Cigna Medical Coverage Policy

Subject **Thermography/Temperature Gradient Studies**

Effective Date **3/15/2014**
Next Review Date **3/15/2015**
Coverage Policy Number **0065**

Table of Contents

Hyperlink to Related Coverage Policies

Chiropractic Care
Magnetic Resonance Imaging (MRI) of the Breast
Mammography
Mechanical Devices for the Treatment of Back Pain
Temporomandibular Joint (TMJ) Disorder Surgery

INSTRUCTIONS FOR USE

*The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, 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 supersedes** 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. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna*

Coverage Policy

Cigna does not cover thermography/temperature gradient studies including the BreastCare™/BreastAlert™ Differential Temperature Sensor (DST) test 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. Magnetic resonance (MR) thermography has also been investigated as a noninvasive alternative to invasive temperature probes for monitoring hyperthermia or ablative treatment for malignancies. 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 case series by Kontos et al. (2011) that found the sensitivity and specificity of thermography for the detection of primary breast cancer to be 25% and 85% respectively, with a negative predictive value (NPV) of 86% and a positive predictive value (PPV) of 24%. Arora et al. (2008) 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).

Temperature Differential Sensor: To provide an additional tool to assist in the early detection of cellular changes that occur within the breast, researchers developed a thermal sensor device that detects varying degrees of heat in breast tissue. It is proposed that testing with BreastAlert™ Temperature Differential Sensor (HumaScan, Inc., Cranford, NJ), previously known as BreastCare DTS™ device (Life Medical Technologies, Fishkill, NY), may detect an abnormal change in breast tissue (e.g., lumps, masses, cancer) before it would be

identified by self-examination, clinical examination or mammography. The device is intended to be used by clinicians as an adjunct to established clinical procedures (e.g., examination, ultrasound, mammography).

BreastAlert includes two round disposable pads containing columns of heat sensitive chemical sensors reflecting an 8.5-degree temperature range between 90 and 98.5 degrees Fahrenheit. The pads are placed on each breast under the bra for 15 minutes and temperature variations are digitally recorded by color changes. The color changes (i.e., blue, green, yellow) are visually reviewed and recorded. An asymmetrical temperature difference between the two breasts of two-degrees Fahrenheit is considered "significant" and as an adjunct to other clinical assessments, may be indicative of the need for further evaluation for breast disease. Because the results rely on mirror image comparison of quadrants of both breasts, the pads are not recommended for women with a history of a mastectomy or lumpectomy or in women with breasts that are not symmetrical. It has also been determined that the presence of mastitis, sclerosing adenosis, or other heat-generating infectious processes could produce false-positive readings.

According to the manufacturer, BreastCare has a sensitivity of 83.0%–88.1%, specificity of 86.5%, false negative rates of 3%–13%, a positive predictive value of 98% and a negative predictive value of 93%–94% (Scantek Medical, 2012). These findings need to be validated through well-designed large population clinical trials published in peer-reviewed scientific journals.

U.S. Food and Drug Administration (FDA): This Class I device was originally 510(k) approved by the FDA in 1984 as a liquid crystal thermographic system under the name of Breast Thermal Activity Indicator (BCSI Laboratories, Inc., New York, NY) "to be used by physicians as an adjunct to routine physical examination including palpation, mammography and other established procedures for the detection of breast disease". Later, the device was distributed as the BreastAlert™ Differential Temperature Sensor (HumaScan Inc., Cranford, NJ) (FDA, 1984).

Literature Review Temperature Differential Sensor: Evidence in the published peer-reviewed scientific literature investigating the clinical utility of BreastCare/BreastAlert and its impact on health outcomes is limited. There is a paucity of studies comparing BreastAlert to mammography and other established diagnostic tools. The accuracy of the device has not been established.

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 28─209 (Choi, et al., 2013; 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 PPV range of 35%─90%, making it difficult to draw any conclusions regarding validity of thermography as a diagnostic indicator for CRPS.

Coronary Artery Plaque
Thermography has been 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.

Literature Review: The evidence evaluating the use of thermography includes few case series (Cuisset, et al., 2009; Rzeszutko,, et al., 2006) with some results indicating that thermography was not able to "consistently differentiate between different lesions at risk, despite a selection of lesions that should appear most distinct to differentiate" (Rzeszutko, et al., 2006).

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).

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 indicated 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: Studies examining the use of thermography as a screening tool for foot complications in diabetics include a non-randomized controlled study (n=79) by Balbinot et al. (2012) which evaluated the sensitivity and specificity of plantar thermography in diagnosing diabetic polyneuropathy. Patients were divided into three groups: control (n = 37), pre-diabetics (n = 13) and type 2 diabetics (n = 29). The plantar images were recorded at baseline and then minutes after a provocative maneuver (Cold Stress Test) using an infrared camera. For the diabetic patients, a sensitivity of 81.3% and specificity of 46.2% was found using the interdigital technique alone, which was better than the thermal recovery index alone. For the pre-diabetic patients, the all tests performed equally well. None of the control subjects had abnormal interdigital readings or thermal recovery indices, which prevented the estimation of sensitivity in this group however, the specificity was 70.6%. The range of sensitivity and specificity results an d the small patient population make it difficult to draw conclusions from this study.

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 (n=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: Dibai-Filho et al. (2013) conducted a nonrandomized controlled study (n=40) to correlate skin surface temperature at the central point of the masticatory muscles with pain intensity in women with myogenous TMD. The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) and the visual analogue scale (VAS) were used to divide 40 university students into four groups: control (n=10), mild pain (n=10), moderate pain (n=10), and severe pain (n=10). Infrared thermography was used to assess the masticatory muscles. No significant correlations were found between pain intensity and skin surface temperature over the masseter and anterior temporalis muscles. No correlations were found between pain intensity and asymmetry of the masseter ($p=0.375$) and anterior temporalis ($p=0.090$) muscles. Study results indicate that "pain intensity in women with myogenous TMD was not associated with skin surface temperature at the central point of the masseter and anterior temporalis muscles" (Dibai-Filho, et al., 2013).

McBeth et al. (1996) conducted a 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.

The limited evidence in the published peer-reviewed medical literature investigating thermography for TMD does not permit conclusions to be drawn regarding effectiveness and clinical utility.

Varicocele
A varicocele is an enlargement of 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.

The Agency for Healthcare Research and Quality (AHRQ) report on non-invasive techniques for diagnosing skin cancers found a number of modalities including thermography to investigational for this indication. It was stated that test accuracy of many of these investigational modalities has not been adequately assessed. It is unclear whether these modalities perform better in diagnosing certain types of skin cancer or among subgroups of patients. In addition, evidence supporting the use of these investigational modalities to replace further diagnostic evaluation is lacking (AHRQ, 2011).

A case series (n=110) by Han et al. (2010) assessed the use of infrared thermography as a predictor of post-herpetic neuralgia. Study results indicated that a patient's age and disease duration were the most important factors predicting post-herpetic neuralgia progression regardless of thermal findings, and that post-herpetic neuralgia cannot be predicted by infrared thermal imaging (Han, et al., 2010).).

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 National Cancer Institute (NCI) states that “there have been no randomized controlled trials evaluating the impact of thermography on breast cancer mortality or its ability to detect breast cancer”. The available data, in

the form of small cohort studies, do not suggest any additional benefit from the use of thermography for breast cancer screening (NCI, 2013).

The American College of Radiology (ACR) report on screening criteria for breast cancer states that mammography is the recommended method for breast cancer screening of women in the general population. Supplemental screening with MRI or ultrasound is recommended in selected high-risk populations. There is insufficient evidence to support the use of other imaging modalities, such as thermography or breast-specific gamma imaging for breast cancer screening (Mainiero, et al., 2013).

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 yet shown that it (i.e., thermography) is an effective screening tool for finding breast cancer early. It should not be used as a substitute for mammograms” (ACS, 2013).

The American College of Obstetricians and Gynecologists (ACOG) does not mention thermography in their guideline on breast cancer screening (ACOG, 2011).

The Council on Chiropractic Practice issued a guideline on vertebral subluxation in chiropractic practice (2008) 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 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 the 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 the 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).

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).

Use Outside of the US

According to the National Screening Unit (NSU), the Cancer Society of New Zealand, the New Zealand Breast Cancer Foundation and the New Zealand Branch of The Royal Australian and New Zealand College of Radiologists (RANZCR) position statement, thermography is currently being marketed to women and general practitioners in New Zealand. The organizations do not support the use of thermography as a breast cancer screening or diagnostic tool as there is insufficient evidence to do so. The position further states that "thermography is not used in either the United Kingdom or Australian breast cancer screening programs. To date, there have been no satisfactory, large scale, prospective, statistically valid, randomized controlled trials assessing the value of breast thermography" (NSU and RANZCR, 2010).

The National Breast and Ovarian Cancer Centre (NBOCC) does not recommend the use of thermography for the early detection of breast cancer. According to the NBOCC, "there is no current scientific evidence to support the use of thermography in the early detection of breast cancer and in the reduction of mortality. There is a need for high quality randomized controlled trials to be conducted comparing the use of thermography and mammography to detect breast cancer in an asymptomatic population. This Position Statement is in agreement with BreastScreen Australia and the Royal Australian and New Zealand College of Radiologists statements on use of thermography to detect breast cancer" (NBOCC, 2010).

Summary
The published, peer-reviewed literature and professional societies do not support the clinical 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.

Specific to BreastCare™/BreastAlert™ Differential Temperature Sensor (DTS) for the early detection and management of breast disease, there is insufficient evidence in the published peer-reviewed scientific literature to support the clinical utility of the. Well-designed, published clinical trials comparing BreastCare/BreastAlert to established breast cancer screening methods (e.g., mammography) are needed before the role of this technology in patient management can be determined. The impact of this test on meaningful net health outcomes, such as patient survival, has not been established.

Overall, the role of thermography in the diagnosis or management of any condition remains unproven.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
93740	Temperature gradient studies

HCPCS Codes	Description
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified

References

1. Agency for Healthcare Research and Quality (AHRQ). Technical Brief No.11. Noninvasive Diagnostic Techniques for the Detection of Skin Cancers. September 2011. Accessed Feb 4, 2012. Available at: http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=796&pageaction=displayproduct

2. Agency for Healthcare Research and Quality (AHRQ). Vulnerable Plaques: A Brief Review of the Concept and Proposed Approaches to Diagnosis and Treatment. Jan 22, 2004. Accessed Feb 1, 2011. Available at URL address: http://www.ahrq.gov/clinic/ta/placque/placque.pdf

3. American Academy of Neurology (AAN). Therapeutics and Technology Assessment Subcommittee. Assessment: clinical autonomic testing. Neurology. 1996 Mar;46(3):873-80.

4. American Academy of Neurology (AAN). Assessment: thermography in neurologic practice. The American Academy of Neurology, Therapeutics and Technology Assessment Subcommittee. Neurology. 1990 Mar;40(3 Pt 1):523-5.

5. American Academy of Orthopedic Surgeons (AAOS). Advisory statement. Thermography. Mar 2005. Accessed Jan 29, 2008. Available at URL address: http://www.aaos.org/about/papers/advistmt/1009.asp

6. American Cancer Society (ACS). Mammograms and other breast imaging procedures. Feb 7, 2013. Accessed Feb 11, 2014. Available at URL address: http://www.cancer.org/healthy/findcancerearly/examandtestdescriptions/mammogramsandotherbreastimagingprocedures/mammograms-and-other-breast-imaging-procedures-newer-br-imaging-tests

7. American Cancer Society (ACS). Guidelines for breast cancer screening: Updated 2003. A Cancer J Clin. 2003;54:141-69.

8. American Cancer Society (ACS). Mammograms and other breast imaging procedures. Revised Dec 13 2011. Accessed Feb 8, 2012. Available at URL address: http://www.cancer.org/acs/groups/cid/documents/webcontent/003178-pdf.pdf

9. American College of Obstetricians-Gynecologists. Practice bulletin no. 122: Breast cancer screening. Obstet Gynecol. 2011 Aug;118(2 Pt 1):372-82.

10. American College of Radiology (ACR). ACR appropriateness criteria®. Low back pain. 2005. Accessed Jan 30, 2008. Available at URL address: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx

11. American College of Radiology (ACR).). ACR appropriateness criteria®. Suspected lower extremity deep vein thrombosis (DVT). 2005. Accessed Jan 30, 2008. Available at URL address: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx

12. American College of Radiology (ACR). ACR appropriateness criteria®. Myelopathy. 2006. Accessed Jan 30, 2008. Available at URL address: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx

13. American College of Radiology (ACR). 2007 digest of council actions. Accessed Jan 30, 2008. Available at URL address: http://www.acr.org/SecondaryMainMenuCategories/mbr_chapter/FeaturedCategories/CouncilResources/DigestofCouncilAction/2007DigestofCouncilActionDoc2.aspx

14. American College of Radiology. ACR Appropriateness Criteria®. Breast Cancer Screening. 2012. Accessed Dec 19, 2012. Available at URL address: http://www.acr.org/Quality-Safety/Appropriateness-Criteria/Diagnostic/Breast-Imaging

15. American Medical Association (AMA). Thermography update. 2007. Accessed Jan 29, 2008. Available at URL address: http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-175.988.HTM

16. American Urology Association (AUA). Varicocele. Feb 2005. Accessed Jan 29, 2008. Available at URL address: http://www.urologyhealth.org/search/index.cfm?topic=510&search=varicocele&searchtype=and

17. Anderson ME, Moore TL, Lunt M, Herrick AL. The 'distal-dorsal difference': a thermographic parameter by which to differentiate between primary and secondary Raynaud's phenomenon. Rheumatology (Oxford). 2007 Mar;46(3):533-8.

18. Armstrong DG, Lavery LA, Wunderlich RP, Boulton AJ. Skin temperatures as a one-time screening tool do not predict future diabetic foot complications. J Am Podiatr Med Assoc. 2003;93(6): 443-7.

19. Armstrong DG, Lipsky BA, Polis AB, Abramson MA. Does dermal thermometry predict clinical outcome in diabetic foot infection? Analysis of data from the SIDESTEP* trial. Int Wound J. 2006 Dec;3(4):302-7.

20. Arora N, Martins D, Ruggerio D, Tousimis E, Swistel AJ, Osborne MP, et al. Effectiveness of a noninvasive digital infrared thermal imaging system in the detection of breast cancer. Am J Surg. 2008 Oct;196(4):523-6.

21. Balbinot LF, Canani LH, Robinson CC, Achaval M, Zaro MA . Plantar thermography is useful in the early diagnosis of diabetic neuropathy. Clinics (Sao Paulo). 2012 Dec;67(12):1419-25.

22. Choi E, Lee PB, Nahm FS. Interexaminer reliability of infrared thermography for the diagnosis of complex regional pain syndrome. Skin Res Technol. 2013 Jan 20. doi: 10.1111/srt.12032. [Epub ahead of print]

23. Clark AT, Mangat JS, Tay SS, King Y, Monk CJ, White PA, Ewan PW. Facial thermography is a sensitive and specific method for assessing food challenge outcome. Allergy. 2007 Jul;62(7):744-9.

24. Council on Chiropractic Practice (CCP). Vertebral subluxation in chiropractic practice. Third edition – 2008. Accessed Feb 7, 2013. Available at URL address: http://www.ccp-guidelines.org/guideline-2008.pdf

25. Dibai-Filho AV, Costa AC, Packer AC, Rodrigues-Bigaton D. Correlation between skin surface temperature over masticatory muscles and pain intensity in women with myogenous temporomandibular disorder. J Back Musculoskelet Rehabil. 2013 Jan 1;26(3):323-8. doi: 10.3233/BMR-130387.

26. Fitzgerald A, Berentson-Shaw J. Thermography as a screening and diagnostic tool: a systematic review. N Z Med J. 2012 Mar 9;125(1351):80-91.

27. Foerster J, Kuerth A, Niederstrasser E, Krautwald E, Pauli R, Paulat R, Eweleit M, Riemekasten G, Worm M. A cold-response index for the assessment of Raynaud's phenomenon. J Dermatol Sci. 2007 Feb;45(2):113-20.

28. Foerster J, Wittstock S, Fleischanderl S, Storch A, Riemekasten G, Hochmuth O, Meffert B, Meffert H, Worm M. Infrared-monitored cold response in the assessment of Raynaud's phenomenon. Clin Exp Dermatol. 2006 Jan;31(1):6-12.

29. Galassi F, Giambene B, Corvi A, Falaschi G. Evaluation of ocular surface temperature and retrobulbar haemodynamics by infrared thermography and colour Doppler imaging in patients with glaucoma. Br J Ophthalmol. 2007 Jul;91(7):878-81.

30. Galvin EM, Niehof S, Medina HJ, Zijlstra FJ, van Bommel J, Klein J, Verbrugge SJ. Thermographic temperature measurement compared with pinprick and cold sensation in predicting the effectiveness of regional blocks. Anesth Analg. 2006 Feb;102(2):598-604.

31. Gat Y, Zukerman Z, Chakraborty J, Gornish M. Varicocele, hypoxia and male infertility. Fluid Mechanics analysis of the impaired testicular venous drainage system. Hum Reprod. 2005 Sep;20(9):2614-9. Epub 2005 Jun 2.

32. Gulevich SJ, Conwell TD, Lane J, Lockwood B, Schwettman RS, Rosenberg N, et al. Stress infrared telethermography is useful in the diagnosis of complex regional pain syndrome, Type 1 (formerly reflex sympathetic dystrophy). Clin J Pain. 1997:13(1):50-9.

33. Han SS, Jung CH, Lee SC, Jung HJ, Kim YH. Does skin temperature difference as measured by infrared thermography within 6 months of acute herpes zoster infection correlate with pain level? Skin Res Technol. 2010 May;16(2):198-201. doi: 10.1111/j.1600-0846.2009.00417.x.

34. Huang CL, Wu YW, Hwang CL, Jong YS, Chao CL, Chen WJ, et al. The application of infrared thermography in evaluation of patients at high risk for lower extremity peripheral arterial disease. J Vasc Surg. 2011 Oct;54(4):1074-80. doi: 10.1016/j.jvs.2011.03.287. Epub 2011 Jul 23.

35. Kontos M, Wilson R, Fentiman I. Digital infrared thermal imaging (DITI) of breast lesions: sensitivity and specificity of detection of primary breast cancers. Clin Radiol. 2011 Jun;66(6):536-9. Epub 2011 Mar 5.

36. Lamey PJ, Biagioni PA, Al-Hashimi I. The feasibility of using infrared thermography to evaluate minor salivary gland function in euhydrated, dehydrated and rehydrated subjects. J Oral Pathol Med. 2007 Mar;36(3):127-31.

37. Leclaire R, Esdaile J, Jequier JC, Hanley J, Rossignol M, Bourdouxhe M. Diagnostic accuracy of technologies used in low back pain assessment: thermography, triaxial dynamometry, spinoscopy, and clinical examination. Spine. 1996 Jun;21(11):1325-30.

38. Lee JG, Kim SG, Lim KJ, Choi KC. Thermographic assessment of inferior alveolar nerve injury in patients with dentofacial deformity. J Oral Maxillofac Surg. 2007 Jan;65(1):74-8.

39. Life Medical Technologies Inc™. BreastCare DTS™. 2007. Accessed Dec 19, 2012. Available at URL address: http://www.lifemt.com/investors/BreastCare.asp?Pin=1007

40. Mainiero MB, Lourenco A, Mahoney MC, Newell MS, Bailey L, Barke LD, et al. ACR Appropriateness Criteria Breast Cancer Screening. J Am Coll Radiol. 2013 Jan;10(1):11-4. doi: 10.1016/j.jacr.2012.09.036.

41. McBeth SB, Gratt BM. Thermographic assessment of temporomandibular disorders symptomology during orthodontic treatment. Am J Orthod Dentofacial Orthop. 1996;109(5):481-8.

42. National Breast and Ovarian Cancer Centre (NBOCC). Statement on use of thermography to detect breast cancer - NBOCC Position statement. Last updated February 2010. Accessed Jan 2, 2014. Available at URL address: http://www.health.qld.gov.au/breastscreen/breastscreen/downloads/media/Thermography%20NBOCC%20Statement.pdf

43. National Cancer Institute (NCI). Breast cancer screening modalities. Dec 5, 2013. Accessed Dec 30, 2013. Available at URL address: http://www.cancer.gov/cancertopics/pdq/screening/breast/healthprofessional/allpages

44. National Comprehensive Cancer Network®, Inc. 2013, (NCCN®), All Rights Reserved. Clinical Practice Guidelines in Oncology™. Breast cancer screening and diagnosis. V.2.2013. Accessed Dec 30, 2013. Available at URL address: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

45. National Heart Lung and Blood Institute (NHLBI). Raynaud's disease. Jun 2006. Accessed Jan 29, 2008. Available at URL address: http://www.nhlbi.nih.gov/health/dci/Diseases/raynaud/ray_what.html

46. National Institute of Dental and Craniofacial Research (NIDCR). TMJ disorders. Jun, 2006. Accessed Jan 29, 2008. Available at URL address: http://www.nidcr.nih.gov/HealthInformation/DiseasesAndConditions/TMDTMJ/TmjDisorders.htm

47. National Institute of Neurological Disorders and Stroke (NINDS). Peripheral neuropathy fact sheet. Jan 13, 2011a. Accessed Jan 29, 2011. Available at URL address: http://www.ninds.nih.gov/disorders/peripheralneuropathy/detail_peripheralneuropathy.htm

48. National Institute of Neurological Disorders and Stroke (NINDS). Low back pain fact sheet. Jan 13, 2011b. Accessed Jan 29, 2011. Available at URL address: http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm

49. National Screening Unit (NSU), Cancer Society of New Zealand, New Zealand Breast Cancer Foundation and the New Zealand Branch of The Royal Australian and New Zealand College of Radiologists (RANZCR). Position Statement: The use of thermography as a breast cancer screening or diagnostic tool. June 2010. Accessed Feb 14, 2014. Available at URL address: http://www.cancernz.org.nz/assets/files/info/CSNZ_PS_Thermography23August2010.pdf

50. Niehof SP, Huygen FJ, van der Weerd RW, Westra M, Zijlstra FJ. Thermography imaging during static and controlled thermoregulation in complex regional pain syndrome type 1: diagnostic value and involvement of the central sympathetic system. Biomed Eng Online. 2006 May 12;5:30.

51. Niehof SP, Beerthuizen A, Huygen FJ, Zijlstra FJ. Using skin surface temperature to differentiate between complex regional pain syndrome type 1 patients after a fracture and control patients with various complaints after a fracture. Anesth Analg. 2008 Jan;106(1):270-7, table of contents.

52. Parisky YR, Sardi A, Hamm R, Hughes K, Esserman L, Rust S, et al. Efficacy of computerized infrared imaging analysis to evaluate mammography suspicious lesions. AJR Am J Roentgenol. 2003 Jan;180(1):263-9.

53. Park JY, Hyun JK, Seo JB. The effectiveness of digital infrared thermographic imaging in patients with shoulder impingement syndrome. J Shoulder Elbow Surg. 2007 Sep-Oct;16(5):548-54.

54. Rzeszutko Ł, Legutko J, Kałuza GL, Wizimirski M, Richter A, Chyrchel M, et al. Assessment of culprit plaque temperature by intracoronary thermography appears inconclusive in patients with acute coronary syndromes. Arterioscler Thromb Vasc Biol. 2006 Aug;26(8):1889-94. Epub 2006 Jun 15.

55. Stanton-Hicks M. Complex regional pain syndrome: manifestations and the role of neurostimulation in its management. J Pain Symptom Manage. 2006 Apr;31(4 Suppl):S20-4.

56. Scantek Medical, Inc. BreastCare./BreastAlert. Differential Temperature Sensor. 2010. Accessed Dec 19, 2012. Available at URL address: http://www.hotstocked.com/companies/s/scantek-medical-inc-SKML-description-55648.html

57. Stefanadis C, Tsiamis E, Vaina S, Toutouzas K, Boudoulas H, Gialafos J,.et al. Temperature of blood in the coronary sinus and right atrium in patients with and without coronary artery disease. Am J Cardiol. 2004 Jan 15;93(2):207-10.

58. Sterns EE, Zee B, SenGupta S, Saunders FW. Thermography: its relation to pathologic characteristics, vascularity, proliferation rate, and survival of patients with invasive ductal carcinoma of the breast. Cancer. 1996 Apr:77(7):1324-8.

59. Sun PC, Jao SH, Cheng CK. Assessing foot temperature using infrared thermography. Foot Ankle Int. 2005 Oct;26(10):847-53.

60. U.S. Food and Drug Administration (FDA). Breast thermal activity indicator. K832989. 1984 Accessed Dec 19, 2012. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=61068

61. U.S. Food and Drug Administration (FDA). 510(k) summary. Dorex Spectrum 9000ob. Mar 9, 2004. Accessed Jan 29, 2007. Available at URL address: http://www.fda.gov/cdrh/pdf3/k033967.pdf

62. U.S. Food and Drug Administration (FDA). 510(k) summary. Infrared Sciences BreastScan IR™ System. Feb 20, 2004. Accessed Jan 29, 2008. Available at URL address: http://www.fda.gov/cdrh/pdf3/k032350.pdf

63. U.S. Food and Drug Administration (FDA). Universe of devices used in the diagnosis and/or treatment of temporomandibular joint disorders and related myofacial pain dysfunction. Jan 29, 2008. Available at URL address: http://www.fda.gov/cdrh/fr/tmj.html

64. Vreugdenburg TD, Willis CD, Mundy L, Hiller JE. A systematic review of elastography, electrical impedance scanning, and digital infrared thermography for breast cancer screening and diagnosis. Breast Cancer Res Treat. 2013 Feb;137(3):665-76. doi: 10.1007/s10549-012-2393-x. Epub 2013 Jan 4.

65. Wasner G, Schattschneider J, Baron R. Skin temperature side differences—a diagnostic tool for CRPS? Pain. 2002;98:19-26.

66. Work Loss Data Institute. Neck and upper back (acute & chronic). Corpus Christi (TX): Work Loss Data Institute; 2007 Jul 5. 266 p. Accessed Jan 30, 2008. Available at URL address: http://www.guidelines.gov/summary/pdf.aspx?doc_id=9841&stat=1&string=thermography

67. Yahara T, Koga T, Yoshida S, Nakagawa S, Deguchi H, Shirouzu K. Relationship between microvessel density and thermographic hot areas in breast cancer. Surg Today. 2003;33:243-8.

68. Zaproudina N, Ming Z, Hanninen OO. Plantar infrared thermography measurements and low back pain intensity. J Manipulative Physiol Ther. 2006 Mar-Apr;29(3):219-23.