UnitedHealthcare® Oxford
Clinical Policy

THERMOGRAPHY

Policy Number: DIAGNOSTIC 028.18 T2 **Effective Date**: December 1, 2018

Instructions for Use

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Related Policy

- Abnormal Uterine Bleeding and Uterine Fibroids

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

NON-COVERAGE RATIONALE

Thermography (including digital infrared thermal imaging, temperature gradient studies, and magnetic resonance (MR) thermography) is unproven and not medically necessary due to insufficient evidence of efficacy.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

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

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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.

Diagnosis of Breast Cancer

A prospective study to evaluate the accuracy of thermography in detecting breast abnormalities was performed by Omranipour et al. (2016). All patients (n=132) who were candidates for breast biopsy were examined by both mammography and thermography before tissue sampling. The authors defined sensitivities and specificities, and positive predictive values (PPVs) and negative predictive values (NPVs), of the 2 modalities in comparison with histologic results as the gold standard. The diagnostic accuracy of thermography was lower than that of mammography (69.7% vs. 76.9%). The sensitivity, specificity, PPV, NPV, and accuracy for mammography were 80.5%, 73.3%, 85.4%, 66.0%, and 76.9%, respectively, whereas for thermography the figures were 81.6%, 57.8%, 78.9%, 61.9%, and 69.7%, respectively. The authors concluded that the study confirms that thermography cannot substitute for mammography for the early diagnosis of breast cancer.

Rassiwala M et al. (2014) studied the use of thermography to screen for breast cancer in India. Given the socio-economic situation in India, there is a strongly felt need for a screening tool which reaches the masses rather than waiting for the masses to reach tertiary centers to be screened with mammography. Digital infra-red thermal imaging (DITI) or breast thermography was studied as an alternative to mammography as a screening test in India. The study involved 1008 female patients of age 20-60 years who had not been previously diagnosed with breast cancer. All the subjects in this population were screened in both breasts using DITI. Based on the measured temperature gradients (ΔT) in thermograms, the subjects were classified in one of the three groups, normal ($\Delta T \leq 2.5$), abnormal ($\Delta T > 2.5$, <3) and potentially having breast cancer ($\Delta T \geq 3$). All those having ($\Delta T > 2.5$) underwent triple assessment that consisted of clinical examination, radiological and histopathological examination. Those with normal thermograms were subjected to only clinical examination. Forty nine female breasts had thermograms with temperature gradients exceeding 2.5 and were subjected to triple assessment. Forty one of these which had $\Delta T \geq 3$ were found to have breast cancer and were offered suitable treatment. Eight thermograms had temperature gradients exceeding 2.5 but less than 3. Most of these were lactating mothers or had fibrocystic breast disease. As a screening modality, DITI showed sensitivity of 97.6%, specificity of 99.17%, positive predictive value 83.67% and negative predictive value 99.89%. Based on the results of this study involving 1008 subjects for screening for breast cancer, thermography was a useful tool for screening. Because it is non-contact, pain-free, radiation free and comparatively portable the authors conclude that it can be used in as a proactive technique for detection of breast carcinoma. This was an uncontrolled study. Ages of the women in the various categories were not reported. Those in the 20-40 year age group are a cohort in which the incidence of breast cancer in the absence of defined risk factors is very low. Finally, the study was not powered to determine whether the use of thermography as a screening tool decreases breast cancer mortality.

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.

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.

The National Comprehensive Cancer Network (NCCN) Breast Cancer Screening and Diagnosis Clinical Practice Guidelines state that current evidence does not support the routine use of thermography as a screening procedure. (NCCN, 2017)

Diagnosis and Staging of Raynaud's Phenomenon (RP)

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.

Horikoshi et al. (2016) conducted a study to devise an effective method to assess the peripheral circulation using an infrared thermographic analysis. Thirty-one patients diagnosed with Raynaud Phenomenon (RP) who underwent thermography of their hands and 25 healthy individuals without pre-existing connective tissue disease or the use of medication that could affect the peripheral perfusion (controls) were enrolled in the study. The skin temperatures of the dorsum of all fingernail folds and the metacarpophalangeal (MCP) joints were measured at baseline. Then the hands were immersed in 10°C water for 10 seconds, and the skin temperatures were measured at 0, 3, 5, 10, 15, 20 and 30 minutes after immersion by thermography. The mean temperature, recovery rate and disparity of the nail fold temperatures were calculated. The distal-dorsal difference (DDD) was calculated by subtracting the mean MCP temperature from the mean nail fold temperature. The baseline nail fold temperature was significantly lower in patients with RP than in controls (30.8±3.1°C vs. 33.2±1.8°C). At 3 and 5 min after immersion, the recovery rate was significantly lower in patients with RP than in controls, and the difference was highest at 5 min (patients with RP: 49.6±27.7; controls: 71.5±26.8). The RP patients had a lower recovery rate, lower DDD and higher disparity than the controls. The temperature disparity was significantly higher in patients with RP than in the controls both at baseline and at all-time points after immersion. The authors concluded that the temperature disparity between fingers is a useful thermographic parameter for evaluating disturbed peripheral circulation in patients with RP. They stated that these findings suggest that the remodeling in RP patients may be due to the underlying abnormal vasculature, and may result in an uneven response to thermal stimuli. A limitation of this study is that the smoking status was not taken into account. A small sample size makes it difficult to decide whether these conclusions can be generalized to a larger population.

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.
The clinical evidence was reviewed on January 27, 2016 with no additional information identified that would change the unproven conclusion for thermography.

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, burns and herpes zoster. There is little evidence that the use of thermography improves health outcomes for patients with these and other conditions.

Oliveira et al. (2017) conducted a systematic review to determine the accuracy of ultrasound, thermography, photography and subepidermal moisture (SEM) in detecting pressure ulcers (PU). Data analysis indicated that photography was not a method which allowed for the early prediction of PU presence. SEM values increased with increasing tissue damage. Thermography identified temperature changes in tissues and skin that may give an indication of early PU development; however the data were not sufficiently robust. Ultrasound detected pockets of fluid/edema at different levels of the skin that were comparable with tissue damage. The authors concluded that SEM and ultrasound were the best methods for allowing a more accurate assessment of early skin/tissue damage. There is a lack of high quality evidence demonstrating a beneficial impact of thermography on health outcomes in patients with pressure ulcers.

Burke-Smith et al. (2015) completed a study to investigate the accuracy of infrared thermography (IRT) and spectrophotometric intracutaneous analysis (SIA) for burn depth assessment, and compare this to the current gold standard: laser Doppler imaging (LDI). They included a comparison of the three modalities in terms of cost, reliability and usability. Twenty patients were recruited with burns. Between 48h and 5 days after burn they recorded imaging using moorLDI2-BI-VR (LDI), FLIR E60 (IRT) and Scanoskin™ (SIA). Twenty-four burn regions were grouped according to burn wound healing: group A healed within 14 days, group B within 14-21 days, and group C took more than 21 days or underwent grafting. Both LDI and IRT accurately determined healing potential in groups A and C, but failed to distinguish between groups B and C. Scanoskin™ interpretation of SIA was 100% consistent with clinical outcome. The authors concluded that FLIR E60 and Scanoskin™ both present advantages to moorLDI2-BI-VR in terms of cost, ease-of-use and acceptability to patients. IRT is unlikely to challenge LDI as the gold standard as it is subject to the systematic bias of evaporative cooling. At present, the LDI color-coded palette is the easiest method for image interpretation, whereas Scanoskin™ monochrome color-palettes are more difficult to interpret. The authors stated that the additional analyses of pigment available using SIA may help more accurately indicate the depth of burn compared with perfusion alone and suggested development of Scanoskin™ software to include a simplified color-palette similar to LDI. This is a small, unblinded, uncontrolled study.

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 Hemoglobin A1c (HbA1c) as standard. The study included 62 individuals (control (n = 32) and diabetic subjects (n = 30)). In the diabetic group, HbA1c 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 HbA1c increases, skin temperature decreases. According to the authors, skin temperature enables early detection of diabetes as compared to HbA1c. 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.

Professional Societies

American Cancer Society (ACS)

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 failed to detect 3 out of 4 cancers that were known to be present in the breast. Digital infrared thermal imaging (DITI), which some people believe is a newer and better type of thermography, has the same failure rate. Thermography should not be used as a substitute for mammograms. (ACS, 2016)

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, 2015)

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, 2016)

American College of Obstetricians and Gynecologists (ACOG)

ACOG's Committee on Gynecologic Practice finds that current published evidence does not demonstrate meaningful outcome benefits with alternative screening modalities (e.g., breast tomosynthesis or thermography) in women with dense breasts who do not have additional risk factors. Evidence is lacking to advocate for additional testing until there are clinically validated data that indicate improved screening outcomes. (ACOG, 2015. Reaffirmed 2017)

American College of Clinical Thermography (ACCT)

The ACCT states that thermography is especially appropriate for younger women (30 - 50) whose denser breast tissue makes it more difficult for mammography to be effective and for women of all ages who are unable to undergo routine mammography. This test can provide a 'clinical marker' to the doctor or mammographer that a specific area of the breast needs particularly close examination. (2016)

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 states that the mammography is still the most effective screening method for detecting breast cancer in its early, most treatable stages. Women should not rely solely on thermography for the screening or diagnosis of breast cancer as there is no evidence that thermography can take the place of mammography. https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257499.htm. (Accessed January 26, 2018)

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 January 26, 2018)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [*2018T0448P*]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2018	• Simplified non-coverage rationale (no change to guidelines) • Archived previous policy version DIAGNOSTIC 028.17 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies 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.