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

See also: Low-Level Laser Therapy (also known as soft laser therapy, Microlight 830, and cold laser therapy)

**Professional**
Original Effective Date: August 22, 2003
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**Institutional**
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**DESCRIPTION**
Monochromatic infrared energy (MIRE™) 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.

**Background**
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.

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 photobiostimulation 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 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." 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.

**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.

**Policy Guidelines**
This is no CPT code that specifically describes the use of skin contact monochromatic infrared energy (MIRE) therapy. However, when the technique is offered in a clinic or physical therapy session, the nonspecific CPT code 97026 (application of a modality to 1 or more area; infrared) may be used. Devices may also be used in the home setting. In this situation, the HCPCS code E0221 (infrared heating pad system) may be used.
RATIONALE

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.

 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. 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.

**Knee Osteoarthritis**
**RANDOMIZED CONTROL 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, 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
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)

CODING
The following codes for treatment and procedures applicable to this policy are included below for informational purposes. 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.

CPT/HCPCS
97139  Therapeutic procedure, one or more areas, each 15 minutes; unlisted therapeutic procedure (specify)
97799  Unlisted physical medicine / rehabilitation service or procedure

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.
REFERENCES


Other References
1. Blue Cross and Blue Shield of Kansas AdHoc Client Committee, November 2004.