



CIGNA MEDICAL COVERAGE POLICY

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Subject Thermography/Temperature Gradient Studies

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Coverage Policy

CIGNA does not cover thermography/temperature gradient studies for any indication, because it is considered experimental, investigational or unproven.

General Background

Thermography (i.e., thermal imaging, infrared imaging, temperature gradient studies) is a noninvasive imaging modality that measures and maps temperature distribution emitted from body surfaces. The theory is that abnormalities such as malignancies, inflammation and infection emit increased heat that will appear as hot spots on imaging. Thermography is limited in that it only indicates if a difference in temperature exists. The diagnostic significance of this information remains unclear. It has not been proven that performing thermography can obviate the need for other diagnostic studies, nor has it been demonstrated that any additional diagnostic value is provided by thermography. The two most commonly used types of thermography are infrared thermography and liquid crystal thermography. Infrared thermography utilizes an infrared camera or computer to sense and

demonstrate areas of differing heat emissions by producing brightly colored patterns. Each color represents a specific temperature level. Liquid crystal thermography uses sheets impregnated with cholesteric liquid crystals that change color in response to variations in surface body temperature. Although thermography is a noninvasive low-risk procedure (i.e., no harmful rays are emitted), several disadvantages have prevented its widespread use. It requires a tightly controlled environment free from draft, temperature fluctuation, and humidity. It also requires a 20-minute to two-hour acclimatization period. The amount of side-to-side temperature differences that define a dysfunction are unknown (Mehta and Lindenfeld, 2003).

Interpretation of the color patterns according to designated anatomic distribution is thought to aid in evaluating and diagnosing a variety of conditions, including breast cancer, complex regional pain syndrome (CRPS), low back pain, neuropathies, Raynaud's disease, temporomandibular disorders (TMD), and varicocele.

U.S. Food and Drug Administration (FDA)

Thermography devices are categorized by the U.S. Food and Drug Administration (FDA) as Class I medical devices under the 510(k) process. Under this process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the device prior to marketing it. According to FDA labeling, thermal imaging is a noninvasive diagnostic technique that allows a practitioner to quantify and visualize skin surface temperature changes. The device allows the user to map body temperature graphically and display the image on a monitor. Images can be captured and stored on a computer. Thermography may be used as an aid for diagnosis, as well as follow-up therapy in such areas as orthopedics, pain management, neurology and diabetic foot care. Examples of these devices include: Breastscan IR System (Infrared Sciences, Corp. Stony Brook, NY), MedHot MTI 2000 Thermal Imaging System (MedHot Thermal Imaging, Inc. Lakeland, FL) and Dorex Spectrum 9000MB Thermography System (Dorex, Inc., Orange, CA).

Breast Cancer

Cancer begins because of an out-of-control growth of abnormal cells due to damage of DNA. Breast cancer is the abnormal growth of breast cells. Types of breast cancers include: ductal, lobular, invasive ductal, invasive lobular, phyllodes tumor, tubular carcinoma, mucinous carcinoma, and medullary cancer. Breast cancer can be localized, or it can metastasize to other parts of the body. Second to nonmelanoma skin cancer, breast cancer is the leading type of cancer in women and second only to lung cancer in female deaths. Breast cancer also occurs in men. Family history, race, exposure to radiation therapy, early onset of menses, late onset of menopause, use of estrogen, hormone replacement therapy, excessive use of alcohol, and obesity may predispose a woman to breast cancer (American Cancer Society [ACS], 2007; National Comprehensive Cancer Network [NCCN] 2007).

Accepted screening methods for breast cancer include: breast self-examination, clinical breast examination, and mammography. Thermography has been proposed as an alternative screening tool for the detection of breast cancer. However, thermography of the breast is cumbersome and complicated. The examination inflicts pain when a needle is used, and there may be a risk of tumor cell seeding by needle insertion (Yahara, et al., 2003).

Proponents of the study have theorized that the chemical and blood vessel activity in cancerous and pre-cancerous breast tissue is at a higher than normal level due to the need for an abundant supply of nutrients to maintain the growth of the abnormal cells. This nutritional need creates an increase in circulation in the diseased area and emits a higher than normal surface temperature, which is identified by thermography (International Academy of Clinical Thermology [IACI], 2003).

Thermography was initially included in the national multicenter breast cancer detection demonstration program. The detection rate with thermography was 42% compared to 92% for mammography. Using thermography with proven diagnostic measures adds no useful clinical information (Stencherever, et. al., 2001). The scientific, peer-reviewed literature and professional societies do not support the use of thermography as a reliable indicator for the presence of breast cancer (Hayes, 2006).

Literature Review: A small study (n=48) utilized liquid crystal contact thermography (Terumo[®], Tokyo, Japan) on women with primary invasive ductal carcinoma (Yahara, et al., 2003). Liquid crystal contact thermography was used in conjunction with a needle-type thermometer. The thermometer was inserted through the skin into the core area of the tumor, into the area surrounding the tumor, and into the normal tissue of the contralateral breast. The authors reported that abnormalities in temperature were reflected by thermography. Findings were related to the temperature change in the surrounding tissue rather than to the temperature of the core tumor

area. Other contributing factors, such as the distance from the skin to the tumor, age, menopausal status, menstrual cycle and abnormal peripheral vascular hemodynamic behavior due to other disease can affect the results of the test. The clinical value and significance of thermography remains unclear, but, with improvements in the technology, the authors suggested that the modality continue to be re-evaluated. In an earlier study, Sterns et al. (1996) determined that in women (n=420) with invasive ductal carcinoma, an abnormal liquid crystal thermogram, found in 18.6% of patients, was associated with large tumor size, high tumor grade, and lymph node positivity, but not with the proliferation rate or microvessel density. An abnormal thermogram was not found to be an independent prognostic indicator of breast cancer.

A four-year, multicenter trial using data from a blinded subject set (n=769 patients/875 biopsied lesions) was conducted to “determine the efficacy of a dynamic computerized infrared imaging system for distinguishing between benign and malignant lesions in patients undergoing biopsy on the basis of mammographic findings” (Parisky, et al., 2003). Since the imaging was less specific in patients with extremely dense breast tissue, breast composition appeared to influence the infrared imaging performance. The imaging also did not perform well for those patients with ductal carcinoma in situ. The infrared imaging machine used in this study (i.e., BCS2100; Computerized Thermal Imaging, Ogden, UT) was not FDA approved, and the authors stated that it was not designed as a screening tool, but as an adjunct for further evaluating mammography and sonography results. Further studies are needed to assess the reliability of infrared imaging for it to be considered of proven diagnostic value.

Complex Regional Pain Syndrome (CRPS)

Complex regional pain syndrome (CRPS), reflex sympathetic dystrophy (RSD) or causalgia is a chronic neurological syndrome characterized by burning pain, autonomic dysfunction, edema, dystrophy, atrophy, and sometimes movement disorder. Excruciating pain is the hallmark of the disease. In some cases, CRPS occurs spontaneously, and the etiology is not identifiable. In other cases, symptoms may occur after an injury or trauma (e.g., fall, sprain, fracture or surgery). There are two types of CRPS: Type I (i.e., RSD), in which nerve injury cannot be identified; and Type II (causalgia), in which a nerve injury can be identified (Niehoff, et al., 2006; Stanton-Hicks, 2006).

Other conditions may have features similar to those of CRPS, making it difficult to diagnose. The diagnosis of CRPS is a clinical diagnosis made by history and physical examination and observation of signs and symptoms. There is no specific diagnostic test that is conclusive for this condition. Laboratory testing is not necessary for diagnostic purposes, nor is it useful in defining appropriate therapies (Galer, et al., 2001). There are some tests that may be performed in order to provide information regarding the patient's condition, but they are not specific to CRPS. These tests include: radiologic testing, bone scan, electrodiagnostic studies, electrophysiologic studies, electromyography, nerve conduction testing and sympathetic blocks (Galer, et al., 2001; Mehta and Lindenfeld, 2003). Due to the temperature asymmetry that may be seen in CRPS, which is regarded as an indication of the presence of the disease, thermography has been proposed as an adjunctive diagnostic tool.

Early diagnosis and treatment of CRPS is recommended for optimal management. Treatment is often multidisciplinary, including rehabilitation, psychological and pain therapies. The goal of the psychological and pain-management interventions is to allow optimal functional restoration. Other treatment options, which depend upon the type and severity of symptoms, include: pharmacotherapy (e.g., anti-inflammatory drugs, neuropathic drugs, calcitonin, bisphosphonates), intravenous regional or local anesthetic, sympathetic blockades, spinal cord stimulation, and sympathectomy. Family and patient education can also be helpful (Sharma, et al., 2006; Reflex Sympathetic Dystrophy Syndrome Association [RSDSA], 2008; Stanton-Hicks, 2006).

Literature Review: Niehof et al. (2008) assessed the validity of skin surface temperature recordings, for diagnosing acute CRPS1 fracture patients. Thermographic recordings of the palmar/plantar side and dorsal side of both hands or feet were made on patients diagnosed with CRPS1 (n=24), on control fracture patients with various complaints (n=84), and on 12 randomly selected (normal healing) fracture patients without any visible signs/complaints. Various calculation methods applied to the thermographic data were compared to obtain indicators of diagnostic value. The absolute difference in mean hand/foot temperature was found to be a weak predictor of CRPS1 patients, while measures such as the average fingertip temperature and total difference in temperature between fingers and toes were reported to have stronger diagnostic value. The sensitivity and specificity varied considerably between the methods used to calculate temperature difference between extremities. The highest sensitivity was 71% and the highest specificity 64%. The highest positive predictive value (PPV) reached 35% and the highest negative predictive value (NPV) 84%. In the opinion of these

investigators, “the validity of thermographic recording to discriminate between CRPS fracture patients and control patients with complaints at the early onset of CRPS1 is limited; therefore, thermography should be considered as an additive diagnostic tool” (Niehof, et al., 2008).

Niehof et al. (2006) “compared the sensitivity and specificity of calculation methods used to assess thermographic images obtained during temperature provocation” in 12 patients with Type I CRPS. The study included patients with unilateral CRPS in the upper extremity. Questionnaires were used to assess the severity of pre- and post-testing pain. Whole-body warming and cooling were induced in the 12 CRPS patients and eight control patients. Fingertip temperatures of both hands were measured using tympanic thermometer (M3000A, First Temp Genius®, Tyco Healthcare Ltd, Gosport, UK). The study reported a sensitivity of 100% and specificity of 75%. During temperature provocation, a sensitivity of 100% and specificity of 83% with an increased area under the curve (AUC) (i.e., the area under the receiver operating characteristic [ROC] curve) were recorded. “Because of the difference between the sensitivity and specificity from average fingertip temperature in favor of the sensitivity and specificity obtained using the asymmetry factor”, the authors noted that the study indicated that temperature measurements of the fingertips alone were not sufficient for diagnostic purposes.

Kim et al. (2003) conducted a study of patients (i.e., 11 with CRPS, five with failed back syndrome, 10 with hyperhidrosis) who received a lumbar sympathetic ganglion block (LSGB). The temperature of multiple areas of the lower extremities was measured both pre- and post-LSGB to obtain the net change in skin temperature. Following LSGB, the net increases in skin temperature at the plantar surface of the feet were 6.2 ± 2.68 C and 3.9 ± 1.89 C at the dorsal surface. These measurements were higher than the measurements in other regions of the lower extremities ($p < 0.05$). The authors noted that patients with peripheral vascular disease were excluded because of limitations stemming from a lack of vasodilatory effect.

In a 2002 study, Wasner et al. measured skin temperature in 25 patients with CRPS I. The study included two control groups. One control group consisted of 15 patients with non-CRPS chronic pain of one limb, and another control group consisted of 20 healthy subjects. The results of the study indicated that temperature differences between the affected and unaffected sides during rest were, on average, significantly greater in the CRPS group than in the two control groups. However, the temperature differences were noted to change dynamically depending on the thermoregulatory state of the patient, with changes sometimes occurring within minutes. The results showed a sensitivity of 32% and specificity of 100%. The authors noted that the symptom of skin temperature asymmetries alone could not be used to diagnose CRPS, but that it could be utilized as a tool to supplement other clinical signs.

Gulevich et al. (1997) investigated the use of thermography in diagnosing CRPS in consecutive patients ($n=185$) referred to a clinic for chronic limb pain. Twenty-four asymptomatic volunteers served as a control group. The three-physician panel could not clearly classify whether CRPS was present in about one-third of the cases (i.e., 70 patients). Seventy-three pairs of limbs were clinically diagnosed with CRPS I, 70 pairs were not CRPS I and 62 pairs were possible CRPS I. There were five false negative thermographic results (sensitivity 93%) and seven false positive results (specificity 89%) in the CRPS I and the not CRPS I patients. Based on an estimated 50% prior probability for these patients, the positive predictive and negative predictive values were 90% and 94%, respectively. The authors noted that many external factors influence skin temperature, confounding thermographic results.

Low Back Pain

At one time or another, most Americans experience back pain. Low back pain (LBP) may be acute (i.e., short-term) or chronic (i.e., persistent for more than three months). Symptoms include pain and restricted motion. LBP may be caused by a sprain, strain, muscle spasm, obesity, poor posture, scar tissue, stress, loss of bone strength and muscle elasticity due to the aging process, and conditions such as sciatica, spinal degeneration, osteoporosis and fibromyalgia. Back pain can be progressive and become serious if left untreated. Evaluation of back pain includes medical history and physical examination and diagnostic studies when indicated (e.g., x-ray, magnetic resonance imaging (MRI), computerized tomography (CT), discography, electromyography). Thermography has been proposed as a diagnostic study for LBP to detect nerve root compression, (NINDS, 2008c). It is proposed that thermography evaluates the functional phenomena regulated by the autonomic nervous system and provides information to evaluate vasomotor activity of the sympathetic nerve fibers and detect sympathetic dysfunction (Zaproudina, et al., 2006). However, the clinical utility of thermography in the diagnosis of low back pain is not supported by the peer-reviewed literature.

Literature Review: Zaproudina et al. (2006) compared skin temperature disorders in patients with unilateral LBP with (n=41) or without (n=24) referred, above the knee, nonradicular leg pain to persons without LBP. They evaluated the relationship between intensity of pain and other clinical signs to thermography results. The study included 65 patients, age range 30–51, with chronic LBP. In addition to thermography, questionnaires were used to record functional disability and mood scores, and spinal mobility tests were performed. Thermography results demonstrated that subjects with LBP experienced a change in plantar surface temperature. In 50.8% of subjects, the plantar surface temperature on the affected side was colder, and in 49.2% the affected side was warmer than the healthy leg. Compared to the control group, the study group's affected sides were colder in severe-pain patients. The plantar surface temperature changes correlated with the LBP intensity.

A prospective, blinded study by Leclaire et al. (1996) compared the diagnostic accuracy of three nonradiographic technologies (i.e., thermography, triaxial dynamometry and spinoscopy) in evaluating low back pain. Forty-one patients with low back pain and 46 control subjects were assessed by each modality by two clinical examiners blinded to clinical status. Thermography, using a Thermovision 890 (Agema Thermovision, Burlington, Ontario) produced a low rate of accuracy compared to triaxial dynamometry, spinoscopy, and clinical examination in assessing patients with recent-onset low back pain. Thermography was not a useful evaluation technique for this condition.

Neuropathy

Neuropathy is an abnormality or disease of the nervous system which interrupts signals sent to and from the brain and spinal cord. There are over 100 types of neuropathies. Neuropathies are classified as predominately motor neuropathy, predominately sensory neuropathy, sensory-motor neuropathy, or autonomic neuropathy. Symptoms of neuropathies depend upon the type of nerves that are damaged, and may include: pain, burning sensation, tingling, prickly sensation, muscle weakness, muscle wasting, and in severe cases, paralysis, and organ and gland dysfunction. Neuropathies may be hereditary (e.g., Charcot-Marie-Tooth) or acquired (e.g., Guillain-Barré syndrome, diabetic neuropathy). They may occur as a result of trauma, tumors, infection, nutritional deficiency, alcohol abuse, systemic disease and autoimmune disorders. Diagnosis may be difficult because of the variation and variety of symptoms, and is made based upon patient history and physical examination in conjunction with laboratory and diagnostic studies appropriate for the presenting symptoms. Treatment of neuropathies depends upon the type of neuropathy and underlying conditions. Because peripheral neuropathies may be accompanied by changes in the skin temperature, thermography has been proposed as a diagnostic tool for these conditions (NINDS, 2008b).

Literature Review: Two studies looked at the use of thermography as a screening tool for foot complications in diabetics. Sun et al. (2005) conducted a study to define a standardized method to quantify foot temperature by using a medical thermal imaging radiometer system (M.T.I.R.S. Spectrum 9000 MB; Bio-vision Technologies Inc., Taipei, Taiwan). Initially, a study was conducted on 16 healthy volunteers to map out anatomical subregions and to obtain average temperature values. Then, two groups of diabetic patients were divided into those with sympathetic skin response (SSR) (n=33) and those without SSR (n=29). Temperature changes were compared between the SSR group and non-SSR group with no statistically significant differences found. Sole temperature with respect to forehead temperature was also studied. The study concluded that normalization of plantar absolute temperature with forehead temperature may provide useful information in identifying subclinical foot problems. Armstrong et al. (2003) conducted a prospective, longitudinal study (n=1588) of diabetic patients to determine if baseline mean skin temperature would be helpful in predicting foot-related complications. A baseline measurement of bilateral foot skin temperature using the Exergen DT 1001 infrared skin temperature probe (Exergen Products, Watertown, MA) was obtained from six plantar sites. Although no significant difference in mean skin temperature was observed based on gender, a difference based on ethnicity was noted. No difference based on laterality (i.e., left vs. right) was observed. Patients who developed Charcot's arthropathy in a two-year follow-up period had slightly higher mean temperatures at baseline than did those without Charcot's arthropathy. This was not true for patients who developed ulcers and/or infections or who had amputations during the follow-up period. The presence of vascular disease was not associated with lower skin temperatures.

In earlier research, thermography using an Agema 870 (Agema, Secaus, NY) had been proposed in association with diagnosis of neuropathic facial pain (Graff-Radford, et al., 1995). The purpose of the study was to determine if electronic thermography (ET) could be used as a diagnostic tool to differentiate between neuropathic facial pain and facial dental pain. Fifty-eight consecutive patients were compared to 22 control

group patients. The study concluded that ET might be useful in differentiating the types of facial pain, but further investigation is needed.

Raynaud's Disease

Raynaud's disease, or Raynaud's phenomenon (RP), is a disorder characterized by episodes of vasospasm, resulting in decreased blood flow to the fingers and toes, and in some cases to the nose, ears, nipples, and lips. Raynaud's disease is considered primary Raynaud's when the etiology is unknown. Secondary Raynaud's, or Raynaud's phenomenon, occurs along with an underlying condition (e.g., rheumatoid arthritis, atherosclerosis, Buerger's disease). Symptoms include painful spasmodic episodes in response to exposure to cold or emotional stress. The affected area pales and/or turns blue. As the spasm subsides, the area turns red and begins to throb, feel cold, numb, and/or tingly. Typically, Raynaud's is not serious and can be managed with minor lifestyle changes. In secondary Raynaud's, treatment depends upon the underlying condition. With severe Raynaud's involving prolonged or repeated episodes, gangrene can develop. Raynaud's is diagnosed by history and physical examination and, in some cases, by a cold simulation study (National Heart Lung and Blood Institute [NHLBI], 2006). Due to the temperature changes experienced by Raynaud's patients, thermography has been proposed as a diagnostic tool for this condition.

Literature Review: Anderson et al. (2007) conducted a review to determine if a difference of more than one degree Celsius was specific for underlying vascular disease (e.g., as seen in systemic sclerosis) and to determine if thermography values could differentiate primary Raynaud's phenomenon (PRP) from secondary disease. Patients included in the study were diagnosed with PRP (n=56), systemic sclerosis (SSc) with Raynaud's (n=45), or undifferentiated connective tissue disease (UCTD) with Raynaud's (n=21). The first eight months of the study thermographic data was obtained by an Inframetrics 600M infrared thermography camera (Flir Systems Ltd, Australia). An Agema 570 infrared thermography camera (Flir systems Ltd, Australia) was used thereafter. Thermographic images were obtained following acclimation of each patient at 23 degrees Celsius (C). The patients then went into a 15 minute warm-up period and thermographic data were obtained. If the results were >1 C, the room temperature was increased to 30 C and the hand was reimaged after 20 minutes of rewarming. From these images, mean temperature for the dorsum of each hand, and mean temperature within an area between the nailbed and the distal interphalangeal joint for each of the index, middle, ring and little fingers were measured. The distal dorsal differences (DDD) were calculated from these measurements. If the finger was colder than the dorsum, the DDD was positive. During the rewarming phase, lag time, maximum temperature recovery rate and percentage of recovery were averaged across both hands per patient. With the exception of the percentage maximum rewarming recovery achieved, all individual DDD and rewarming curve parameters were significantly different for PRP and SSc groups. There were a number of variable between the SSc and UCTD groups that differed. There were no differences between the PRP and UCTD groups, suggesting that thermographic variables could not be used to distinguish between these two conditions, but could distinguish between PRP and UCTD compared to SSc. "A DDD >18 C in any finger at 30 C had a positive predictive value of 70%, and a negative predictive value of 82%, in identifying the patient with RP secondary to SSc. From the results of the multinomial logistic regression, a score was derived incorporating age, number of fingers with DDD >18 C at 30 C and maximum rewarming gradient. This score (with a suitable cut-off) was 82% sensitive and 82% specific in identifying RP secondary to SSc, with a positive predictive value of 73% and a negative predictive value of 89%." Limitations of the study include the retrospective study design, small patient population and the lack of a control group.

Foerster et al. (2007) investigated whether or not cold-response thermography could be used as a diagnostic tool and as an indicator of the therapeutic efficacy of the treatment of RP. Study patients included SSc patients (n=46) and PRP patients (n=40). PRP patients had experienced at least one episode of finger-tip localized discoloration associated with pain on cold-exposure within two weeks of the examination, were not on immunosuppressive medication and were free of systematic inflammatory disease. The control group (n=53) was comprised of departmental personnel and patients without acute or chronic systemic inflammatory disease. Patients were subjected to local fingertip cooling in a 12 C water bath for 90 seconds. Immediately following the bath, temperatures were measured using an "improved cold-response monitor" developed for the study. Compared to controls, the time to regain 50% and 63% of pre-cooling temperature was significantly elevated in PRP (p<0.001 for both) and scleroderma-associated RP (p<0.001; p<0.0001, respectively). There were no significant differences between the groups in mean rewarming times. The mean cold response index (CRI) for controls was 2.4 ± 0.3 compared to 2.7 ± 0.3 in PRP (p<0.0001) and 2.7 ± 0.3 in SSc (p<0.0001). To demonstrate CRI sensitivity to change, the SSc patients were exposed to a single hyperthermia treatment. Hyperthermia increased baseline temperature (26.7 ± 3.6 C before vs. 29.9 ± 3.6 C following application), but

the extent of cooling was unchanged (11.4 ± 2.9 C vs. 12.2 ± 4.1 C). However, the CRI did significantly decrease from 2.68 ± 0.28 before vs. 2.45 ± 0.0003 after ($p=0.0003$). The authors noted that a limitation of the study was the significant overlap between rewarming in patients and controls indicating that this method could not be used for the diagnosis of RP. The small patient population is also a limitation of the study.

Foerster et al. (2006) conducted a study on the use of a novel thermographic duosensor, developed by the authors, to measure fingertip surface temperature in 139 patients with RP. The skin surface temperature and blood flow were measured following exposure to cold. Patient self-assessments were also obtained. A retrospective analysis indicated that the return to precooling surface temperature was significantly longer when compared to controls (i.e., ten individuals without Raynaud's). The t values (i.e., the entire curve recorded for an individual expressed in minutes) in the RP patients were significantly increased compared to the control patients (8.08 ± 3.65 minutes vs. 3.23 ± 1.65 minutes). The t value yielded a specificity of 94.6% and predictive value of 95.3% for the presence of RP.

Temporomandibular Disorders (TMD)

Temporomandibular disorders (TMD), or temporomandibular joint and muscle (TMJ) disorders are disorders of the jaw joint and the attached muscles. The TMJ connects the mandible to the temporal bone allowing jaw movement that enables talking, chewing and yawning. The three categories of TMD are myofascial pain, internal derangement of the joint, and arthritis. TMJ may accompany other disorders such as chronic fatigue syndrome, fibromyalgia, and rheumatoid arthritis, or may occur in response to trauma. Symptoms include: pain, stiffness, limited movement, malalignment of teeth, and/or a painful noise on opening and closing of the mouth (National Institute of Dental and Craniofacial Research [NIDCR], Jun 2006).

TMD are difficult to diagnose because the exact etiology and symptoms are unclear. There are no widely accepted standard tests for diagnosing the disorders. In the majority of cases, the patient's symptoms combined with a physical examination of the face and jaw provided sufficient information to diagnose these disorders. Routine x-rays may be used to identify underlying osteoarthritis or other bony abnormalities of the TMJ. Arthrography, magnetic resonance imaging (MRI), and computed tomography (CT) are generally not indicated, although selected studies may be appropriate for persistent TMD when clinical examination indicates the presence of internal derangement and surgery is being considered. Thermography is proposed as an effective diagnostic tool because it records variations in facial skin surface temperatures seen in areas affected by TMD (McBeth, et al., 1996).

Literature Review: McBeth et al. (1996) conducted a small blinded study ($n=39$) performing thermography on patients undergoing orthodontic treatment, patients with TMD and a control group. The findings indicated that thermographic imaging, using an Agema 870 unit (Agema Infrared Systems, Secaucus, N.J.), could separate normal patients from patients with pain and correlated well with clinical findings. Thermography identified painful clicking TMD with a sensitivity of 87% and no painful clicking (controls) with a specificity of 86%. The results also demonstrated a strong correlation with pain to muscle palpation.

Varicocele

A varicocele is an enlargement of the pampiniform plexus within the scrotum, and occurs when there is a backup of normal blood flow in the veins along the spermatic cord. The backflow may develop due to incompetent or absent valves within the gonadal or spermatic veins and cause dilatation and enlargement of the veins. A varicocele often develops during puberty and develops slowly. Sudden onset may be indicative of a renal tumor that has affected blood flow through the spermatic vein. Although they are typically asymptomatic, swelling and pain associated with exertion can be present. Diagnosis is made by physical examination, but a varicocele may or may not be palpable. Varicocele is a major cause of male infertility. Thermography has been proposed as a diagnostic study for varicocele because there is an increase in testicular temperature in the affected testicle due to the abnormal blood flow. Thermography results may record the difference in temperature between the affected and unaffected testicle aiding in the diagnosis of the varicocele (Medline Plus, 2007; Gat, et al., 2005; American Urology Association [AUA], 2005).

Literature Review: Gat et al. (2005) conducted a retrospective review of 740 consecutive infertile men, 120 of whom were prediagnosed with varicocele. Ages ranged from 20–52. All patients underwent physical examination, thermography and venography, and were treated by sclerotherapy of the internal spermatic veins. Varicoceles were identified by thermography on all men including subclinical, nonpalpable varicoceles and bypasses. Thermography, using a flexible liquid crystal thermostrip (FertiPro, Breemen, Belgium) detected 103

left-sided and 681 right-sided subclinical varicoceles, which were not identified by palpation but were confirmed by venography. The authors stated that the ideal treatment modality is to obtain the most detailed anatomic, physiological and pathophysiological information possible, and thermography can accomplish this goal, especially with right varicocele which is not palpable.

Other Indications

Thermography has also been proposed as a diagnostic tool in the assessment of atherosclerotic plaques, arthritis, soft tissue injuries, burn therapy, spinal conditions, inflammatory disease, deep vein thrombosis, and numerous other neurological and musculoskeletal disorders.

Thermography is being investigated as a technique to detect the presence of vulnerable plaque or atherosclerotic plaque that is at high risk for rupturing and triggering unstable angina or acute myocardial infarction. The Agency for Healthcare Research and Quality (AHRQ) notes that multiple diagnostic methods have been proposed to identify vulnerable plaques, including angiography, intravenous ultrasound (IVUS), angioscopy, and thermography catheters. However these methods are in the investigational phase, since none is supported by large, prospective natural history studies or by clinical studies demonstrating risk reduction. Regarding the diagnostic role of thermography, the AHRQ summarized that “there is no clear evidence that temperature differentials correlate with specific plaque vulnerability, and that the independent role of thermography is limited without the structural definition obtained from high resolution imaging techniques” (AHRQ, 2004).

Armstrong et al. (2006) utilized an infrared thermometer (Thermo-Trace™; Deltatrac, Pleasanton, CA) to determine if the differences in skin temperature correlated with infection severity and clinical outcomes in diabetics with foot infections. Participants (n=332) were a subgroup from the SIDESTEP study which compared the effectiveness of antibiotics for the treatment of diabetic foot infections. Measurements were taken from the infected foot and compared to the contralateral healthy foot prior to and upon discontinuation of intravenous therapy (DCIV). If the patient was an amputee, comparison temperatures were taken at the distal aspect of the same limb. At baseline, the mean temperature differential between limbs was 2.81 ± 5.75 degrees Fahrenheit (F) compared to 2.43 ± 4.84 F ($p=0.225$). There was no correlation between skin temperature differential and white blood count, C-reactive protein, erythrocyte sedimentation rate, or DFI wound score. A small subset of patients with a baseline temperature differential ≥ 10 F demonstrated a favorable response compare to patients with a < 10 F differential. There were no significant differences between the skin temperatures measured at baseline compared to the skin temperatures at DCIV. There were no significant correlations in temperature measurements and laboratory markers of systemic infection, or wound severity.

Several 2007 studies have utilized thermography in various conditions. Clark et al. utilized facial thermography to detect temperature changes during oral food challenges to assess allergic reactions (n=24). Lamey et al. investigated the use of thermography in the evaluation of minor labial salivary gland function (n=10). Lee et al. “evaluated the injury and recovery of the inferior alveolar nerve” in 20 patients with Class III dentofacial deformities. Other studies utilized thermography for the evaluation of ocular surface temperature in glaucoma (n=32) (Galassi, et al.), shoulder impingement syndrome (n=100) (Park, et al.), and peripheral nerve injury (n=36) (Ya’ish, et al). In a 2006 study involving 25 patients, Galvin et al. concluded that thermography provides an “early and objective assessment of the success and failure of axillary regional blockades”.

Although some of these studies have suggested that thermography might have a role in the diagnostic evaluation of these conditions, future studies with large patient populations and comparisons to conventional diagnostic tools are indicated to validate their findings and to confirm the clinical utility of thermography.

Professional Societies/Organizations

The American Cancer Society Guidelines for Breast Cancer Screening (updated 2003) reports that screen-film mammography is the current gold standard for breast cancer screening. The guidelines note that other modalities can be useful diagnostic adjuncts (e.g., ultrasound or MRI). The clinical evidence indicates that the use of thermography as a potential new imaging technology for breast cancer detection screening is ineffective. In a discussion of mammograms and other breast imaging procedures the ACS states “no study has ever shown that it (i.e., thermography) is an effective screening tool for the early detection of breast cancer. It should not be used as a replacement for mammograms” (ACS, 2008).

The American College of Obstetricians and Gynecologists (ACOG), in a guideline statement on breast cancer screening (2003), noted that thermography is not a recommended intervention or practice. Due to insufficient evidence, The National Screening Unit, The Cancer Society of New Zealand and The New Zealand Breast Cancer Foundation do not support the use of thermography as a screening or diagnostic tool for breast cancer (2005).

The American Academy of Neurology (AAN) Therapeutics and Technology Assessment Subcommittee reviewed the utilization of thermography, and concluded that it was not reliably useful for evaluating neck and back pain, radiculopathy, musculoskeletal pain, or entrapment neuropathy (1990). An updated AAN statement from this committee concluded that thermography had been a subject of previous evaluation and would not be further evaluated. The committee stated that there was inadequate evidence to justify thermography's use in detecting radiculopathies, but that it is a reasonable test to use in patients with RSD (AAN, 1996).

The American Chiropractic Association's Policies on Public Health and Related Matters (1999) state that infrared imaging is "germane to chiropractic practice in cases where a physiological test is required". The policies claim that thermography is a useful procedure for the diagnosis of selected neurological and musculoskeletal conditions. The Council on Chiropractic Practice issued a guideline on vertebral subluxation in chiropractic practice (2003) which included the use of skin temperature instrumentation via thermography to detect temperature changes in spinal and paraspinal tissues related to vertebral subluxation. However, evidence in the scientific, peer-reviewed literature does not support the diagnostic utility of thermography for the diagnosis of neurological and musculoskeletal conditions.

In an advisory statement, the American Academy of Orthopedic Surgeons (AAOS, 2005) states that a "review of the literature indicates a lack of specificity, reliability, and reproducibility for this technique in the diagnosis of specific musculoskeletal conditions and neural injuries or disease states" and that "the use of thermography as a clinically useful diagnostic or prognostic test in orthopaedic surgery cannot at this time be scientifically justified."

The American Medical Association's (AMA) policy on thermography states, "In view of the lack of sufficient proof of effectiveness, it is the policy of the AMA that the use of thermography for diagnostic purposes cannot be recommended at this time. It should be noted that research protocols using thermography are continuing and data derived from these studies will require careful evaluation. The AMA will continue to monitor the published literature on thermography, with periodic reports as appropriate. The AMA affirms the principle that proponents of a test, procedure, or treatment should bear the burden of proving that it is safe and effective for the proposed purpose through well-designed and well-controlled clinical trials" (AMA, 2007).

The American College of Radiology (ACR) has developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical conditions. They report that the gold standard examination for the diagnosis of suspected lower extremity deep vein thrombosis (DVT) is venography, with ultrasound as the most effective alternative. Thermography has limited utility for most cases of DVT, and it is unlikely that it can identify most patients with nonobstructive DVT. The committee has discarded thermography as a diagnostic test. The committee's guideline criteria for evaluating sudden onset of a cold, painful leg state that the standard imaging modality is angiography. Thermography has little to contribute in this clinical setting (ACR, 2005). The guideline for diagnosing acute low back pain, with or without radiculopathy, states that thermography has been found to be too nonspecific in diagnosing this condition (ACR, 2005). Regarding the diagnosis of myelopathy, the ACR's appropriateness criteria states that "no high quality evidence supports" the use of thermography in the evaluation of myelopathy (ACR, 2006). In their 2007 digest of council actions, the ACR states that "the position of the American College of Radiology is that thermography has not been demonstrated to have value as a screening, diagnostic, or adjunctive imaging tool."

In guidelines for the diagnosis and classification of primary headache disorders, the National Headache Foundation (NHF) states that thermography was considered for use in the diagnosis of primary headache disorders but not recommended (Martin and Elkind, 2004).

In their guidelines on work-related acute and chronic disorders of the neck and upper back (2007), the Work Loss Data Institute lists thermography as a diagnostic tool "considered but not recommended".

The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA) (2008) does not include the use of thermography in their discussion of the diagnosis, management and treatment of complex regional pain syndrome.

Summary

Thermography is a noninvasive, diagnostic study that measures and maps temperature emission from various areas of the body's surface. Proponents of thermography suggest that diseased and injured tissue emits a temperature pattern that can be differentiated from healthy tissue. Therefore, thermography has been proposed as an adjunct and stand-alone diagnostic tool in multiple conditions.

The published, peer-reviewed literature and professional societies do not support the diagnostic utility of thermography. The limited available studies are primarily in the form of case series, retrospective reviews or narrative reviews with small patient populations, lacking control groups and/or comparison to proven diagnostic studies. There is a lack of evidence in the peer-reviewed scientific literature to substantiate the accuracy of thermography. The role of thermography in the diagnosis or management of any condition remains unproven.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
93740	Temperature gradient studies
93760	Thermogram, cephalic (code deleted 01/01/09)
93762	Thermogram, peripheral (code deleted 01/01/09)

ICD-9-CM Diagnosis Codes	Description
	All codes

*Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2008	0065	Thermography/Temperature Gradient Studies
Great-West Healthcare	10/26/2006	04.270.02	Thermography

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.