Prior Authorization Review
Panel MCO Policy Submission

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Plan: Aetna Better Health

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Policy Name: Thermography

Type of Submission – Check all that apply:

- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

CPB 0029 Thermography

Clinical content was last revised on 03/29/2016. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

Revision and Update History since last PARP submission:
02/14/2018 - This CPB has been updated with additional background information and references.
1/10/2019 – Next tentative scheduled review date by Corporate

Name of Authorized Individual (Please type or print):

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Signature of Authorized Individual:

www.aetnabetterhealth.com/pennsylvania
Updated 02/14/2018
Thermography

Policy

Aetna considers thermography (including digital infrared thermal imaging, magnetic resonance (MR) thermography and temperature gradient studies) experimental and investigational because available medical literature indicates thermography to be an ineffective diagnostic technique.

Aetna considers dynamic infrared blood perfusion imaging (DIRI) for intra-operative and post-operative perfusion assessment (e.g., flap evaluation) experimental and investigational because of insufficient evidence regarding its clinical effectiveness.

Background

Thermography

Thermography is the measurement of temperature variations at the body surface. The scientific evidence suggests that thermography may only confirm the presence of a temperature difference, and that other procedures are needed to reach a specific diagnosis. Thermography may add little to what doctors already know based on history, physical examination, and other studies.

Thermography studies are non-invasive imaging techniques that are intended to measure the skin surface temperature distribution of various organs and tissues. The infrared radiation from the tissues reveals temperature variations by producing brightly colored patterns on a liquid crystal display. Interpretation of the color pattern is thought to contribute to the diagnosis of many disorders including breast cancer, Raynaud's phenomenon, digital artery vasospasm, impaired spermatogenesis in infertile men, deep vein thrombosis, reflex sympathetic dystrophy/complex regional pain syndrome, vertebral subluxation, and others.

In contrast to the skin surface thermography techniques used by some chiropractors and other providers, a newer invasive test called a temperature gradient study involves an intravenous catheter. The catheter is threaded into the coronary arteries to directly measure temperature differences on the inner artery walls.

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*
Researchers believe this information may be related to the presence of unstable coronary artery plaques and could be useful in diagnosing vulnerable patients. Madjid et al (2006) have shown that inflamed atherosclerotic plaques are hot and their surface temperature correlates with an increased number of macrophages and decreased fibrous-cap thickness. Multiple animal and human experiments have shown that temperature heterogeneity correlates with arterial inflammation in vivo. Several coronary temperature mapping catheters are currently being developed and studied. These thermography methods can be used in the future to detect vulnerable plaques, potentially to determine patients’ prognosis, and to study the plaque-stabilizing effects of different medications.

A number of medical authorities have concluded that thermography has no proven medical value, including the American Medical Association, the Office of Health Technology Assessment (OHTA), and the American Academy of Neurology. Based on a study by the OHTA, the Health Care Financing Administration (now the Center for Medicare and Medicaid Services) withdrew Medicare coverage of thermography.

Devices that have been used for thermography skin temperature differential analysis include the Nervoscope, the Temp-O-Scope, and the Neurocalometer.

There is insufficient evidence for the use of thermography for detection of breast cancer. A structured evidence review of thermography for breast cancer (Kerr, 2004) reached the following conclusions: "The evidence that is currently available does not provide enough support for the role of infrared thermography for either population screening or adjuvant diagnostic testing of breast cancer. The major gaps in knowledge at this time can only be addressed by large-scale, prospective randomised trials. More robust research on the effectiveness and costs of technologically advanced infrared thermography devices for population screening and diagnostic testing of breast cancer is needed, and the conclusions of this review should be revisited in the face of additional reliable evidence".

Other reviews have also found a need for additional research on thermography. Kennedy et al (2009) noted that thermography was first introduced as a screening tool for breast cancer in mid-1950s. However, after a 1977 study found thermography to lag behind other screening tools, the medical community lost interest in this diagnostic approach. These researchers discussed each screening tool with a focus brought to thermography. They stated that no single diagnostic tool provides excellent predictability; however, a combination that incorporates thermography may boost both sensitivity as well as specificity. The authors concluded that in light of technological advances and maturation of the thermographical industry, more research is needed to confirm the potential of thermography in providing an effective non-invasive, low-risk adjunctive tool for the early detection of breast cancer.

Mammography is currently the gold standard for breast cancer screening. Thus, sensitivities, specificities, as well as positive and negative predictive values of thermography need to be compared with those of mammography in order to ascertain if thermography is equivalent or superior to mammography. Presently, there is a lack of scientific data comparing the 2 screening techniques. In addition,
there are no published evidence-based practice guidelines and/or position statements that recommend thermography as the appropriate method of screening for early detection of breast cancer.

Arora et al (2008) examined the effectiveness of a non-invasive digital infrared thermal imaging (DITI) system in the detection of breast cancer. A total of 92 patients for whom a breast biopsy was recommended based on prior mammogram or ultrasound underwent DITI. Three scores were generated: (i) an overall risk score in the screening mode, (ii) a clinical score based on patient information, and (iii) assessment by artificial neural network. Sixty of 94 biopsies were malignant and 34 were benign. Digital infrared thermal imaging identified 58 of 60 malignancies, with 97 % sensitivity, 44 % specificity, and 82 % negative predictive value depending on the mode used. Compared to an overall risk score of 0, a score of 3 or greater was significantly more likely to be associated with malignancy (30 % versus 90 %, p < 0.03). The author concluded that DITI is a valuable adjunct to mammography and ultrasound, especially in women with dense breast parenchyma. Moreover, the authors reported a high negative predictive value for thermography where "the location of the lesion under question based on prior imaging was assessed to generate a positive or negative clinical assessment", i.e., where they were unblinded to the results of the prior mammography or ultrasound. The specificity was only 11 % and the negative predictive value of thermography was only 66 % in the blinded screening mode. Furthermore, the authors stated that DITI is not currently recommended or approved as a substitute for screening mammography, and correlation of findings on DITI should be made with alternative imaging techniques. They stated that further studies are needed using a representative screening population of persons who have not been selected for biopsy based upon prior imaging results.

An American Cancer Society report Mammograms and Other Breast Imaging Procedures (2010) stated that "[t]hermography is a way to measure and map the heat on the surface of the breast using a special heat-sensing camera. It is based on the idea that the temperature rises in areas with increased blood flow and metabolism, which could be a sign of a tumor. Thermography has been around for many years, and some scientists are still trying to improve the technology to use it in breast imaging. But no study has ever shown that it is an effective screening tool for finding breast cancer early. It should not be used as a substitute for mammograms. Newer versions of this test are better able to find very small temperature differences. They may prove to be more accurate than older versions, and are now being studied to find out if they might be useful in finding cancer". Thermography is listed under "newer and experimental breast imaging methods" in this report.

Additionally, the United Kingdom's NHS Cancer Screening Programmes (2010) stated that "thermography is not a replacement for mammography. It is a relatively new test and isn't reliable enough to use either to diagnose or screen for cancer. Mammography is still the best test and is used as a world wide standard for breast screening in women over 50".

The Food and Drug Administration (FDA, 2011) stated that breast thermography should not be used instead of mammography, noting that thermography has not been approved as a stand-alone tool for breast cancer screening or diagnosis.
Telethermographic devices produce infrared images and do not require exposure to radiation or breast compression, which some healthcare providers claim make them superior to mammographic devices. However, the FDA stated that “there is simply no evidence” that breast thermography can take the place of mammography. The agency has sent warning letters to manufacturers and practitioners who have made misleading claims about breast thermography use.

Currently, there is insufficient evidence to support the use of thermography for the diagnosis of complex regional pain syndrome (CRPS). The use of thermography in the diagnosis of CRPS type 1 (CRPS1) is based on the presence of temperature asymmetries between the involved area of the extremity and the corresponding area of the uninvolved extremity. However, the interpretation of thermographical images is subjective and not validated for routine use. Huygen et al (2004) developed a sensitive, specific and reproducible arithmetical model as the result of computer-assisted infra-red thermography in patients with early stage CRPS1 in one hand. Eighteen patients with CRPS1 on one hand and 13 healthy volunteers were included in the study. The severity of the disease was determined by means of pain questionnaires [visual analogue scale (VAS) pain and McGill Pain Questionnaire], measurements of mobility (active range of motion) and edema volume. Asymmetry between the involved and the uninvolved extremities was calculated by means of the asymmetry factor, the ratio and the average temperature differences. The discrimination power of the 3 methods was determined by the receiver-operating curve (ROC). The regression between the determined temperature distributions of both extremities was plotted. Subsequently the correlation of the data was calculated. In normal healthy individuals the asymmetry factor was 0.91 (0.01) (SD), whereas in CRPS1 patients this factor was 0.45 (0.07) (SD). The performance of the arithmetic model based on the ROC curve was excellent. The area under the curve was 0.97 (p < 0.001), the sensitivity and specificity was 92 % and 94 %, respectively. Furthermore, the temperature asymmetry factor was correlated with the duration of the disease and VAS pain.

Gradl and colleagues (2003) stated that CRPS1 represents a frequent complication following distal radial fractures. These investigators studied the value of clinical evaluation, radiography and thermography in the early diagnosis of CRPS1. A total of 158 patients with distal radial fractures were followed-up for 16 weeks after trauma. Apart from a detailed clinical examination 8 and 16 weeks after trauma, thermography and bilateral radiographs of both hands were carried out. At the end of the observation period 18 patients (11 %) were clinically identified as CRPS1. The severity of the preceding trauma and the chosen therapy did not influence the process of the disease. Sixteen weeks after trauma easy differentiation between normal fracture patients and CRPS1 patients was possible. Eight weeks after distal radial fracture clinical evaluation showed a sensitivity of 78 % and a specificity of 94 %. On the other hand, thermography (58 %) and bilateral radiography (33 %) revealed poor sensitivities. The specificity was high for radiography (91 %) and again poor for thermography (66 %). These authors concluded that the results of the study support the importance of clinical evaluation in the early diagnosis of CRPS1. Plain radiographs facilitate the diagnosis as soon as bony changes develop.
Arterial wall thermography has also been used to identify rupture-prone vulnerable coronary plaque. However, the clinical value of arterial thermography in interventional cardiology has not been established.

Schaar and colleagues (2007) noted that rupture of vulnerable plaques is the principal cause of acute coronary syndrome and myocardial infarction. Identification of vulnerable plaques is therefore essential to enable the development of treatment modalities to stabilize such plaques. Thermography is one of the several novel methods being examined for detecting vulnerable plaques. It evaluates the temperature heterogeneity as an indicator of the metabolic state of the plaque. The authors concluded that while several invasive and non-invasive techniques are currently under development to assess vulnerable plaques, none has proven its value in an extensive in-vivo validation and all have a lack of prospective data.

García-García and colleagues (2008) stated that thin-capped fibroatheroma is the morphology that most resembles plaque rupture. Detection of these vulnerable plaques in-vivo is essential to being able to study their natural history and evaluate potential treatment modalities and, therefore, may ultimately have an important impact on the prevention of acute myocardial infarction and death. The investigators reported that, currently, conventional grayscale intra-vascular ultrasound, virtual histology and palpography data are being collected with the same catheter during the same pullback. A combination of this catheter with either thermography capability or additional imaging, such as optical coherence tomography or spectroscopy, would be an exciting development. Intra-vascular magnetic resonance imaging also holds much promise. The investigators stated that, to date, none of the techniques described above has been sufficiently validated and, most importantly, their predictive value for adverse cardiac events remains elusive. The investigators concluded that very rigorous and well-designed studies are needed for defining the role of each diagnostic modality. Until researchers are able to detect in-vivo vulnerable plaques accurately, no specific treatment is warranted.

Madjid and colleagues (2006) stated that up to 2/3 of acute myocardial infarctions develop at sites of culprit lesions without a significant stenosis. New imaging techniques are needed to identify those lesions with an increased risk of developing an acute complication in the near future. Inflammation is a hallmark feature of these vulnerable/high-risk plaques. These investigators have demonstrated that inflamed atherosclerotic plaques are hot and their surface temperature correlates with an increased number of macrophages and reduced fibrous-cap thickness. They noted that animal and human studies have reported that temperature heterogeneity correlates with arterial inflammation in-vivo. Several coronary temperature mapping catheters are currently being developed. These thermographic methods can be used in the future to detect vulnerable plaques, potentially to ascertain patients' prognosis, and to examine the plaque-stabilizing effects of various pharmacotherapies.

Sharif and Murphy (2010) noted that critical coronary stenoses have been shown to contribute to only a minority of acute coronary syndromes and sudden cardiac death. Autopsy studies have identified a subgroup of high-risk patients with disrupted vulnerable plaque and modest stenosis. Consequently, a clinical need exists to develop methods to identify these plaques prospectively before disruption.
and clinical expression of disease. Recent advances in invasive as well as non-invasive imaging techniques have shown the potential to identify these high-risk plaques. The anatomical characteristics of the vulnerable plaque such as thin cap fibro-atheroma and lipid pool can be identified with angioscopy, high frequency intra-vascular ultrasound, intra-vascular magnetic resonance imaging (MRI), and optical coherence tomography. Efforts have also been made to recognize active inflammation in high-risk plaques using intra-vascular thermography. Plaque chemical composition by measuring electro-magnetic radiation using spectroscopy is also an emerging technology to detect vulnerable plaques. Non-invasive imaging with MRI, computed tomography, and positron emission tomography also holds the potential to differentiate between low-risk and high-risk plaques. However, at present none of these imaging modalities is able to detect vulnerable plaque nor have they been shown to definitively predict outcome. Nevertheless in contrast, there has been a parallel development in the physiological assessment of advanced athero-sclerotic coronary artery disease. Thus, recent trials using fractional flow reserve in patients with modest non flow-limiting stenoses have shown that deferral of percutaneous coronary intervention with optimal medical therapy in these patients is superior to coronary intervention. The authors concluded that further trials are needed to provide more information regarding the natural history of high-risk but non flow-limiting plaque to establish patient-specific targeted therapy and to refine plaque stabilizing strategies in the future.

There is insufficient evidence to support the use of thermography in post-herpetic neuralgia. Han and associates (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). Demographical data collected included age, gender, time of skin lesions onset, development of PHN, and co-morbidities. The temperature differences between the unaffected and affected dermatome were calculated. Differences greater than 0.6 degrees C for the mean temperature across the face and trunk were considered abnormal. The affected side was warmer in 35 patients and cooler in 33 patients than the contralateral side. A patient's age and disease duration affected treatment outcomes. However, the temperature differences were not correlated with pain severity, disease duration, allodynia, development of PHN, and use of anti-viral agents (p > 0.05). The authors concluded that a patient's age and disease duration are the most important factors predicting PHN progression, irrespective of thermal findings, and PHN can not be predicted by infrared thermal imaging.

An Agency for Healthcare Research and Quality's report on non-invasive diagnostic techniques for the detection of skin cancers (Parsons et al, 2011) listed thermography as one of the investigational diagnostic techniques for the detection of skin cancers.

Kontos et al (2011) determined the sensitivity and specificity of DIITI in a series of women who underwent surgical excision or core biopsy of benign and malignant breast lesions presenting through the symptomatic clinic. Digital infrared thermal imaging was evaluated in 63 symptomatic patients attending a 1-stop diagnostic breast clinic. 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 despite being non-invasive and painless, 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 Canadian Agency for Drugs and Technologies in Health’s technology assessment on Infrared thermography for population screening and diagnostic testing for breast cancer” (Morrison, 2012) states that “No randomized controlled trials have been conducted that compare the effectiveness of thermography with mammography for screening in well women, and there is no evidence regarding the cost-effectiveness of thermography used for screening. Prospective cohort studies of symptomatic patients or patients with abnormal mammograms or ultrasounds do not provide the type of evidence needed to justify the use of thermography for breast screening. Results indicate that thermography performance is worse than mammography in terms of sensitivity, specificity, and predictive values; however, some of the studies’ authors have suggested there may be a role for thermography as an adjunct diagnostic test in some cases”.

Kim et al (2012) evaluated the accuracy of the size and location of the ablation zone produced by volumetric MRI-guided high-intensity focused ultrasound (HIFU) ablation of uterine fibroids on the basis of MR thermometric analysis and assessed the effects of a feedback control technique. A total of 33 women with 38 uterine fibroids were treated with an MR imaging-guided HIFU system capable of volumetric feedback ablation. Size (diameter times length) and location (3-D displacements) of each ablation zone induced by 527 sonications (with \( n = 471 \) and without \( n = 56 \) feedback) were analyzed according to the thermal dose obtained with MR thermometry. Prospectively defined acceptance ranges of targeting accuracy were ± 5 mm in left-right (LR) and cranio-caudal (CC) directions and ± 12 mm in antero-posterior (AP) direction. Effects of feedback control in 8- and 12-mm treatment cells were evaluated by using a mixed model with repeated observations within patients. Overall mean sizes of ablation zones produced by 4-, 8-, 12-, and 16-mm treatment cells (with and without feedback) were 4.6 mm ± 1.4 (standard deviation) × 4.4 mm ± 4.8 (\( n = 13 \)), 8.9 mm ± 1.9 × 20.2 mm ± 6.5 (\( n = 248 \)), 13.0 mm ± 1.2 × 29.1 mm ± 5.6 (\( n = 234 \)), and 18.1 mm ± 1.4 × 38.2 mm ± 7.6 (\( n = 32 \)), respectively. Targeting accuracy values (displacements in absolute values) were 0.9 mm ± 0.7, 1.2 mm ± 0.9, and 2.8 mm ± 2.2 in LR, CC, and AP directions, respectively. Of 527 sonications, 99.8 % (526 of 527) were within acceptance ranges. Feedback control had no statistically significant effect on targeting accuracy or ablation zone size. However, variations in ablation zone size were smaller in the feedback control group. The authors concluded that sonication accuracy of volumetric MRI-guided HIFU ablation of uterine fibroids appears clinically acceptable and may be further improved by feedback control to produce more consistent ablation zones.

Brkljacic et al (2013) noted that breast cancer is a common malignancy causing high mortality in women especially in developed countries. Due to the contribution of mammographic screening and improvements in therapy, the mortality rate from breast cancer has decreased considerably. An imaging-based early detection of breast cancer improves the treatment outcome. Mammography is generally established not only as diagnostic but also as screening tool, while breast ultrasound plays a major role in the diagnostic setting in distinguishing solid lesions from cysts and in guiding tissue sampling. Several indications are established for
contrast-enhanced MRI. Thermography was not validated as a screening tool and the only study performed long ago for evaluating this technology in the screening setting demonstrated very poor results. The conclusion that thermography might be feasible for screening cannot be derived from studies with small sample size, unclear selection of patients, and in which mammography and thermography were not blindly compared as screening modalities. Thermography cannot be used to aspirate, biopsy or localize lesions pre-operatively since no method so far was described to accurately transpose the thermographic location of the lesion to the mammogram or ultrasound and to surgical specimen. The authors concluded that thermography cannot be proclaimed as a screening method, without any evidence whatsoever.

The Work Loss Data Institute’s guideline on “Low back -- lumbar & thoracic (acute & chronic)” (2013) listed thermography (infrared stress thermography) as one of the interventions/procedures that was considered, but is not recommended.

Sanchis-Sanchez et al (2014) noted that musculoskeletal injuries occur frequently. Diagnostic tests using ionizing radiation can lead to problems for patients, and infra-red thermal imaging could be useful when diagnosing these injuries. A systematic review was performed to determine the diagnostic accuracy of infra-red thermal imaging in patients with musculoskeletal injuries. A meta-analysis of 3 studies evaluating stress fractures was performed and found a lack of support for the usefulness of infra-red thermal imaging (including thermography) in musculoskeletal injuries diagnosis.

Dibai-Filho and Guirro (2015) reviewed recent studies published on the use of infra-red thermography (IRT) for the assessment of myofascial trigger points (MTrPs). A search of the MEDLINE, CINAHL, PEDro, and SciELO databases was carried out between November 2012 and January 2013 for articles published in English, Portuguese, or Spanish from the year 2000 to 2012. Because of the nature of the included studies and the purpose of this review, the analysis of methodological quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies tool. The search retrieved 11 articles, 2 of which were excluded based on language (German and Chinese); 3 were duplicated in different databases, 1 did not use IRT for diagnostic purposes, and the other did not use IRT to measure the skin temperature. Thus, the final sample was made up of 4 observational investigations: 3 comparative studies and 1 accuracy study. The authors concluded that at present, there are few studies evaluating the accuracy and reliability of IRT for the diagnosis and assessment of MTrPs. Of the few studies present, there is no agreement on skin temperature patterns in the presence of MTrPs.

Burke-smith et al (2015) states that currently the only evidence-based adjunct to clinical evaluation of burn depth is laser Doppler imaging (LDI), although preliminary studies of alternative imaging modalities with instant image acquisition are promising. These researchers investigated the accuracy of IRT and spectrophotometric intracutaneous analysis (SIA) for burn depth assessment, and compared this to the current gold standard: LDI. They included a comparison of the 3 modalities in terms of cost, reliability and usability. These investigators recruited 20 patients with burns presenting to the Chelsea and Westminster Adult Burns Service. Between 48 hours and 5 days after burn, these researchers recorded imaging using (i) moorLDI2-BI-VR (LDI), (ii) FLIR E60 (IRT) and (iii) Scanoskin (SIA).
Subsequent clinical management and outcome was as normal, and not affected by the extra images taken. A total of 24 burn regions were grouped according to burn wound healing: group A healed within 14 days, group B within 14 to 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 (p > 0.05). Scanoskin interpretation of SIA was 100 % consistent with clinical outcome. The authors concluded that FLIR E60 and Scanoskin both presented advantages to moorLDI2-BI-VR in terms of cost, ease-of-use and acceptability to patients. Infra-red thermography 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. However the additional analyses of pigment available using SIA may help more accurately indicate the depth of burn compared with perfusion alone. The authors suggested development of Scanoskin software to include a simplified color-palette similar to LDI and additional work to further investigate the potential of SIA as an alternative to the current gold standard.

Evaluation of Burn Wounds:

Prindeze and associates (2015) noted that despite advances in perfusion imaging, burn wound imaging technology continues to lag behind that of other fields. Quantification of blood flow is able to predict time for healing, but clear assessment of burn depth is still questionable. Active dynamic thermography (ADT) is a non-contact imaging modality capable of distinguishing tissue of different thermal conductivities. Utilizing the abnormal heat transfer properties of the burn zones, these researchers examined if ADT was useful in the determination of burn depth in a model of early burn wound evaluation. Duroc pigs (castrated male; n = 3) were anesthetized, and 2 burns were created with an aluminum billet at 3 and 12 seconds. These contact times resulted in superficial partial and deep partial thickness burn wounds, respectively. Active dynamic thermography and laser Doppler imaging (LDI) imaging were performed every 30 minutes post-burn for a total of 5 imaging sessions ending 150 minutes post-burn. For ADT, imaging excitation was performed for 42 to 120 seconds with dual quartz-infrared lamps, and subsequent infrared image capture was performed for 300 seconds; MATLAB-assisted image analysis was performed to determine burn zone region of interest thermal relaxation and characteristic patterns. Laser Doppler imaging was performed with a moorLDI system, and biopsies were captured for histology following the 150-minute imaging session. Both ADT and LDI imaging modalities were able to detect different physical properties at 30, 60, 90, 120, and 150 minutes post-burn with statistical significance (p < 0.05). Resultant ADT cooling curves characterized greater differences with greater stimulation and a potentially more identifiable differential cooling characteristic. Histological analysis confirmed burn depth. The authors concluded that this preliminary work confirmed that ADT can measure burn depth and is deserving of further research either as a stand-alone imaging technology or in combination with a device to assess perfusion.

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Evaluation of Dry Eye Disease:

Tan and colleagues (2016) evaluated the effectiveness of IR ocular thermography in screening for dry eye disease (DED); IR ocular thermography was performed on 62 dry eye and 63 age- and sex-matched control subjects. Marking of ocular surface and temperature acquisition was done using a novel “diamond” demarcation method. A total of 30 static- and 30 dynamic-metrics were studied and receiver operating characteristic curves were plotted. Effectiveness of the temperature metrics in detecting DED were evaluated singly and in combination in terms of their area under the curve (AUC), Youden's index and discrimination power (DP). Absolute temperature of the extreme nasal conjunctiva 5s and 10s after eye opening were best detectors for DED. With threshold value for the first metric set at 34.7°C, sensitivity and specificity was 87.1% (95% CI: 76.2 to 94.3%) and 50.8% (95% CI: 37.9 to 63.6%), respectively. With threshold value for the second metric set at 34.5°C, sensitivity and specificity was 77.6% (95% CI: 64.7 to 87.5%) and 61.9% (95% CI: 48.8 to 73.9%), respectively. The 2 metrics had moderate accuracy and limited performances with AUC of 72% (95% CI: 63 to 81%) and 73% (95% CI: 64 to 82%); Youden index of about 0.4 and DP of 1.07 and 1.05, respectively. None of the dynamic metrics was good detector for DED. Combining metrics was not able to increase the AUC. The authors concluded that the findings of this study suggested some utility for the application of IR ocular thermography for evaluation of patients with DED.

Evaluation of Leprosy:

Cavalheiro and associates (2016) examined if IRT would be able to measure the change in temperature in the hands of people with leprosy. The study assessed 17 leprosy patients who were under treatment at the National Reference Center for
Sanitary Dermatology and Leprosy, and 15 people without leprosy for the control group. The infrared camera FLIR A325 and Therma CAM Researcher Professional 2.9 software were used to measure the temperature. The room was air-conditioned, maintaining the temperature at 25° C; the distance between the camera and the limb was 70 cm. The vasomotor reflex of patients was tested by a cold stress on the palm. The study showed a significant interaction between the clinical form of leprosy and temperature, where the control group and the borderline-borderline form revealed a higher initial temperature, while borderline-lepromatous and lepromatous leprosy showed a lower temperature. Regarding vasomotor reflex, lepromatous leprosy patients were unable to recover the initial temperature after cold stress, while those with the borderline-tuberculoid form not only recovered but exceeded the initial temperature. The authors concluded that IRT proved a potential tool to assist in the early detection of neuropathies, helping in the prevention of major nerve damage and the installation of deformities and disabilities that are characteristic of leprosy.

Management of Infantile Hemangioma:

In a preliminary, prospective, observational study, Burkes et al (2016) applied a functional imaging method, dynamic IRT, to investigate infantile hemangiomas (IH) status versus control skin and over time. A total of 25 subjects with superficial or mixed IHs (age of less than 19 months) over 59 clinic visits were included in this study. Infrared images of IHs and control sites, standardized color images, and three-dimensional (3D) images were obtained. Tissue responses following application and removal of a cold stress were recorded with video IRT. Outcomes included areas under the curve during cooling (AUCcool) and rewarming (AUCrw) and thermal intensity distribution maps. AUCcool and AUCrw were significantly higher and cooling rate slower for IHs versus uninvolved tissue indicating greater heat, presumably due to greater perfusion and metabolism for the IH. Infra-red distribution maps showed specific areas of high and low temperature. Significant changes in IH thermal activity were reflected in the difference (AUCcool - AUCrw), with 6.2 at 2.2 months increasing to 37.6 at 12.8 months; IH cooling rate increased with age, indicating slower recovery, and interpreted as reduced proliferation and/or involution. The authors concluded that dynamic IRT was a well-tolerated, quantitative functional imaging modality appropriate for the clinic, particularly when structural changes, i.e., height, volume, color, were not readily observed. They stated that dynamic IRT may aid in monitoring progress, individualizing treatment, and evaluating therapies.

Monitoring of Diabetes Mellitus:

Staffa et al (2016) stated that foot complications in persons with diabetes mellitus (DM) are associated with substantial costs and loss of quality of life. Increasing evidence suggests changes in skin temperature, measured using an IRT system, may be a predictor of foot ulcer development in patients with DM. In a case study, these researchers described the long-term IRT findings and overall clinical outcomes of a patient with DM and peripheral vascular disease (PVD). Foot temperature measurements using IRT were obtained slightly more than 1 year before and immediately following endovascular treatment of a 76-year old man, a non-smoker with type 2 DM, hypertension, and ischemic heart disease with cardiac arrhythmia. Although he was otherwise asymptomatic, the infrared measurement
showed an average temperature difference of 2.3˚C between the left and right foot until he developed a small, trauma-induced wound on the left foot, at which time left foot temperature increased. He was diagnosed with recto-sigmoid adenocarcinoma, underwent surgery and chemotherapy, and subsequently was evaluated for PVD. Before undergoing peripheral angiography and percutaneous transluminal angioplasty, IRT evaluation showed a hot spot on the left heel. Immediately following endovascular treatment, the mean temperature difference between the right and left foot was low (0.2˚C), but a Stage I pressure ulcer was visible on the left heel. Skin breakdown in that area was observed 2 months later, and the wound continued to increase in size and depth. The patient died shortly thereafter due to complications of cancer. In this case study, a series of infrared images of foot skin temperatures appeared to show a relationship with blood circulation and wound/ulcer development and presentation. The authors concluded that IRT has the ability to instantaneously measure the absolute temperature of the skin surface over a large area without direct skin contact. However, they stated that these devices are very sensitive; and prospective clinical studies are needed to determine the validity, reliability, sensitivity, and specificity of these measurements for routine use in patients who are at risk for vascular disease and/or foot ulcers.

Predicting Pressure Ulcers:

In a systematic review, Oliveira and colleagues (2017) examined the clinical significance of ultrasound (US), thermography, photography and sub-epidermal moisture (SEM) measurement in detecting skin/tissue damage and thus predicting the presence of pressure ulcers (PUs); determined the relative accuracy of one of these assessment methods over another; and made recommendations for practice pertaining to assessment of early skin/tissue damage. The following databases, Cochrane Wounds Group Specialized Register, the Cochrane Central Register of Controlled Trials, Ovid Medline, Ovid Embase, Elsevier version, Ebsco CINAHL, ClinicalTrials.gov, WHO International Clinical Trials Registry (ICTR) and The EU Clinical Trials Register were searched for terms including; thermography, ultrasound, sub-epidermal moisture, photograph and pressure ulcer. These investigators identified 4 SEM, 1 thermography and 5 ultrasound studies for inclusion in this review. Data analysis indicated that photography was not a method that allowed for the early prediction of PU presence; SEM values increased with increasing tissue damage, with the sacrum and the heels being the most common anatomical locations for the development of erythema and stage I PUs. Thermography identified temperature changes in tissues and skin that may give an indication of early PU development; however the data were not sufficiently robust; US detected pockets of fluid/edema at different levels of the skin that were comparable with tissue damage. Thus, SEM and US were the best methods for allowing a more accurate assessment of early skin/tissue damage. Using the EBL Critical Appraisal Tool, the validities of the studies varied between 33.3 to 55.6 %, meaning that there is potential for bias within all the included studies. All of the studies were situated at level IV, V and VII of the evidence pyramid. These researchers noted that although the methodological quality of the studies warrants consideration, these studies showed the potential that SEM and US have in early PU detection. The authors concluded that SEM and US are promising in the detection and prediction of early tissue damage and PU presence. However, they stated that these methods should be further studied to clarify their potential for use more widely in PU prevention strategies.
Determining the Efficacy of Stroke Rehabilitation:

Hegedus (2017) stated that maintaining good physiological circulation in the extremities requires an optimally functioning muscle pump. Stroke symptoms indicate a change in venous circulation. In this study, these researchers measured changes in joint function and microcirculation, and the correlation between them. A total of 16 randomly selected post-stroke patients with hemiparesis affecting mainly the upper extremities began undergoing rehabilitation 13 ± 4 days following stroke. Thermograms were taken with a Fluke Ti 20 (Fluke Corporation, WA) pre-treatment and post-treatment, and a physiotherapy documentation form was completed. Treatment comprised 15 physiotherapy, massage, and galvanic therapy sessions per patient, with the side exhibiting no neurological symptoms as a control. Joint function showed significant improvement on the affected side (p < 0.05).

Thermographic examinations revealed microcirculatory dysfunction in the affected extremities in 100% of the cases. Following treatment, temperature increased significantly (p ≥ 0.5°C) on the affected side. A strong correlation (r) was observed between joint function and temperature change (p < 0.05). The authors concluded that thermography was shown to be a reliable method for monitoring the effects of stroke rehabilitation treatment. They stated that thermographic testing may enable clinicians to predict the course of the trauma and the effectiveness of treatment even at the acute stage.

Intraoperative Infra-Red Thermography in Surgery of Glioblastoma Multiforme:

Naydenov and colleagues (2017) noted that IRT is a real-time non-contact diagnostic tool with a broad potential for neurosurgical applications. These researchers described the intraoperative use of this technique in a single patient with newly diagnosed glioblastoma multiforme (GBM). An 86-year-old woman was admitted to the clinic with a 2-month history of slowly progressing left-sided paresis. Neuroimaging studies demonstrated an irregular space-occupying process consistent with a malignant glioma in the right fronto-temporo-insular region. An elective surgical intervention was performed by using 5-aminolevulinic acid fluorescence (BLUE 400, OPMI) and intraoperative IRT brain mapping (LWIR, 1.25 mRad IFOV, 0.05°C NETD). After dura opening, the cerebral surface appeared inconspicuous. However, IRT revealed a significantly colder area (Δt° 1.01°C), well corresponding to the cortical epicenter of the lesion. The underlying tumor was partially excised and the histological result was GBM. The authors concluded that intraoperative IRT appeared to be a useful technique for subcortical convexity brain tumor localization. Moreover, they stated that further studies with a large number of patients are needed to prove the reliability of this method in GBM surgery.

Dynamic Infrared Blood Perfusion Imaging

Dynamic infrared blood perfusion imaging (DIRI) is a new infrared imaging technique that is intended to detect changes in blood flow in tissue and organs by sensing passively emitted infrared radiation from tissues. Potential clinical applications of DIRI include: use as an adjunctive screening tool for breast cancer and other cancers; evaluation of response to cancer chemotherapy; monitoring response to therapy in diabetic peripheral vascular disease; identifying perforator vessels during pre-surgical planning; assessing post-operative perfusion of pedicle flaps following reconstructive surgery (i.e., of the breast); mapping of functional
cortex in patients undergoing tumor surgery; and determining cardiac bypass graft patency and perfusion of the myocardium in cardiac surgery. Agostini and colleagues (2009) stated that dynamic infrared imaging is a promising technique in breast oncology. Currently available evidence, however, is limited to evaluations of DIRI’s technical feasibility. There is an absence of evidence of the impact of DIRI on health outcomes. The BioScanIR System (OmniCorder Technologies, Inc., Bohemia, NY) is an example of a DIRI device that is commercially available.

Lohman et al (2015) stated that over the last decade, microsurgeons have used a greater variety of more complex flaps. At the same time, microsurgeons have also become more interested in technology, such as indo-cyanine green (ICG) angiography, dynamic infra-red thermography (DIRT), and photo-spectrometry, for pre-operative planning and post-operative monitoring. These technologies are now migrating into the operating room, and are used to optimize flap design and to identify areas of hypo-perfusion or problems with the anastomoses. Although relatively more has been published about ICG angiography, information is generally lacking about the intra-operative role of these techniques. A systematic analysis of articles discussing intra-operative ICG angiography, DIRT, and photo-spectrometry was performed to better define the sensitivity, specificity, expected outcomes, and potential complications associated with these techniques. For intra-operative ICG angiography, the sensitivity was 90.9 % (95 % confidence interval [CI]: 77.5 to 100) and the accuracy was 98.6 % (95 % CI: 97.6 to 99.7). The sensitivity of DIRT was 33 % (95 % CI: 11.3 to 64.6), the specificity was 100 % (95 % CI: 84.9 to 100), and the accuracy was 80 % (95 % CI: 71.2 to 89.7). The sensitivity of intra-operative photo-spectrometry was 92 % (95 % CI: 72.4 to 98.6), the specificity was 100 % (95 % CI: 98.8 to 100), and the accuracy was also 100 % (95 % CI: 98.7 to 100). The authors concluded that these technologies for intra-operative perfusion assessment have the potential to provide objective data that may improve decisions about flap design and the quality of microvascular anastomoses. However, more work is needed to clearly document their value.

Just and colleagues (2016) investigated static IRT and DIRT for intra- and post-operative free-flap monitoring following oropharyngeal reconstruction. A total of 16 patients with oropharyngeal reconstruction by free radial forearm flap were included in this prospective, clinical study. Prior (“intraop_pre”) and following (“intraop_post”) completion of the microvascular anastomoses, IRT was performed for intra-operative flap monitoring. Further IR images were acquired 1 day (“postop_1”) and 10 days (“postop_10”) after surgery for post-operative flap monitoring. Of the 16, 15 transferred free radial forearm flaps did not show any perfusion failure. A significant decreasing mean temperature difference (∆T: temperature difference between the flap surface and the surrounding tissue in Kelvin) was measured at all investigation points in comparison with the temperature difference at “intraop_pre” (mean values on all patients: ∆T intraop_pre = -2.64 K; ∆T intraop_post = -1.22 K, p < 0.0015; ∆T postop_1 = -0.54 K, p < 0.0001; ∆T postop_10 = -0.58 K, p < 0.0001). Intra-operative DIRT showed typical pattern of non-pathological rewarming due to re-established flap perfusion after completion of the microvascular anastomoses. The authors concluded that static and dynamic IRT is a promising, objective method for intra-operative and post-operative monitoring of free-flap reconstructions in head and neck surgery and to detect perfusion failure, before macroscopic changes in the tissue surface are obvious. They noted that a lack of significant decrease of the
temperature difference compared to surrounding tissue following completion of microvascular anastomoses and an atypical re-warming following a thermal challenge are suggestive of flap perfusion failure.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "++":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>CPT codes not covered for indications listed in the CPB:</td>
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</tr>
<tr>
<td>93740</td>
<td>Temperature gradient studies</td>
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<tr>
<td>ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):</td>
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<tr>
<td>C00.0 - C96.9</td>
<td>Malignant neoplasms</td>
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<tr>
<td>E10.51 - E10.59</td>
<td>Diabetes mellitus with circulatory complications [Type 1 or 2]</td>
</tr>
<tr>
<td>E11.51 - E11.59</td>
<td></td>
</tr>
<tr>
<td>I25.10 - I25.9</td>
<td>Coronary atherosclerosis</td>
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<tr>
<td>I73.9</td>
<td>Peripheral vascular disease, unspecified</td>
</tr>
<tr>
<td>M79.601 - M79.609</td>
<td>Pain in limb</td>
</tr>
<tr>
<td>M84.421S - M84.429S</td>
<td>Fracture of upper extremity, sequela</td>
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<tr>
<td>S42.209S - S42.496S</td>
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<td>S49.001S - S49.199S</td>
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<tr>
<td>S52.001S - S52.92xS</td>
<td></td>
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<tr>
<td>S59.001S - S59.299S</td>
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<tr>
<td>S62.90xS - S62.92xS</td>
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<tr>
<td>S52.501+ - S52.509+</td>
<td>Fracture of radius [open or closed]</td>
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<tr>
<td>S52.531+ - S52.539+</td>
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<tr>
<td>Z01.810</td>
<td>Encounter for preprocedural cardiovascular examination</td>
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<tr>
<td>Z01.818</td>
<td>Encounter for other preprocedural examination</td>
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<tr>
<td>Z01.89</td>
<td>Encounter for other specified special examinations [not covered for intra-operative and post-operative perfusion assessment]</td>
</tr>
<tr>
<td>Z12.0 - Z12.9</td>
<td>Encounter for screening for malignant neoplasms</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


Amendment to
Aetna Clinical Policy Bulletin Number:
0029 Thermography

There are no amendments for Medicaid.