APPENDIX to Thermography/Temperature Gradient Studies Policy

Prior Authorization Requirements

This service (or procedure) is considered **investigational** in all instances. If you would like to submit additional information please forward to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Thermography/temperature gradient studies are a type of infrared imaging science. Thermographic cameras detect radiation in the infrared range of the electromagnetic spectrum (roughly 900-14,000 nanometers [0.9-14 µm]) and produce images of that radiation. Since infrared radiation is emitted by all objects based on their temperature, according to the black body radiation law, thermography makes it possible to "see" one's environment with or without visible illumination. When viewed by a thermographic camera, warm objects stand out well against cooler backgrounds; humans and other warm-blooded animals become easily visible against the environment, day or night. As a result, thermography's extensive use can historically be ascribed to the military and security services.

Interpretation of the color patterns is thought to assist in the diagnosis of many disorders such as complex regional pain syndrome ([CRPS], previously known as reflex sympathetic dystrophy), breast cancer, Raynaud's phenomenon, digital artery vasospasm in hand-arm vibration syndrome, peripheral nerve damage following trauma, impaired spermatogenesis in infertile men, degree of burns, deep vein thrombosis, gastric cancer, tear-film layer stability in dry-eye syndrome, Frey's syndrome, headaches, low-back pain, and vertebral subluxation.

Thermography may also assist in treatment planning and procedure guidance such as identifying restricted areas of perfusion in coronary artery bypass grafting, identifying unstable atherosclerotic plaque, assessing response to methylprednisone in rheumatoid arthritis, and locating high undescended testicles.

Thermography can include various types of telethermographic infrared detector images and heat-sensitive cholesteric liquid crystal systems. There are more than 20 thermography devices that have received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) based on demonstration of substantial equivalence to existing products. These devices include, but are not limited to, the following:

- AG Thermographic Camera (AG Digital Technology Corp., Flagstaff, AZ)
- EMD Thermography System (EM Diagnostics, North Attleboro, MA)
- ICI P and S Series IR Cameras (Infrared Cameras Inc., Beaumont, TX)
- BreastScan IR System (Infrared Sciences, Corp., Stony Brook, NY)
- MedHot MTI 2000 Thermal Imaging System (MedHot Thermal Imaging, Inc., Lakeland, FL)
- Dorex Spectrum 9000MB Thermography System (Dorex, Inc., Orange, CA)

The American Chiropractic Association (1999) suggested that high-resolution infrared imaging is of value in the diagnostic evaluation of patients when the clinical history suggests the presence of one of the following situations:

- To obtain early diagnosis and monitor reflex sympathetic dystrophy syndromes
- To evaluate spinal nerve root fiber irritation and distal peripheral nerve fiber pathology for detection of sensory/autonomic dysfunction
- To evaluate and monitor soft tissue injuries, including segmental dysfunction/subluxation, sprain, and myofascial conditions (strains and myofascial pain syndromes) not responding to clinical treatment
- To evaluate the physiological significance of equivocal or minor anatomical findings seen on myelogram, computed tomography (CT), and/or magnetic resonance imaging (MRI)

The above-listed evaluations are based on consensus guidelines and have no supporting references or documentation.

Literature Review

The two main indications under consideration for the use of thermography are the diagnosis of complex regional pain syndrome (CRPS) and breast cancer. The validation of a thermographic diagnostic test must include direct comparisons with the existing standard of care in order to:

- Demonstrate diagnostic accuracy (sensitivity, specificity, positive and negative predictive values) compared with that of the test or tests it purports to replace; and
- Determine whether thermography leads to differential treatment and improved health outcomes beyond that conferred by the standard of care (in other words, demonstrate clinical utility).

Clinical trials directly comparing health outcomes of patients' diagnosed using thermography, versus the standard of care, are needed to evaluate the effectiveness of this technology. Following is a summary of the key literature to date:

Breast Cancer

Breast cancer is the potential application of thermography with the most published literature. However, the literature is confined to case series testing of the diagnostic accuracy of the procedure. No published studies have demonstrated how the results of thermography can be used to enhance patient management and/or improve patient health outcomes (clinical utility).

Hayes Inc., (2006) assessed the usefulness of thermography, particularly infrared imaging (IRI) and dynamic IRI (DIRI), for breast cancer detection in four studies. Only two studies were published in the peer-reviewed literature. The authors advised that some study results (Arena et al., 2003; Parisky et al., 2003) reported that DIRI had high sensitivity (97%-98%) which indicated that it detected almost all of the breast cancers; however, the specificity was poor to moderate (14%-55%). Also, like mammography, DIRI incorrectly identified many benign masses as being malignant. The one study that evaluated the diagnostic efficacy of IRI reported 83% sensitivity and 81% specificity, and 98% sensitivity when IRI was combined with mammography and clinical breast examination (Keyserlingk et al., 1998). However, this study did not report outcomes that were statistically significant, nor was the specificity reported. Further, none of the studies reviewed determined whether the sensitivity and/or sensitivity of diagnosis improved with DIRI combined with mammography (Amalu, 2004; Keyserlingk et al., 1998; Parisky et al., 2003). Hayes concluded that from the available studies reviewed at that time, there was insufficient evidence to determine whether the sensitivity and/or specificity of diagnosis improved when DIRI was combined with mammography, or whether health outcomes were improved with breast thermography. In an updated review of the literature in 2008 by Hayes Inc., only one article was found pertaining to thermography use in breast cancer (Longatto et al., 2007). Hayes reported that the efficacy was unchanged from the 2006 review.

In 2011, the FDA issued an alert regarding the use of thermography for breast cancer screening:

> The FDA is issuing this communication to alert the public, including women and health care providers, that thermography is not a replacement for screening mammography and should not be used by itself to diagnose breast cancer. The FDA is not aware of any valid scientific data to show that thermographic devices, when used on their own, are an effective screening tool for any medical condition including the early detection of breast cancer or other breast disease.

Two systematic reviews of the published literature were identified. A 2012 systematic review identified six studies, one study using thermography for breast cancer screening and five using thermography to diagnose breast cancer among symptomatic women or those with a positive mammogram (Fitzgerald & Berentson-Shaw, 2012). In the screening study, more than 10,000 women were invited to participate, and sample sizes in the diagnosis studies ranged from 63 and 2,625 participants. The screening study found that, compared to mammography, thermography had a sensitivity of 25% and specificity of 74%. In the diagnostic studies, which all used histology as the reference standard, sensitivity ranged from 25% to 97% and specificity ranged from 12% to 85%. In addition, a 2013 systematic review identified eight studies on

thermography for diagnosis of breast cancer that included a valid reference standard (Vreugdenburg et al., 2013). Six of the eight studies, with sample sizes between 29 and 769 patients, included women scheduled for biopsy. The sensitivity of thermography in the individual studies ranged from 25% to 97% and specificity ranged from 12% to 85%. Study findings were not pooled. For example, a study by Arora and colleagues (2008) included 92 patients presenting for breast biopsy. When used in a screening mode (any positive reading was considered abnormal) for breast cancer, the sensitivity of thermography was 97% and specificity was 12%; when evaluated in a clinical mode (the lesion in question was used to determine an abnormal score), sensitivity was 90% and specificity was 44%.

Chronic Regional Pain Syndrome

The literature for diagnosis of CRPS is limited to non-randomized studies which are small and do not demonstrate improvement in health outcomes. For example, a study by Schurmann and coworkers (2007) reported on imaging in 18 patients with complex regional pain syndrome (CRPS) I and 13 patients with an incomplete clinical picture. Based on the study, the authors concluded that imaging methods (e.g., three-phase bone scan, magnetic resonance imaging, and thermography) are not able to reliably differentiate between normal post-traumatic changes and changes due to CRPS I. The authors went on to say that clinical findings remain the gold standard for diagnosis. They add that imaging procedures might serve as additional tools to establish the diagnosis in doubtful cases.

A study by Krumova and colleagues (2008) reported on skin temperature measurements in 22 patients with complex regional pain syndrome (CPRS), 18 with non-CRPS pain, and 23 healthy controls. Using long-term thermography, there was asymmetry in limb temperature in the CRPS group and, to some extent, in non-CRPS pain patients that was not seen in healthy controls). However, the significance of these results is uncertain. Some of the differences could be due to effects of medication, (e.g., antiseizure or antidepressant medications. In addition, the similarity of some findings between those with CRPS and non-CRPS pain limits applicability for use in diagnosis. Another example is a study published by Shada and colleagues that addressed the use of infrared thermography for differentiating between a melanoma metastasis and benign cutaneous lesions (Shada et al., 2012). The study included 74 individuals with 251 palpable skin lesions. Thermographic images were taken of the lesions and diagnosis was confirmed by biopsy or clinical diagnosis; the sensitivity and specificity of thermography varied by lesion size. For lesions between 0 and 5 mm (n=40), the sensitivity was 39% and specificity was 100%. For lesions between 5 and 15 mm (n=46), the sensitivity was 0.58% and the specificity was 98%. Sensitivity and specificity were 95% and 100%, respectively, for lesions between 15 and 30 mm and 78% and 89%, respectively, for lesions above 30 mm.

Other Conditions

A number of other studies have been published on a range of potential applications of thermography. None of these studies have examined the impact of thermography on patient management decisions or health outcomes.

The following are examples of studies conducted outside of the United States investigating the association between thermographic findings and various other conditions:

- Post-herpetic neuralgia in patients with herpes zoster (Han et al., 2010; Park et al., 2012)
- Surgical site healing in patients who underwent knee replacements (Romano et al., 2012)
- Ulcer healing in patients with pressure ulcers (Nakagami et al., 2010)
- Post-treatment pain in patients with coccygodynia (Wu et al., 2009)
- Screening of dry eyes (Lowenthal et al., 1993)
- Early diagnosis of diabetic neuropathy (Balbinot et al., 2012)

The evidence from these case series is considered unreliable due to methodological limitations including, but not limited to, non-randomized allocation of treatment and lack of a sufficient comparison group.

Thermography has also been investigated as a method to detect the presence of vulnerable plaque or atherosclerotic plaque that is at high risk for rupturing and triggering unstable angina or acute myocardial infarction in case series (Cuisset et al., 2009; Rzeszutko et al., 2006). In 2004, in an Agency for Healthcare Research and Quality report regarding the diagnostic role of thermography and identification of vulnerable plaques, the authors concluded “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.” The Rzeszutko and colleagues (2006) case series reported that results did not "consistently differentiate between different lesions at risk, despite a selection of lesions that should appear most distinct to differentiate.”

Additionally, thermography has been proposed as a diagnostic tool for Raynaud's disease or Raynaud's phenomenon, due to temperature changes experienced in Raynaud's patients. However, studies evaluating the use of thermography for diagnosing Raynaud's (Anderson et al., 2007; Foerester et al., 2006; Foerester et al., 2007) were retrospective, had small patient populations, and in some studies, lacked a control group. There is insufficient evidence to validate thermography as a diagnostic tool for this condition.

In 2011, AHRQ performed a review regarding non-invasive techniques for diagnosing skin cancers, which included thermography (Parsons et al., 2011). The report advised the test accuracy and evidence supporting the use of these investigational modalities (including thermography) to replace further diagnostic evaluation, was insufficient.

While some of these studies have suggested that thermography might have a role in the diagnostic evaluation of various conditions, future studies with large patient populations and comparisons to conventional diagnostic tools are indicated to validate their findings and to confirm the clinical utility of thermography.

Practice Guidelines and Position Statements

American Academy of Radiology (ACR)

- In 2005, the ACR advised that thermography has limited utility for most cases of deep vein thrombosis and the committee discarded thermography as a diagnostic test.
- In 2005, the ACR guideline for diagnosing acute low back pain with or without radiculopathy stated thermography has been found to be too non-specific in diagnosing this condition.

- A 2007 digest of ACR council actions stated that "thermography has not been demonstrated to have value as a screening, diagnostic, or adjunctive imaging tool."
- A 2011 statement on myelopathy states that there is no high-quality evidence in support of thermography.
- A 2012 statement on breast imaging states that there is insufficient evidence to support the use of thermography for breast cancer screening.
- A 2013 report on appropriate screening criteria for breast cancer stated that mammography is the recommended method for breast cancer screening in women in the general population. There is insufficient evidence to support the use of other imaging modalities, such as thermography or breast-specific gamma imaging for breast cancer screening (Mainiero, et al., 2013).

American College of Obstetricians and Gynecologists (ACOG)

A 2011 practice bulletin on breast cancer did not address thermography as a screening option (Bulletin 122).

American Cancer Society (ACS)

In 2012, the ACS posted an informational statement on mammograms and other breast imaging procedures specifically addressed thermography. It noted that though thermography has been studied for many years, "no study has yet shown that it [i.e., thermography] is an effective screening tool for finding breast cancer early."

American Medical Association (AMA)

In 2007, the AMA policy on thermography stated the following:

> In view of the lack of sufficient proof of effectiveness, it is the policy of the AMA that the use of thermography for diagnostic purposes cannot be recommended at this time. It should be noted that research protocols using thermography are continuing and data derived from these studies will require careful evaluation. The AMA will continue to monitor the published literature on thermography, with periodic reports as appropriate. The AMA affirms the principle that proponents of a test, procedure, or treatment should bear the burden of proving that it is safe and effective for the proposed purpose through well-designed and well-controlled clinical trials.

Council on Chiropractic Practice

In 2008, the Council on Chiropractic Practice issued an updated clinical practice guideline which includes the following recommendation on skin temperature instrumentation, "temperature reading devices employing thermocouples, infrared thermometry or thermography (liquid crystal, telethermography, multiple IR detectors, etc.) may be used to detect temperature changes in spinal and paraspinal tissues related to vertebral subluxation." The recommendation was based on expert opinion and literature support in the form of observational, pre-post, and/or case studies but not controlled studies.

Medicare National Coverage

The Medicare coverage policy, current as of April 2011 states, "Thermography for any indication (including breast lesions which were excluded from Medicare coverage on July 20, 1984) is excluded from Medicare coverage because the available evidence does not support this test as a useful aid in the diagnosis or treatment of illness or injury. Therefore, it is not considered effective."

Work Loss Data Institute

The 2011 guidelines included statements that thermography is not recommended for acute and chronic neck, upper back and lumbar pain and that thermography is not recommended for treating chronic pain (2011a; 2011b).

Summary

There is insufficient evidence to support the use of thermography, a non-invasive infrared scanning device, for screening, diagnosis, treatment planning or treatment monitoring. Studies are lacking that thermography can accurately diagnose any condition or improve the accuracy of another diagnostic tool. Moreover, there are no published studies evaluating whether use of thermography in patient management, such as to select a treatment or determine treatment effectiveness, improves health outcomes. Thus, thermography is considered investigational.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	93740	Temperature gradient studies
	93799	Unlisted cardiovascular service or procedure (when specified as thermography)

Type	Number	Description
HCPC	None	
ICD9 Procedure	88.81	Cerebral thermography
	88.82	Ocular thermography
	88.83	Bone thermography
	88.84	Muscle thermography
	88.85	Breast thermography
	88.86	Blood vessel thermography
	88.89	Thermography of other sites
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

Complex Regional Pain Syndrome (CRPS) - A chronic pain condition that is believed to be the result of dysfunction in the central or peripheral nervous systems. Typical features include dramatic changes in the color and temperature of the skin over the affected limb or body part, accompanied by intense burning pain, skin sensitivity, sweating, and swelling. Complex regional pain syndrome I is frequently triggered by tissue injury; the term describes all patients with the above symptoms but with no underlying nerve injury. Patients with CRPS II experience the same symptoms but their cases are clearly associated with a nerve injury.

Raynaud's phenomenon - A condition in which cold temperatures or strong emotions cause blood vessel to spasm, blocking blood flow to the fingers, toes, ears, and nose. Initially, the digit(s) involved turn white because of the diminished blood supply. The digit(s) then turn blue because of prolonged lack of oxygen. Finally, the blood vessels reopen, causing a local flushing phenomenon, which turns the digit(s) red. This three-phase color sequence (white to blue to red), most often occurs when exposed to cold temperatures.

Vertebral subluxation - A chiropractic term that is used to describe a myriad of signs and symptoms (syndrome) thought to occur as a result of a misaligned or dysfunctional spinal segment.

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- N/A

Key / Related Searchable Words

- DIRI
- Dorex Spectrum thermography system
- Dynamic infrared imaging
- Infrared camera
- Infrared imaging
- IRI
- Infrared thermal imaging
- MedHot thermal imaging
- Temperature gradient studies
- Thermal imaging
- Thermography

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
1/11/2008	BCBSA Medical Policy adoption	Medical Policy Committee

Effective Date	Action	Reason
9/25/2009	Criteria Revised Policy title change. Prior Policy title: Thermography	Medical Policy Committee
8/23/2013	Policy revision without position change. Policy placed on No Further Routine Literature Review and Update status.	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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