UnitedHealthcare®

**MEDICAL POLICY**

# THERMOGRAPHY

**Policy Number:** 2014T0448J
**Effective Date:** May 1, 2014

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**Related Policies:**
Abnormal Uterine Bleeding and Uterine Fibroids

***INSTRUCTIONS FOR USE***

*This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.*

*UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.*

## BENEFIT CONSIDERATIONS

**Essential Health Benefits for Individual and Small Group:**
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

## COVERAGE RATIONALE

**Thermography (including digital infrared thermal imaging, temperature gradient studies, and magnetic resonance (MR) thermography) is unproven and not medically necessary.** There is insufficient evidence to conclude that thermography has a beneficial impact on health outcomes. The available evidence is limited and weak, and standards for image evaluation and cut-off values that would allow clinical recommendations based on this technology have not been established.

## APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

| CPT® Code | Description |
|---|---|
| 93740 | Temperature gradient studies |
| 76498 | Unlisted magnetic resonance procedure (e.g., diagnostic, interventional) |



## DESCRIPTION OF SERVICES

Thermography involves imaging of the body's vascular heat emissions. The most common parameters considered to be indicative of illness and of potentially diagnostic value are mean temperature, spatial thermal variations, and temporal thermal variations, including the frequency of thermal variations. These irregularities in the body surface's thermal patterns occur in response to vasomotor dysfunction. It has been suggested that thermography may be a prognostic tool for the detection, diagnosis, and/or prognosis of peripheral vascular and neurological disorders. In addition, the efficacy of thermography for disease diagnosis and prognosis is being evaluated in many other medical disciplines such as oncology, dentistry, urology, and dermatology. The most commonly used types of thermography devices are liquid crystal sheets that are placed directly on the skin, infrared cameras (also called digital infrared thermal imaging), and temperature gradient studies. Temperature gradient studies assess heart or circulatory functions by contrasting temperatures of certain vessels via an intravenous catheter. Magnetic resonance (MR) thermography is being studied as a noninvasive alternative to invasive temperature probes for monitoring hyperthermia or ablative treatment.

## CLINICAL EVIDENCE

The clinical evidence was reviewed on February 14, 2014 with no additional information identified that would change the unproven and not medical necessary conclusion.

***Diagnosis of Breast Cancer:***
In a systematic review, Fitzgerald et al. (2012) evaluated the effectiveness of digital infrared thermography for the detection of breast cancer in a screening population and as a diagnostic tool in women with suspected breast cancer. One study reported results for thermography in screening population and five studies reported diagnostic accuracy of thermography in women with suspected breast cancer. According to the authors, overall, studies were of average quality. Sensitivity for thermography as a screening tool was 25% (specificity 74%) compared to mammography. Sensitivity for thermography as a diagnostic tool ranged from 25% (specificity 85%) to 97% (specificity 12%) compared to histology. The authors concluded that currently there is insufficient evidence to support the use of thermography in breast cancer screening. The authors stated that there is also insufficient evidence to show that thermography provides benefit

to patients as an adjunctive tool to mammography or to suspicious clinical findings in diagnosing breast cancer.

In a prospective, controlled study by Ohashi and Uchida (2000) (n = 828), thermography had an overall diagnostic accuracy of 82% and a false-positive rate of 41%. In a prospective, multicenter, blinded, study, Parisky et al. (2003) (n = 769) reported sensitivity, specificity, positive predictive value, and a negative predictive value of 97%, 14%, 24%, and 95%, respectively. Lack of statistical analysis and exclusion of a large number of patients from data analysis compromised the quality of the evidence in both studies.

Wishart et al. (2010) studied digital infrared breast imaging (Sentinel BreastScan) in 100 women prior to breast needle core biopsy (CB). Analysis of the infrared scans was performed, blinded to biopsy results, in four different ways: Sentinel screening report, Sentinel artificial intelligence (neural network), expert manual review, and NoTouch BreastScan a novel artificial intelligence program. Of 106 biopsies performed in 100 women, 65 were malignant and 41 were benign. Sensitivity of Sentinel screening (53%) and Sentinel neural network (48%) was low but analysis with NoTouch software (70%) was much closer to expert manual review (78%). Sensitivity (78%) and specificity (75%) using NoTouch BreastScan were higher in women under 50 and the combination of mammography and digital infrared breast scan, with NoTouch interpretation, in this age group resulted in a sensitivity of 89%. According to the investigators, digital infrared breast scan using NoTouch is an effective adjunctive test for breast cancer detection in women under 70 and appears to be particularly effective in women under 50 where maximal sensitivity (78%) and specificity (75%) were observed. This study included an extremely small number of participants. These findings require confirmation in a larger trial.

Arora et al. (2008) evaluated the detection of breast cancer with digital infrared thermal imaging (DITI) in a prospective clinical trial of 92 patients for whom a breast biopsy was recommended based on prior mammogram or ultrasound, Three scores were generated: an overall risk score in the screening mode, a clinical score based on patient information, and a third assessment by artificial neural network. Sixty of 94 biopsies were malignant and 34 were benign. DITI identified 58 of 60 malignancies, with 97% sensitivity, 44% specificity, and 82% negative predictive value depending on the mode used.

Kontos et al. (2011) determined the sensitivity and specificity of digital infrared thermal imaging (DITI) in a series of 63 women who underwent surgical excision or core biopsy of benign and malignant breast lesions. Thermography had 90 true-negative, 16 false-positive, 15 false-negative and 5 true-positive results. The sensitivity was 25%, specificity 85%, positive predictive value 24%, and negative predictive value 86%. The authors concluded that because of the low sensitivity for breast cancer, DITI is not indicated for the primary evaluation of symptomatic patients nor should it be used on a routine basis as a screening test for breast cancer.

***Diagnosis and Staging of Raynaud's Phenomenon (RP):***
Three earlier studies of 31 to 58 patients with primary or secondary Raynaud's phenomenon were identified (Cherkas et al., 2001, Coughlin et al., 2001, Merla et al., 2002). In these studies, sensitivity of DITI for RP ranged from 86% to 100%, with a specificity of 84 to 100%. Lack of blinding, small sample size, insufficient statistical analysis, and differences in imaging and data interpretation compromise the quality of the evidence.

Pauling et al. (2012) performed a systematic review evaluating the use of infrared thermography (IRT) as an endpoint in clinical trials of Raynaud's phenomenon (RP). Thirty-two studies evaluating 654 patients with RP were assessed. Significant heterogeneity between studies precluded any attempt at formal meta-analysis. Most studies were small (median 15.5 patients) and open-label design (19/32, 59.4%). The majority of studies (18/32, 56.3%) reported improvements in both clinical and thermographic endpoints. Thermographic parameters showing agreement with clinical endpoints in therapeutic trials included baseline hand/finger absolute temperature and parameters derived following local cold challenge. The authors concluded that

no single thermographic parameter has emerged as the preferred endpoint for clinical trials of RP. According to the authors, objective microvascular imaging tools such as IRT have the potential to overcome the limitations of self-report assessment of RP. Future studies should continue to evaluate IRT in an attempt to validate objective microvascular assessment tools in therapeutic trials of RP.

Schlager et al. (2010) investigated the correlation of infrared thermography (IT) with laser Doppler perfusion imager (LDPI) among patients with primary Raynaud's phenomenon (n=25) and healthy controls (n=22). IT of the volar surface of the subjects' left hands was performed to record skin temperature while skin perfusion of the same area was determined using LDPI. Good correlation of baseline measurements was found between IT and LDPI in primary Raynaud patients and healthy controls. Following cold challenge, correlation was weaker in both groups. Correlation after cold provocation was statistically significant among patients with primary Raynaud's phenomenon in contrast to controls. According to the investigators, a significant correlation was found between IT and LDPI in primary Raynaud patients and in healthy controls. Following cold provocation, correlation decreased in both groups. Thus, at room temperature IT might substitute for skin perfusion measured by LDPI. This study is limited by a small sample size.

***Diagnosis of Neurological Disorders:***
The studies included 35 to 165 patients with nerve damage including lumbosacral radiculopathy (Harper et al., 1991), peripheral neuropathy (Park et al., 1994), and cervical disc herniation (Zhang et al., 1994). In all studies, temperature differences between corresponding body sites served as the primary outcome measure. In these studies, DITI achieved a sensitivity of 78% to 94% and a specificity of 20% to 44% for the diagnosis of lumbosacral radiculopathy. The positive predictive value (45% to 50%) was significantly lower than that of electromyography (100%) and computed tomography myelography (80%) (Harper et al., 1991). DITI demonstrated significant temperature changes in localized body surface thermal patterns (thermatomes) in patients with cervical disc herniation depending on the level of disc protrusion (Zhang et al., 1999). Small sample sizes, heterogeneous study populations, insufficiently defined inclusion and exclusion criteria, a lack of randomization, and, in some cases, lack of blinding compromised the quality of the evidence.

***Diagnosis of Orofacial Pain and Other Facial Disorders:***
The studies included 40 to 328 patients with orofacial pain or disorders including inferior alveolar nerve deficit, infraorbital nerve injury, neuropathic facial pain, trigeminal neuralgia, and temporal mandibular joint (TMJ) dysfunction (Gratt et al., 1995, McGimpsey et al., 2000, Graff-Radford et al., 1995, Canavan and Gratt, 1995, Gratt et al., 1996). Outcome measures included temperature differences between the affected and unaffected side of the face and comparisons of thermograms of age- and sex-matched healthy volunteers. In these studies, DITI achieved an overall accuracy of 89%, 85% sensitivity, and 92% specificity for the diagnosis of TMJ dysfunction (Canavan and Gratt, 1995, Gratt et al., 1996). A loss of facial thermal symmetry was observed for patients with sympathetically independent traumatic trigeminal neuralgia with peripheral facial neuropathy (Graff-Radford et al., 1995). Contradictory results were obtained for the diagnosis of infraorbital nerve injury (Gratt et al., 1995, McGimpsey et al., 2000). Small sample sizes, heterogeneous study populations, insufficiently defined inclusion and exclusion criteria, a lack of randomization, and, in some cases, lack of blinding compromised the quality of the evidence.

***Diagnosis of Coronary Artery Plaque****:*
Thermography was performed in 40 patients with acute coronary syndrome (ACS). Gradient (deltaTmax) between blood temperature and the maximum wall temperature during pullback was measured. In 16 patients (40%) deltaTmax was greater than or equal to 0.1 degrees C. In 23 patients (57.5%) the highest deltaTmax was found in the culprit segment. The investigators concluded that thermography was safe and feasible. However, they were not able to convincingly and consistently differentiate between different lesions at risk, despite a selection of lesions that should appear most distinct to differentiate (Rzeszutko et al., 2006).

Cuisset et al (2009) assessed intracoronary thermography by measuring intracoronary pressure and temperature variations in 18 patients with an acute myocardial infarction. Crossing the occlusion, the temperature rose by 0.059 +/- 0.02 degrees C and this increase was correlated with the distal coronary pressure. A balloon coronary occlusion (BCO) with the sensor distally in the distal part of the vessel (low flow/low pressure conditions) systematically induced an increase in temperature (0.14 +/- 0.07 degrees C) while with the sensor proximally to the balloon occlusion (low flow/normal pressure conditions), no change occurred. According to the investigators, the study findings suggest that thermistor-based sensors are not suited for assessing thermal heterogeneity in the vascular wall and that the data obtained so far in patients with acute coronary syndromes might have been flawed by pressure (and flow) artifacts.

In a review of the diagnosis and treatment of vulnerable plaque of coronary and carotid arteries, the Agency for Healthcare Research and Quality (AHRQ) indicates that multiple diagnostic methods have been proposed to identify vulnerable plaques, including 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 stated 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).

Small sample sizes and lack of controlled trials compromised the quality of the evidence for evaluating the benefits of thermography for coronary artery plaque.

***Other Conditions:***
Thermography has also been investigated for many other conditions including back pain, complex regional pain syndrome, impingement syndrome, and herpes zoster. There is little evidence that the use of thermography improves health outcomes for patients with these and other conditions.

Zaproudina et al. (2013) evaluated the influence of different factors on infrared thermography (IRT) findings. The relations between skin temperature and side-to-side temperature difference values, and influence of age, gender, anthropometric characteristics and pain intensity on those values were analyzed in non-specific neck pain (NP) patients (n = 91) using mixed model analysis. The results of the study suggested that the side-to-side temperature difference values as signs of impaired skin temperature regulation are dynamic and better detectable in cold skin. According to the investigators, these results underline the need of caution in interpretation of IRT findings.

In a prospective blind study, Leclaire et al. (1996) assessed the diagnostic accuracy and comparability of thermography, triaxial dynamometry, and spinoscopy in the assessment of low back pain. Forty-one patients with low back pain and 46 control subjects were assessed by each technology and by two clinical examiners blind to clinical status. Twenty patients were trained to simulate a healthy back without low back pain, and 50% of the control subjects were trained to simulate the presence of a low back pain disorder. Each technology was interpreted on two occasions by each of two readers. Thermography performed significantly worse than did triaxial dynamometry, spinoscopy, and clinical examination. The diagnostic accuracy of the last three was similar, and inter-rater comparability did not differ significantly. The investigators concluded that the diagnostic accuracy of thermography in recent onset low back pain does not support its use.

Sivanandam et al. (2012) tested the potential of infrared (IR) thermography in diagnosing as well as predicting type 2 diabetes and its complications compared with biochemical assay of HbA(1c) as standard. The study included 62 individuals (control (n = 32) and diabetic subjects (n = 30)). In the diabetic group, HbA(1c) showed negative correlation with carotid region and the mean skin temperature was lower than the normal group at body regions namely knee, tibia, forehead, and palm. The palm region showed highest area under the curve of 0.711 and the threshold was set

as ≤33.85 °C, thereby sensitivity (90%) and specificity (56%) was obtained in determining the undiagnosed diabetes with positive predictive value of 65%, negative predictive value of 85% and accuracy of 73%. As HbA(1c) increases, skin temperature decreases. According to the authors, skin temperature enables early detection of diabetes as compared to HbA(1c). The decrease in skin temperature may be due to the decrease in the basal metabolic rate, poor blood perfusion and high insulin resistance. The authors stated that thermography can be used as a diagnostic as well as prognostic tool for the diabetes. These findings require confirmation in a larger study. In addition, future studies must be powered to address how finding obtained by IRT would change physician management and improve glycemic control in persons with diabetes.

Han et al. (2010) examined the usefulness of infrared thermography as a predictor of post-herpetic neuralgia (PHN). Infrared thermography was performed on the affected body regions of 110 patients who had been diagnosed with acute herpes zoster (HZ). The temperature differences between the unaffected and affected dermatome were calculated. Temperature differences were not correlated with pain severity, disease duration, allodynia (pain from stimuli not normally painful, as seen with fibromyalgia), development of PHN, and use of antiviral agents. Based on the results of the study, the authors stated that patient age and disease duration are the most important factors predicting PHN progression, irrespective of thermal findings, and PHN cannot be predicted by infrared thermal imaging.

Park et al. (2012) examined the usefulness of infrared thermography in acute herpes zoster (HZ) as a predictor for the development of postherpetic neuralgia (PHN). The authors collected data from a total of 55 patients diagnosed with HZ and evaluated the body surface thermographic parameters between the lesion and contralateral normal skin. Temperatures of the lesions were found to be warmer than the control side in most patients with acute HZ. The patient group who developed PHN was compared with those who did not. In logistic regression analysis to identify independent risk factors of PHN, older age (>60 years old) and temperature difference more than 0.5 °C were found to be statistically significant. According to the authors, further studies are required to support these preliminary results and to understand in depth the association between thermal changes in acute HZ and the development of PHN.

Kamao et al. (2011) evaluated the use of thermography for dry eye screening in a prospective, controlled study. The study included 30 eyes of 30 patients diagnosed with dry eye and 30 eyes of 30 normal subjects. Immediately after eye opening, the temperature in the dry eye did not differ significantly from that in normal eyes in any of the 3 regions tested. The decrease in the ocular surface temperature in dry eyes was significantly greater than that in normal eyes at 10 seconds after eye opening. When the changes in ocular surface temperature of the cornea were used as an index for dry eye, the sensitivity was 0.83 and the specificity was 0.80 after 10 seconds. According to the authors, measurements of the ocular surface temperature obtained with thermography after 10 seconds of eye opening may provide a simple, noninvasive screening test for dry eyes. This study failed to show how thermography would impact patient management or disease outcomes in patients with dry eye.

Huang et al. (2011) investigated the usefulness of infrared thermography in evaluating 51 patients at high risk for lower extremity peripheral arterial disease (PAD). Ankle-brachial index (ABI) and segmental pressure were analyzed for PAD diagnosis and stenotic level assessment. The cutaneous temperature at shin and sole were recorded by infrared thermography before and after a walking test. Twenty-eight subjects had abnormal ABI, while PAD was diagnosed in 20. The rest temperatures were similar in PAD and non-PAD patients. However, the post-exercise temperature dropped in the lower extremities with arterial stenosis, but was maintained or elevated slightly in the extremities with patent arteries. The authors concluded that infrared thermography offers another non-invasive, contrast-free option in PAD evaluation and functional assessment. However, these findings require confirmation in a larger trial.

Nakagami et al. (2010) investigated whether thermography can be used to detect latent inflammation in pressure ulcers and predict pressure ulcer prognosis in a clinical setting. Thirty-

five patients with stage II-IV pressure ulcers on the torso, who underwent thermographic assessment on discovery of their pressure ulcer were included in the study. The patients were followed up for at least 3 weeks. Thermography was performed immediately after dressing removal. Pressure ulcers were classified into two groups depending on whether or not the wound site temperature was lower or higher than the periwound skin: the low temperature group and the high temperature group respectively. The relative risk for delayed healing in high temperature cases was 2.25. Sensitivity was 0.56, specificity was 0.82, positive predictive value was 0.75, and negative predictive value was 0.67. The investigators concluded that the results indicate that using thermography to classify pressure ulcers according to temperature could be a useful predictor of healing at 3 weeks, even though wound appearances may not differ at the point of thermographical assessment. The higher temperature in the wound site, when compared with periwound skin, may imply the presence of critical colonization, or other factors which disturb the wound healing. This study failed to show how thermography would impact patient management or disease outcomes.

Niehof et al. (2008) assessed the validity of skin surface temperature recordings, based on various calculation methods applied to the thermographic data, to diagnose acute complex regional pain syndrome type 1 (CRPS1) fracture patients. Thermographic recordings of the palmar/plantar side and dorsal side of both hands or feet were made on CRPS1 patients and in control fracture patients with/without and without complaints similar to CRPS1 (total in the three subgroups = 120) just after removal of plaster. Based on the study results, the investigators concluded that the validity of skin surface temperature recordings under resting conditions to discriminate between acute CRPS1 fracture patients and control fracture patients with/without complaints is limited, and only useful as a supplementary diagnostic tool.

A report from the Agency for Healthcare Research and Quality (AHRQ) on noninvasive diagnostic techniques for the detection of skin cancers indicated that thermography is one of the investigational diagnostic techniques for the detection of skin cancers (Parsons et al. 2011).

**Magnetic Resonance (MR) Thermography**
In a prospective study, Kim et al. (2012) evaluated the accuracy of the size and location of the ablation zone produced by volumetric magnetic resonance (MR) imaging-guided high-intensity focused ultrasound ablation of uterine fibroids on the basis of MR thermometric analysis and assessed the effects of a feedback control technique in 33 women. Size and location of each ablation zone induced by 527 sonications were analyzed according to the thermal dose obtained with MR thermometry. Based on the results of the study, the authors concluded that sonication accuracy of volumetric MR imaging-guided high-intensity focused ultrasound ablation of uterine fibroids appears clinically acceptable and may be further improved by feedback control to produce more consistent ablation zones. However, the study did not confirm the utility of such findings in improving care and outcome of patients.

Kickhefel et al. (2011) assessed the feasibility, precision, and accuracy of real-time temperature mapping (TMap) during laser-induced thermotherapy (LITT) for liver lesions with a gradient echo (GRE) sequence using the proton resonance frequency (PRF) method. LITT was performed on 34 lesions in 18 patients with simultaneous real-time visualization of relative temperature changes. Correlative contrast-enhanced T1-weighted magnetic resonance (MR) images of the liver were acquired after treatment using the same slice positions and angulations as TMap images acquired during LITT. Based on the results of the study, the authors concluded that MR temperature mapping appears reasonably capable of predicting tissue necrosis on the basis of indicating regions having greater temperatures than 52°C and could be used to monitor and adjust the thermal therapy appropriately during treatment. However, this study was limited by the small sample size.

Terraz et al. (2010) evaluated the feasibility and effectiveness of MR-guided radiofrequency (RF) ablation for small liver tumors with poor conspicuity on both contrast-enhanced ultrasonography (US) and computed tomography (CT), using fast navigation and temperature monitoring. Sixteen

malignant liver nodules were treated with multipolar RF ablation on a 1.5-T wide-bore MR system in ten patients. Real-time MR-based temperature mapping was performed. MR-specific treatment data were recorded. Correct placement of RF electrodes was obtained in all procedures. MR thermometry was available for 14 of 16 nodules (88%) with an accuracy of 1.6 degrees C in a non-heated region. No correlation was found between the size of the lethal thermal dose and the ablation zone at follow-up imaging. The primary and secondary effectiveness rates were 100% and 91%, respectively. The investigators concluded that RF ablation of small liver tumors can be planned, targeted, monitored and controlled with MR imaging within acceptable procedure times. According to the investigators, temperature mapping is technically feasible, but the clinical benefit remains to be proven.

Puls et al. (2009) evaluated the technical success, technique effectiveness, complications, and survival after laser ablation of liver metastases from colorectal cancer. The study included 87 consecutive patients with 180 liver metastases from colorectal carcinoma. They underwent laser ablation with magnetic resonance (MR) thermometry in 170 sessions. Technical success, technique effectiveness, and complication and survival rates were evaluated retrospectively. Technical success was achieved in 178 of 180 sessions (99%). Follow-up after 24-48 hours demonstrated an effectiveness rate of 85.6%. Local tumor progression rate was 10% after 6 months. Mean survival from the time of diagnosis of the primary tumor was 50.6 months for all patients treated. The investigators concluded that laser ablation of liver metastases of colorectal cancer with MR thermometry appears safe and efficacious. According to the investigators, direct comparison with other ablative modalities in a prospective clinical trial would be necessary to definitely show one modality is superior.

A clinical trial to evaluate the safety and feasibility of MRI guided focal prostate cancer laser ablation is currently recruiting participants. See the following Web site for more information: http://clinicaltrials.gov/ct2/show/NCT01094665. Accessed February 14, 2014.

Overall, the evidence is too limited to draw definitive conclusions regarding the clinical efficacy of MR thermography for monitoring hyperthermia or ablative treatment.

**Professional Societies**

***The American Cancer Society (ACS):*** In the 2003 American Cancer Society Guidelines for Breast Cancer Screening, which include an adaptation of the 2001 Institute of Medicine assessment of the evidence for various breast cancer screening modalities, thermography was classified as a method that is ineffective as a screening tool based on the clinical evidence (Smith et al., 2003). In a cancer reference information Web site discussion of mammograms and other breast imaging procedures, the ACS states that no study has shown that thermography is an effective screening tool for the early detection of breast cancer. Thermography should not be used as a substitute for mammograms (ACS, 2010).

***The American College of Radiology (ACR)*:** For the diagnosis of myelopathy, the ACR appropriateness criteria state that no high quality evidence supports the use of thermography in the evaluation of myelopathy (ACR, 2011).

For breast cancer screening, the ACR appropriateness criteria state that there is insufficient evidence to support the use of imaging modalities such as thermography (ACR, 2012).

***The American College of Obstetricians and Gynecologists (ACOG)*:** ACOG does not address thermography in the 2011 Practice Bulletin for breast cancer screening (ACOG, 2011).

## U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA regulates telethermographic systems such as those used for breast cancer detection as Class II devices. The FDA has cleared numerous thermographic imaging systems for marketing

under the 510(K) process; however, most of these devices or systems are not cleared specifically for breast evaluation purposes. The FDA is warning women that breast thermography should not be substituted for mammography as a screen for breast cancer. See the following Web site for more information: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm257259.htm Accessed February 14, 2014.

Telethermographic systems include, but are not limited to, the following: Telesis Digital Infrared Thermal Imaging System-Spectrum 9000MB (Telesis Technologies Inc, His-Chih City, Taiwan; June 7, 2002) for the adjunctive detection of breast cancer or other uses; Dorex Spectrum 9000MB Thermography System (DOREX Inc, Orange, CA; November 14, 2002) for the adjunctive diagnosis and/or follow-up in areas of orthopedics, pain management, neurology, and diabetic foot care; Mark I Thermal Imager (IX-DR Inc, Howell, MI; February 11, 2003) as an adjunctive medical imaging modality; MHS 7000 Thermal Imaging System (Micro Health Systems Inc, Parkland, FL; March 26, 2003) for providing thermal images of the human body in all age groups from adult to pediatric and neonatal; IRIS-IV Infrared Imaging System (Biocare Medical Technology LLC, Woodbury, CT; April 16, 2003), indicated for the viewing and documenting of temperature differences prior to grafting, cooling of the myocardial, and perfusion of the tissue distal to the anastomosis after grafting; BCS 2100 (Computerized Thermal Imaging, Inc) developed for use as an adjunct to mammography x-ray.

See the following Web site for more information regarding BCS 2100 (Computerized Thermal Imaging, Inc): http://www.fda.gov/ohrms/dockets/ac/02/briefing/3918b1_sponsor-Final.pdf. Accessed February 14, 2014.

See the following Web site for more information regarding Telesis Digital Infrared Thermal Image System (K020783). Dorex Spectrum 9000MB Thermography System (K023434). Mark I Thermal Imager (K023925). MHS 7000 Thermal Imaging System (K030018). IRIS-IV Infrared Imaging System (K030165): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm Accessed February 14, 2014.

See the following Web site for information regarding product code LHQ (system, telethermographic(adjunctive): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed February 14, 2014.

**Additional Products**
Neurocalometer, Neurodermothermograph, Nervo-Scope® Analagraph®

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not cover thermography. Refer to the National Coverage Determination (NCD) for Thermography (220.11). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Noninvasive Peripheral Arterial Studies. (February 14, 2014)

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## POLICY HISTORY/REVISION INFORMATION

| Date | Action/Description |
|---|---|
| 05/01/2014 | • Reorganized policy content<br>• Added benefit considerations language for Essential Health Benefits for Individual and Small Group plans to indicate:<br>o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)<br>o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to |

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| | offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans<br>o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage<br>• Updated coverage rationale; added language to indicate the unproven service is "not medically necessary"<br>• Archived previous policy version 2013T0448I |