 - 414.07 Coronary atherosclerosis
- 443.81 Peripheral angiopathy in diseases classified elsewhere
- 729.5 Pain in limb
- 813.41 - 813.42 Closed fracture of radius
- 813.51 - 813.52 Open fracture of radius
- 905.2 Late effect of fractures of upper extremity
- V45.81 Aortocoronary bypass graft status
- V58.11 - V58.12 Encounter for antineoplastic chemotherapy and immunotherapy
- V72.81 Pre-operative cardiovascular examination
- V72.83 Other specified pre-operative examination
- V72.84 Pre-operative examination, unspecified
- V76.0 - V76.9 Special screening for malignant neoplasms

The above policy is based on the following references:

10. Mackin GA. Medical and pharmacologic management of upper extremity neuropathic pain syndromes. J Ha
12. Radhakrishna M, Burnham R. Infrared skin temperature measurement cannot be used to detect myofascial Rehabil. 2001;82(7):902-905.
43. Fitzgerald A, Berentson-Shaw J. Thermography as a screening and diagnostic tool: A systematic review. N
46. Brkljacic B, Miletic D, Sardanelli F. Thermography is not a feasible method for breast cancer screening. Col

Copyright Aetna Inc. All rights reserved. Clinical Policy Bulletins are developed by Aetna to assist in administering plan benefits and constitute neither
This Clinical Policy Bulletin contains only a partial, general description of plan or program benefits and does not constitute a contract. Aetna does not
therefore, cannot guarantee any results or outcomes. Participating providers are independent contractors in private practice and are neither employee
Treating providers are solely responsible for medical advice and treatment of members. This Clinical Policy Bulletin may be updated and therefore is
CPT only copyright 2008 American Medical Association. All Rights Reserved.