Thermography (for New Jersey Only)

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Instructions for Use

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Application

This Medical Policy only applies to the state of New Jersey.

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 federal, state, or contractual requirements 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 and Guidelines 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

In medicine, thermography is a procedure in which a heat-sensing infrared camera is used to record the surface heat produced by different parts of the body. Abnormal tissue growth can cause temperature changes, which may show up on the thermogram (NCI). While the most common use is screening for breast cancer, it has been suggested that thermography may be a tool for the detection, diagnosis, and/or prognosis of a wide variety of medical conditions. The role of thermography is considered

complimentary to other techniques and alone is not sufficient for medical practitioners to make or confirm a diagnosis (Fitzgerald, 2012).

Clinical Evidence

There is insufficient clinical evidence demonstrating the safety and/or efficacy of thermography for breast cancer screening and/or diagnosis. Current data suggests that thermography technology is inferior to mammography to screen or diagnose breast cancer.

Breast Cancer

In a 2018 retrospective cohort study, Neal et al. aimed to determine the outcome of patients presenting for evaluation of abnormal breast thermography. The study population included thirty eight female patients who had thermography at a National Cancer Institute-designated comprehensive cancer center and a National Comprehensive Cancer Network center, and were referred for conventional breast imaging (mammogram and/or ultrasound) for evaluation of an abnormal finding. The results showed 95% (36 of 38) of patients who presented for breast imaging evaluation following abnormal thermography did not have breast cancer. The two patients diagnosed with breast cancer had known co-existing suspicious clinical symptoms including palpable mass and erythematous breast. No asymptomatic woman referred for evaluation of a thermography abnormality was found to have breast cancer. None of the patients who had abnormal thermography, negative conventional breast imaging and longer follow-up were found to subsequently have breast cancers, and there were no false-negative mammograms and/or breast ultrasounds. The authors concluded that patients may be referred for breast imaging with mammogram and/or ultrasound after abnormal thermography, and the large majority of patients will have negative conventional breast imaging. This study is limited in part by its retrospective design and very small number of participants.

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.

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.

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.

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 a small number of participants and does not allow conclusion on the use of thermography instead of mammography. The use of thermography as an adjunct to mammography requires confirmation.

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, 2019).

Other Conditions

Thermography has also been investigated for many other conditions including, but not limited to, 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.

Circulatory System

Hegedűs (2018) conducted a case series of randomly selected patients to assess the potential role of thermography in determining the efficacy of stroke rehabilitation in sixteen randomly selected poststroke patients with hemiparesis affecting mainly the upper extremities. Patients began undergoing rehabilitation 13 ± 4 days following stroke. Thermograms were taken with a Fluke Ti 20 (Fluke Corporation, WA) pretreatment and post-treatment, and documentation of 15 physiotherapy, massage, and galvanic therapy sessions. The side exhibiting no neurological symptoms was used as the control. The objective was to measure the changes in joint function and microcirculation and to examine the correlation between them. The results showed significant improvement in joint function on the affected side ($P < .05$). Thermographic examinations revealed microcirculatory dysfunction in the affected extremities in 100% of the cases. Following treatment, temperature increased significantly ($P \geq .5°C$) on the affected side. A strong correlation (r) was observed between joint function and temperature change ($P < .05$). The authors concluded that the extremities on the affected side showed microcirculatory dysfunction compared with the control side in 100% of the cases, and that thermography is a reliable method for monitoring the effects of stroke rehabilitation treatment. This study is limited by a small number of participants and a design that does not provide information on the role of the technology to improve patients' outcomes. Additional studies may provide more information on a possible role of thermography for stroke rehabilitation.

Horikoshi et al. (2016) conducted a study to assess the peripheral finger 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. The design of this study does not allow to assess the role that thermography could play in the diagnostic of RP as compared to other diagnostic methods in clinical practice.

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 were 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. Furthermore, this study does not address the use of IRT in clinical practice above and beyond its possible role in research.

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 that compare this to other diagnostic approaches.

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 and a design that does not inform on the role that thermography could play in the diagnostic of RP as compared to other diagnostic methods in clinical practice.

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.

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. Difficulty in interpreting the data and the myriad of confounding factors, e.g., impact of blood flow, make this method’s practical application difficult to utilize in a daily practice and needs to be addressed in future studies (Rzeszutko et al., 2006).

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).

Endocrine System

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.

Integumentary System

Smit et al. (2018) conducted a systematic review and meta-analysis of the literature regarding the available objective methods to intraoperatively assess free flap tissue perfusion, and the effects on (partial) flap loss. Sixty-four articles were included reporting on 2369 procedures in 2009 patients with various indications. Reported methods were fluorescence imaging (FI), laser Doppler, oxygen saturation, ultrasound, (dynamic) infrared thermography, venous pressure, and microdialysis. Intraoperative tissue perfusion was adequately measured by the use of FI and laser Doppler, leading to surgical intervention or altered flap design, and increased flap survival. The results showed FI and laser Doppler are most suitable to intraoperatively measure free flap tissue perfusion, resulting in improved flap survival. No convincing evidence was found for the use of other methods. The authors concluded that this review is based on limited literature, and additional studies are necessary to investigate the predictive value of intraoperative perfusion measurement.

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 study that provide insufficient evidence to define the role of IRT in the clinical management of burn patients.

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 and requires independent confirmation with comparisons to other predictive tests before being translated to clinical practice.

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).

Musculoskeletal System

de Melo et al (2018) conducted a systematic review to assess the scientific efficacy of infrared thermography (IT) on the diagnosis of temporomandibular joint disorders (TMDs). Two independent reviewers selected the studies, reviewed the abstract information, and assessed the quality. The methodology of the included articles was evaluated by using the QUADAS-2 tool. Nine studies fulfilled the eligibility criteria and were included in the systematic review. Four studies concluded that IT presents low accuracy or is not an accurate instrument for TMD diagnosis, but there was substantial variation in sensitivity, specificity, and receiver operating characteristic curve values. Five studies concluded that IT appears to be promising or may be a complementary diagnostic aid in the evaluation of TMDs. These studies presented sensitivity values ranging from 70% to 90% and specificity values ranging from 62% to 92%. All studies were judged as being "at risk of bias" and as having "concerns regarding applicability." The authors concluded that the literature is still lacking in sufficient number of studies regarding the reliability of IT for the diagnosis of TMDs.

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.

Nervous System

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.

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.

Magnetic Resonance (MR) Thermography

Digestive System

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 and lack of comparison with other approaches to define clinical benefit.

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.

Nervous System

McCracken et al. (2016) Surgery is indicated for cerebral cavernous malformations (CCM) that cause medically refractory epilepsy. Real-time magnetic resonance thermography (MRT)-guided stereotactic laser ablation (SLA) is a minimally invasive approach to treating focal brain lesions. The authors conducted a study of 5 consecutive patients to describe MRT-guided SLA, a novel approach to treating CCM-related epilepsy, with respect to feasibility, safety, imaging, and seizure control. Five patients with medically refractory epilepsy undergoing standard presurgical evaluation were found to have corresponding lesions fulfilling imaging characteristics of CCM and were prospectively enrolled. Each underwent stereotactic placement of a saline-cooled cannula containing an optical fiber to deliver 980-nm diode laser energy via twist drill craniostomy. MR anatomic imaging was used to evaluate targeting prior to ablation. MR imaging provided evaluation of targeting and near real-time feedback regarding extent of tissue thermocoagulation. Patients maintained seizure diaries, and remote imaging (6-21 months post-ablation) was obtained in all patients. The results showed that imaging revealed no evidence of acute hemorrhage following fiber placement within presumed CCM. MRT during treatment and immediate post-procedure imaging confirmed desired extent of ablation, and no adverse events or neurological deficits were seen. Four of 5 (80%) patients achieved freedom

from disabling seizures after SLA alone (Engel class 1 outcome), with follow-up ranging 12-28 months. Reimaging of all subjects (6-21 months) indicated lesion diminution with surrounding liquefactive necrosis, consistent with the surgical goal of extended lesionotomy. The authors concluded that MRT-guided SLA of epileptogenic CCM is a potentially safe and effective alternative to open resection. Additional evidence for the role of MRT in this indication and longer follow-up are needed for these findings to be translated to clinical practice.

Reproductive System

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.

Professional Societies

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).

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 2019).

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 (2020).

European Society of Breast Imaging (EUSOBI)

In a 2017 position statement, the EUSOBI (and 30 national breast radiology bodies) states that screening with thermography or other optical tools as alternatives to mammography are discouraged.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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. See the following website for more information: https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257499.htm. (Accessed February 19, 2020)

See the following website for information regarding product code LHQ [system, telethermographic (adjunctive)]: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 19, 2020)

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) exist; see the LCDs for Noninvasive Peripheral Arterial Studies, Non-Invasive Vascular Studies and Non-Invasive Cerebrovascular Arterial Studies. (Accessed February 28, 2020)

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Policy History/Revision Information

Date	Summary of Changes
05/01/2021	• Created state-specific policy version for New Jersey (no change to guidelines)
02/01/2021	**Template Update** • Reformatted policy; transferred content to new template **Application** • Added language to indicate this policy does not apply to the state of Kentucky; refer to the state-specific policy version
05/01/2020	**Application** • Added language to indicate this policy does not apply to the states of Louisiana, Nebraska, and Tennessee; refer to the state-specific policy version **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *CMS*, and *References* sections to reflect the most current information • Archived previous policy version CS120.I

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right 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 InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical 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.