CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Thermography/Temperature Gradient Studies**

Effective Date **3/15/2011**
Next Review Date **3/15/2012**
Coverage Policy Number **0065**

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INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines.*

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 most commonly used types of thermography are infrared, also called digital infrared thermal imaging (DITI), liquid crystal and temperature gradient studies. 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. Temperature gradient studies assess heart or circulatory functions by contrasting temperatures of certain vessels via an intravenous catheter. 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.

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
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 thermography 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).

Literature Review: Clinical trials evaluating the accuracy of thermography for diagnosing breast cancer include a study by Arora et al. (2008) that reported sensitivity and specificity values of 97% and 44% respectively, with a negative predictive value (NPV) of 82%. A multicenter trial (n=769 patients/875 biopsied lesions)by Parisky et al. (2003) was conducted to determine the efficacy of a thermography for distinguishing between benign and malignant lesions in patients undergoing biopsy on the basis of mammographic findings. The imaging was found to be less specific in patients with extremely dense breast tissue suggesting that breast composition may have influenced the infrared imaging performance. The imaging also did not perform well for those patients with ductal carcinoma in situ. Other studies (n=48–420) have reported that the "clinical value and significance of thermography remains unclear" (Yahara, et al., 2003) and found thermography to not be an independent prognostic indicator of breast cancer (Sterns, et al.,1996).

The scientific, peer-reviewed literature does not support the use of thermography as a reliable diagnostic tool for breast cancer.

Complex Regional Pain Syndrome (CRPS)
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. 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). 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. 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.

Literature Review: The evidence evaluating the accuracy of thermography for diagnosing CRPS includes comparative and validity studies with patient populations ranging from 70─209 (Niehof, et al., 2008; Wasner, et al., 2002; Gulevich, et al., 1997). Reported accuracy rates have varied considerably (i.e., sensitivity 32%─93%; specificity 64%─100%) with NPVs ranging from 84%─94%, and a positive predictive values (PPV) range of 35%─90%, making it difficult to draw any conclusions regarding validity of thermography as a diagnostic indicator for CRPS.

Low Back Pain
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, 2011b). 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).

Literature Review: Few studies in the published, peer-reviewed medical literature have examined the diagnostic accuracy of thermography for back pain. A study (n=65) by Zaproudina et al. (2006) reported that Thermography results demonstrated that subjects with LBP experienced a change in plantar surface temperature. A prospective, blinded study (n=87) 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. Thermography produced a low rate of accuracy compared to triaxial dynamometry, spinoscopy, and clinical examination in assessing patients with recent-onset low back pain.

The accuracy and clinical utility of thermography in the diagnosis of low back pain is not supported by the peer-reviewed literature.

Neuropathy
Neuropathy is an abnormality or disease of the nervous system which interrupts signals sent to and from the brain and spinal cord. Neuropathies 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. Because peripheral neuropathies may be accompanied by changes in the skin temperature, thermography has been proposed as a diagnostic tool for these conditions (NINDS, 2011a).

Literature Review: Two studies have examined the use of thermography as a screening tool for foot complications in diabetics. Sun et al. (2005) conducted a study (n=78) to define a standardized method that quantified foot temperature in diabetic patients. Temperature changes were compared between patients with sympathetic skin response and those without SSR with no statistically significant differences found. 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. The presence of vascular disease was not found to be associated with lower skin temperatures.

The use of thermography for the screening and diagnosing of neuropathies is not supported by the peer-reviewed medical literature.

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 is diagnosed by history and physical examination and, in some cases, by a cold simulation study (National Heart Lung and Blood Institute [NHLB], 2006). Due to the temperature changes experienced by Raynaud's patients, thermography has been proposed as a diagnostic tool for this condition.

Literature Review: Limitations of the studies evaluating the use of thermography for diagnosing RP include small patient populations, retrospective study design, and in some cases lack of a control group. A retrospective study (n=139) by Anderson et al. (2007) reported that thermography was 82% sensitive and 82% specific in identifying secondary RP, with a positive predictive value of 73% and a negative predictive value of 89%.

Foerster et al. (2007) investigated whether or not cold-response thermography could be used as a diagnostic tool for RP. 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).

A retrospective study (n=139) by Foerster et al. (2006) used a thermographic duosensor to measure fingertip surface temperature in patients with RP. Study results indicated that the return to precooling surface temperature was significantly longer when compared to controls (i.e., 10 individuals without Raynaud's). The t value yielded a specificity of 94.6% and predictive value of 95.3% for the presence of RP.

There is insufficient evidence in the scientific literature demonstrating the validity of thermography as a diagnostic tool for this condition.

Temporomandibular Disorders (TMDs)
TMDs, or temporomandibular joint and muscle (TMJ) disorders are disorders of the jaw joint and the attached muscles. Symptoms of TMD 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). TMDs 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 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. Diagnosis is made by physical examination, but a varicocele may or may not be palpable. 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 (Gat, et al., 2005; American Urology Association [AUA], 2005).

Literature Review: One study by Gat et al. (2005) retrospectively reviewed 740 consecutive infertile men, 120 of whom were prediagnosed with varicocele. 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 detected 103 left-sided and 681 right-sided subclinical varicoceles, which were not identified by palpation but were confirmed by venography.

Although the results of this one study are promising, there is insufficient evidence in the published peer-reviewed medical literature demonstrating the clinical utility of thermography as a diagnostic tool for varicoceles.

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).

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”.

Overall, 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 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 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).

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”.

In their 2007 digest of council actions, the American College of Radiology (ACR) states that “thermography has not been demonstrated to have value as a screening, diagnostic, or adjunctive imaging tool.” 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). The ACR has stated 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).

In an advisory statement, the American Academy of Orthopedic Surgeons (AAOS, 2005) states that “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 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.

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).

Summary
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. It has not been demonstrated how the results of thermography can be used to enhance patient management and improve patient health outcomes. 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

ICD-9-CM Diagnosis Codes	Description
	All codes

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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