BlueCross BlueShield of Louisiana

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Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions

Policy # 00178
Original Effective Date: 08/24/2005
Current Effective Date: 06/18/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers skin contact monochromatic infrared energy (MIRE™)‡ as a technique to treat cutaneous ulcers, diabetic neuropathy and musculoskeletal conditions, including but not limited to temporomandibular disorders, tendonitis, capsulitis and myofascial pain to be **investigational.***

Background/Overview

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.

Monochromatic infrared energy 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 to 45 minutes.

Monochromatic infrared energy 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. MIRE devices are also being developed for the treatment of baldness and snoring. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The Anodyne®‡ Professional Therapy System is a MIRE device that received marketing clearance from the U.S. 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." The Clarimedix system (Clarimedix), received 510(k) clearance in 2006 (K062635) listing the SMI™‡ SpectroPad (a.k.a. Anodyne Therapy System) as a predicate device. Clarimedix is indicated for use for the treatment of chronic pain by emitting energy in the infrared spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied. The HealthLight™ infrared therapy device (Bioremedi Therapeutic Systems)

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received marketing clearance from the FDA in 2011 (K101894) listing the SMI SpectroPad as a predicate device. The BioRemedi HealthLight System is available by prescription only and is indicated for heat therapy, ie, temporarily relieves minor pain, stiffness, and muscle spasm and temporarily increases local blood circulation.

Centers for Medicare and Medicaid Services (CMS)
No National Coverage Determination found.

Rationale/Source

The most recent literature search was performed through November 4, 2013. Literature searches have identified 6 controlled trials of skin contact MIRE therapy and 2 systematic reviews of the technology. Following is a summary of the key literature to date:

Diabetic Peripheral Neuropathy

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. 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.

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 d/wk for 90 days). 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 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. 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. 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. There was no significant difference between active or sham treatment groups in current perception threshold measured at 6 weeks and 3 months following treatment.

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Patients served as their own controls in 2 studies (1 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 examine the effects of MIRE neuropathy protocol on sensation on the feet of patients with diabetes and a loss of protective sensation; to determine the effects of a published MIRE neuropathy protocol on sensation of the feet of patients with diabetes and a loss of protective sensation; to examine MIRE's effect on pain; and to examine the relationship between transcutaneous oxygen levels and loss of protective sensation. 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 et al reported on the results of a sham-controlled randomized trial of 27 patients with diabetic peripheral neuropathy. 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.

Section Summary. 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. 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. Patients were treated with 1 to 12 sessions of skin contact MIRE. The authors report an 88% to 90% improvement rate within each diagnostic group. However, there was no control group or a discussion of how treatment response was assessed. Kochman et al reported on the use of skin contact MIRE in the treatment of 49 patients with diabetic neuropathy. 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 et al 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. 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.

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Knee Osteoarthritis

Randomized Controlled Trials. Hsieh et al reported a double-blind randomized controlled trial of short-term MIRE for osteoarthritis. Seventy-three patients with knee osteoarthritis received six 40-minute sessions of active or placebo MIRE (sham control) over the knee joints for a period of 2 weeks. Outcomes were measured weekly over 4 weeks with a number of validated questionnaires that assessed pain, functioning, and quality of life. While some outcome measures showed improvement over time, there were no significant differences between the active and sham groups for any of the measured outcomes.

Summary

The available literature regarding skin contact MIRE as a technique to treat various cutaneous conditions consists of small controlled trials and observational studies. MIRE has also been investigated for knee osteoarthritis. The current evidence from the studies with the strongest methodology, ie, 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, randomized controlled trials 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.

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	97026
HCPCS	A4639, E0221
ICD-9 Diagnosis	All relative diagnoses
ICD-9 Procedure	No codes

Policy History

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08/03/2005	Medical Director review
08/16/2005	Medical Policy Committee review
08/24/2005	Managed Care Advisory Council approval
05/26/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. Policy updated with literature search. No change to coverage eligibility.
06/04/2009	Medical Director review
06/17/2009	Medical Policy Committee approval. No change to coverage.

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06/03/2010	Medical Policy Committee approval
06/16/2010	Medical Policy Implementation Committee approval. No change to coverage.
06/02/2011	Medical Policy Committee approval
06/15/2011	Medical Policy Implementation Committee approval. No change to coverage.
06/14/2012	Medical Policy Committee review
06/20/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

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