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Medical Policy

BlueCross BlueShield Kansas
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Title: Anodyne® - Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions

Related Policies:	▪ *Low-Level Laser Therapy*

Professional	**Institutional**
Original Effective Date: August 22, 2003	Original Effective Date: August 22, 2003
Revision Date(s): March 13, 2013; September 30, 2014; March 31,2015; March 24, 2016; February 24, 2021	Revision Date(s): March 13, 2013; September 30, 2014; March 31, 2015; March 24, 2016; February 24, 2021
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State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

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DESCRIPTION

Monochromatic infrared energy (MIRE™) is a therapy that uses pulsed infrared light at a wavelength of 880 nm through pads that contain an array of 60 super luminous infrared diodes. Use of MIRE™ has been proposed as a therapy for multiple conditions including cutaneous ulcers, diabetic neuropathy, and musculoskeletal and soft tissue injuries.

BACKGROUND

MIRE refers to light at a wavelength of 880 nm. MIRE can be delivered through pads containing an array of 60 super luminous 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.

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. 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 photo biostimulation has been proposed, as well as increased circulation related to an increase in plasma of the potent vasodilator nitric oxide.

REGULATORY STATUS

The Anodyne ® Professional Therapy System is a MIRE device that received marketing clearance from the 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) 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.

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POLICY

Skin contact monochromatic infrared energy is considered **experimental / 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.

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.

RATIONALE

The most recent literature review was performed through November 11, 2014.

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition. Literature searches have identified 6 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 performed through November 11, 2014.

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.[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.

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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 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).[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 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 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 (1) to examine the effects of MIRE neuropathy protocol on sensation on the feet of patients with diabetes and a loss of protective sensation; (2) 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; (3) to examine MIRE's effect on pain; and (4) to 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 et al 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.

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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% 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.[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 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.[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.

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.

Knee Osteoarthritis

Randomized Control Trials

Hsieh et al reported a double-blind randomized controlled trial of short-term MIRE for osteoarthritis (OA).[14] 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 of Evidence

The available literature regarding skin contact monochromatic infrared energy (MIRE) as a technique to treat various cutaneous conditions consists of small controlled trials and

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observational studies. MIRE has also been investigated for knee osteoarthritis. 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, randomized control 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.

Practice Guidelines and Position Statements
The 2010 Guidelines from the Association for the Advancement of Wound Care provides an A-level recommendation for infrared or monochromatic light for advanced or adjunctive treatment of pressure ulcers that are unresponsive to A-level management.[15]

U.S. Preventive Services Task Force Recommendations
Not applicable

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
97139	Unlisted therapeutic procedure (specify)
97799	Unlisted physical medicine / rehabilitation service or procedure

- There is no CPT code that specifically describes the use of skin contact monochromatic infrared energy (MIRE) therapy.
- Devices may also be used in the home setting. In this situation, the HCPCS code E0221 (infrared heating pad system) may be used.

ICD-10 DIAGNOSES
Experimental / Investigational on all diagnoses related to this medical policy.

REVISIONS	
03-13-2013	Policy was updated and relocated from the "Experimental / Investigational" webpage to the current "Medical Review, Medical Policies" page on BCBSKS.com.
	In the Policy Title, revised "Anodyne® Therapy" to read "Monochromatic Infrared Energy (Anodyne®)"
	In the Policy section: ▪ Revised the following medical policy language: "Anodyne® therapy for all therapy is experimental / investigational due to the lack of appropriate studies."
	Rationale section added.
	In the Coding section: ▪ Added CPT code 97139
	Reference section added.

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REVISIONS	
09-30-2014	In the Policy title, revised "Monochromatic Infrared Energy (Anodyne®)" to read "Anodyne® - Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions"
	Updated Description section
	Updated Rationale section
	Updated References section
03-31-2015	Updated Description section
	Updated Rationale section
	In Coding section: ▪ Updated Nomenclature for CPT: 97139
	Updated References section
03-24-2016	Medical policy reviewed with no changes.
02-24-2021	Medical policy reviewed with no changes.
04-20-2022	Archived

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OTHER REFERENCES

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