MEDICAL POLICY

POLICY TITLE	**SKIN CONTACT MONOCHROMATIC INFRARED ENERGY FOR THE TREATMENT OF CUTANEOUS ULCERS, DIABETIC NEUROPATHY, AND OTHER MISCELLANEOUS MUSCULOSKELETAL CONDITIONS**
POLICY NUMBER	**MP-1.094**

Original Issue Date (Created):	**June 14, 2004**
Most Recent Review Date (Revised):	**September 24, 2013**
Effective Date:	**November 1, 2013**

I. POLICY

Skin contact monochromatic infrared energy is considered **investigational** as a technique to treat cutaneous ulcers, diabetic neuropathy, and musculoskeletal conditions, including but not limited to temporomandibular disorders, tendonitis, capsulitis, and myofascial pain. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:
MP-1.097 Transcutaneous Laser Therapy

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[N] SeniorBlue HMO
[N] SeniorBlue PPO
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

* Refer to FEP Medical Policy Manual MP-1.01.22 Skin Contact Monochromatic Infrared Energy as a Technique to treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions. The FEP Medical Policy manual can be found at: http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980

III. DESCRIPTION/BACKGROUND

Monochromatic infrared energy treatment is a therapy that uses infrared light therapy through contact with the skin for potential use in multiple conditions including cutaneous ulcers, diabetic neuropathy, and musculoskeletal and soft tissue injuries.

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Monochromatic infrared energy (MIRE) refers to light at a wavelength of 880 nm. MIRE can be delivered through pads containing an array of 60 superluminous infrared diodes emitting pulsed near-infrared irradiation. The pads can be placed on the skin, and the infrared energy is delivered in a homogeneous manner in a session lasting from 30–45 minutes.

Regulatory Status

The Anodyne Professional Therapy System is a MIRE device that received marketing clearance from the U.S. Food and Drug Administration (FDA) in 1994 through the 510(k) process. A device specifically for home use is also available. The labeled indication is for "increasing circulation and decreasing pain." MIRE devices have been investigated as a treatment of multiple conditions including cutaneous ulcers, diabetic neuropathy, musculoskeletal and soft tissue injuries, including temporomandibular disorders, tendonitis, capsulitis, and myofascial pain. The proposed mechanism of action is not known, although some sort of photobiostimulation has been proposed, as well as increased circulation related to an increase in plasma of the potent vasodilator nitric oxide.

IV. RATIONALE

The most recent literature search for this policy was performed for the period of October 2011 through September 2012. Literature searches have identified 5 controlled trials of skin contact monochromatic infrared energy (MIRE) therapy and 2 systematic reviews of the technology. Following is a summary of the key literature to date:

Systematic Reviews. A 2008 systematic review included all clinical studies, including retrospective and prospective experimental studies and case series, evaluating MIRE for the treatment of diabetic peripheral neuropathy. (1) Ten studies were identified, including 4 retrospective chart reviews, 5 studies with an experimental research design, and 2 studies that used a prospective randomized, placebo-controlled design (discussed below). Six of the 10 studies had a sample size of 50 subjects or less. Although the studies suggested that MIRE had efficacy for improving lower extremity sensation, balance, gait, and decreasing fall risk, the systematic review concluded that poor study designs, small sample sizes, limited information regarding treatment volume or intensity, concomitant use of conventional physical therapy modalities, and a lack of long-term follow-up decreased the validity of most of the studies.

A 2011 systematic review examined the use of physical therapy interventions for balance dysfunction in patients with diabetic peripheral neuropathy. MIRE was one of several interventions evaluated, and there was insufficient evidence to recommend MIRE as a treatment for balance dysfunction. (2)

Sham-controlled Trials. A double-blind randomized controlled trial (RCT) with 69 patients with diabetes and a vibration perception threshold between 20 and 45 V were randomized to

active or sham treatment (7 days a week for 90 days). (3) Objective measures (Semmes-Weinstein monofilament testing, vibration perception threshold, and nerve conduction velocity) did not improve in either group. The subjective neuropathy-specific quality-of-life instrument (NeuroQoL) showed at least as much improvement in the sham control as in the active group.

Two additional sham-controlled RCTs found MIRE to be no more effective than sham stimulation in treating patients with diabetic peripheral neuropathy. (4, 5) Clifft et al. reported a double-blind controlled trial with 39 subjects randomized to active or sham MIRE 3 times a week for 4 weeks. (4) Both groups showed significant improvements in plantar sensation after 4 and 8 weeks, with no significant difference between the active and sham groups. Nawfar and Yacob reported a single-blinded study with 30 feet from 24 patients randomized to 12 daily treatments of active or sham MIRE. (5) There was no significant difference between active or sham treatment groups in current perception threshold measured at 6 weeks and 3 months following treatment.

Patients served as their own controls in two studies (one limb treated with an active device and the other limb treated with a sham device). Franzen-Korzendorfer et al. conducted a clinical study in patients with diabetes and loss of protective sensation to 1) examine the effects of MIRE neuropathy protocol on sensation on the feet of patients with diabetes and a loss of protective sensation; 2) determine the effects of a published MIRE neuropathy protocol on sensation of the feet of patients with diabetes and a loss of protective sensation; 3) examine MIRE's effect on pain; and 4) examine the relationship between transcutaneous oxygen levels and loss of protective sensation. (6) Participants underwent a series of twelve 30-minute MIRE treatments 2 to 4 times per week for 3 to 5 weeks. No significant differences were observed between active and sham treatments for transcutaneous oxygen values, pain, or sensation. Both active and sham MIRE-treated feet had significantly improved sensation when compared to pretest baseline scores. No statistical relationship was found between transcutaneous oxygen and sensation.

Leonard and colleagues reported on the results of a sham-controlled randomized trial of 27 patients with diabetic peripheral neuropathy. (7) Patients served as their own controls as each limb was treated either with an anodyne device or a placebo device for 2 weeks, then both limbs were treated with the anodyne device. Outcomes were assessed with a Semmes-Weinstein monofilament. The authors reported improved sensitivity, less pain, and better balance in limbs treated with the active device.

Conclusion. The available controlled trials are small and of short duration. In 4 of 5 sham-controlled trials identified to date, MIRE therapy provided no more improvement in peripheral sensation, balance, pain, or quality of life than sham therapy in patients with peripheral diabetic neuropathy.

Observational Studies. Several retrospective or prospective case studies were identified that reported that MIRE treatment was associated with an improvement in peripheral neuropathy, as measured by changes in sensitivity recorded by the Semmes-Weinstein monofilament. (8-10) The lack of a control group limits interpretation of these studies. Thomasson reported on the outcomes of a series of 563 patients treated with skin contact MIRE who were diagnosed with trapezius tendonitis, splenius capitis tendonitis, temporomandibular capsulitis, or myofascial pain. (11) Patients were treated with 1 to 12 sessions of skin contact MIRE. The authors report an 88–90% improvement rate within each diagnostic group. However, there was no control group or a discussion of how treatment response was assessed. Kochman and colleagues reported on the use of skin contact MIRE in the treatment of 49 patients with diabetic neuropathy. (12) The principal outcome was change in sensation, as measured with a Semmes-Weinstein monofilament. Four diode arrays were used, the first placed on the distal posterior aspect of the tibia, the second placed over the anterior distal tibia, and the third and fourth placed on the dorsal and ventral surfaces of the foot, respectively. On the basis of Semmes-Weinstein monofilament values, 98% exhibited improved sensation after 6 treatments, and all had improved sensation after 12 treatments. However, the absence of a control group limits interpretation of these findings. Horwitz and colleagues investigated the use of skin contact MIRE as a technique to promote healing of 5 patients with venous or diabetic ulcers (4 patients) and 1 patient with an ulcer related to scleroderma. (13) Patients were instructed to use a skin contact MIRE device at home. While the ulcers improved in all patients, the small number of patients and the lack of a control group prevent scientific interpretation.

Summary

The available literature regarding skin contact MIRE as a technique to treat various cutaneous conditions consists of small controlled trials and observational studies. The current evidence from the studies with the strongest methodology, i.e., sham-controlled trials with a between-group design, shows no improvement in outcomes for patients treated with MIRE. This evidence does not support the efficacy of this technology. Well-designed, prospective, RCTs with larger subject numbers are needed to determine with certainty whether MIRE is an effective treatment for cutaneous conditions. As a result, this technology is considered investigational.

V. DEFINITIONS

PHOTOBIOSTIMULATION refers to a process associated with low-level laser therapy, which activates enzymatic processes in the cells, which increase cellular metabolism.

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VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES

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3. *Lavery LA, Murdoch DP, Williams J et al. Does anodyne light therapy improve peripheral neuropathy in diabetes? A double-blind, sham-controlled, randomized trial to evaluate monochromatic infrared photoenergy. Diabetes Care 2008; 31(2):316-21.*
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6. *Franzen-Korzendorfer H, Blackinton M, Rone-Adams S et al. The effect of monochromatic infrared energy on transcutaneous oxygen measurements and protective sensation: results of a controlled, double-blind, randomized clinical study. Ostomy Wound Manage 2008; 54(6):16-31.*
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13. *Horwitz LR, Burke TJ, Carnegie D. Augmentation of wound healing using monochromatic infrared energy. Exploration of a new technology for wound management. Adv Wound Care 1999; 12(1):35-40.*
14. ***C**enters for Medicare and Medicaid Services (CMS) National Coverage Determination 270.6 Infrared Therapy Devices Effective 10/24/06. CMS [Website]: http://www.cms.gov Accessed July 19, 2013.*
15. *Durable Medical Equipment Regional Carrier (DME MAC A) Region A Local Coverage Determination (LCD) L12873 Infrared Heating Pad System. Effective 10/01/03.[Website]: http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L12873_2007-07-01_rev_2013-03_PA_2013-04.pdf Accessed July 19, 2013.*

IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered;

CPT Codes®								
97026								

HCPCS Code	Description
A4639	REPLACEMENT PAD FOR INFRARED HEATING PAD SYSTEM, EACH
E0221	INFRARED HEATING PAD SYSTEM

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The following ICD-10 diagnosis codes will be effective October 1, 2014

ICD-10-CM Diagnosis Code*	Description
	Investigational for all diagnosis
E10.620-E10.628	Type 1 diabetes mellitus with skin complications code range
E10.40-E10.49	Type 1 diabetes mellitus with neurological complications code range
I70.231-I70.249	Atherosclerosis of native arteries of leg with ulceration code range
M77.9	Enthesopathy, unspecified
M79.1	Myalgia/Myofascial pain syndrome

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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X. POLICY HISTORY

MP 1.094	**CAC 10/28/03**
	CAC 11/30/04
	CAC 11/29/05
	CAC 11/28/06
	CAC 11/27/07
	CAC 11/25/08
	CAC 11/24/09 Consensus review - Remains investigational, references updated
	CAC 5/25/10 Adopted BCBSA Criteria
	CAC 4/26/11 Consensus
	CAC 6/26/12 Consensus-Policy statement remains the same, references updated. Added FEP variation to reference FEP Medical Policy Manual MP-1.01.22 Skin Contact Monochromatic Infrared Energy as a Technique to treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions.
	7/26/13 Admin coding review complete--rsb
	CAC 9/24/13 Consensus. No changes to policy statement. Added rationale section. References updated.

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