
Medical Policy



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***Current Policy Effective Date: 5/1/22**
(See policy history boxes for previous effective dates)

Title: Monochromatic Infrared Energy (MIRE) Device for the Treatment of Cutaneous Ulcers, Diabetic Neuropathy and Miscellaneous Musculoskeletal Conditions

Description/Background

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

Regulatory Status

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

The above mentioned devices are listed as examples. This list may not be all inclusive and mention of a particular device is not intended to be an endorsement of particular product.

Medical Policy Statement

Monochromatic infrared energy (MIRE) 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. It has not been scientifically demonstrated to be as effective as conventional treatment.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

A4639

E0221

97026

Rationale

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.

Diabetic Peripheral Neuropathy

Systematic Reviews

Li et al (2008) performed a systematic review which 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 next). 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.

Ites et al (2011) conducted a systematic review that 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

Robinson et al (2017) conducted a systematic review and meta-analysis of randomized controlled studies examining the effects of MIRE on plantar sensitivity and neuropathic pain in patients with diabetic sensorimotor peripheral neuropathy. Of the 2549 studies identified, six met selection criteria, with 304 patients (594 feet) randomized. The analysis found MIRE was not associated with improvement in plantar tactile sensitivity (SMD = 0.22, 95%CI -0.07 to 0.51). There were subgroups of studies with short-term (up to 2 weeks) follow-up that showed significant improvement in plantar sensitivity (SMD = 0.41, 95% CI 0.18–0.64). However, neuropathic pain was significantly increased in patients who received MIRE (MD = 0.49, 95% CI 0.30–0.68). The reviewers noted limited evidence on MIRE for the indications studied and low quality of evidence.³

Sham-controlled Trials

Lavery et al (2008) reported on a double-blind randomized controlled trial (RCT) of 69 patients with diabetes and a vibration perception threshold between 20 and 45 volts were randomized to active or sham treatment (7 d/wk for 90 days).⁴ 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.^{5,6} Clift et al (2005) reported a double-blind controlled trial with 39 subjects randomized to active or sham MIRE 3 times a week for 4 weeks.⁵ 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 (2011) reported a single-blinded study with 30 feet from 24 patients randomized to 12 daily treatments of active or sham MIRE.⁶ 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 (2008) 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.⁷ 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 (2004) reported on the results of a sham-controlled randomized trial of 27 patients with diabetic peripheral neuropathy.⁸ 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.

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.^{9,10,11} The lack of a control group limits interpretation of these studies. Thomasson (1996) 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.¹² 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 (2002) reported on the use of skin contact MIRE in the treatment of 49 patients with diabetic neuropathy.¹³ 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 (1999) 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.¹⁴ 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 Controlled Trials

Hsieh et al (2012) reported a double-blind randomized controlled trial of short-term MIRE for osteoarthritis.¹⁵ 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 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 experimental/investigational.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Association for the Advancement of Wound Care

Association for the Advancement of Wound Care (2014) published venous and pressure ulcer guidelines which provided an A-level recommendation for infrared or monochromatic light for advanced or adjunctive treatment of pressure ulcers that are unresponsive to A-level management.¹⁶

U.S. Preventive Services Task Force Recommendations

Not applicable.

Clinical Trials

A search of clinicaltrials.gov did not reveal any current trials for MIRE.

Government Regulations

National:

National Coverage Determination (NCD) for Infrared Therapy Devices (270.6), Effective date 10/26/2006, Implementation date 1/16/2007

Indications and Limitations of Coverage

“Effective for services performed on and after October 24, 2006, the Centers for Medicare & Medicaid Services has determined that there is sufficient evidence to conclude the use of infrared therapy devices and any related accessories **is not reasonable and necessary** under section 1862(a)(1)(A) of the Social Security Act (the Act). The use of infrared and/or near-infrared light and/or heat, including monochromatic infrared energy, is non-covered for the treatment, including the symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of the skin and/or subcutaneous tissues.”¹⁷

Local:

CGS Administrators, LLC, 17013-DME MAC, J-B

Local Coverage Determination (LCD): Infrared Heating Pad Systems (L33825)

Original Effective Date: For services performed on or after 10/01/2015

Revision Effective Date: For services performed on or after 01/01/2020

Coverage Indications, Limitations, and/or Medical Necessity

As indicated in CMS’ National Coverage Determination (NCD) for Infrared Therapy Devices (270.6), there are no indications for which these devices have been demonstrated to have any therapeutic effect. The device and any related accessories will be denied as not medically reasonable and necessary.¹⁸

CGS Administrators, LLC, 17013-DME MAC, J-B

Local Coverage Article: Infrared Heating Pad Systems – Policy Article (A52477)

Original Effective Date: 10/01/2015

Revision Effective Date: 01/01/2020

Non-Medical Necessity Coverage and Payment Rules

INFRARED HEATING Pad Systems are considered for coverage under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)); however, the CMS National Coverage Determination 270.6 precludes payment for these items (see INFRARED HEATING Pad Systems Local Coverage Determination). In order for a beneficiary’s equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.¹⁹

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Low-Level Laser Therapy
Near Infrared Spectroscopy Examination of Wounds

References

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2. Ites KI, Anderson EJ, Cahill ML et al. Balance interventions for diabetic peripheral neuropathy: a systematic review. *J Geriatr Phys Ther* 2011; 34(3):109-16.
3. Robinson CC, Klahr PDS, Stein C et al. Effects of monochromatic infrared phototherapy in patients with diabetic peripheral neuropathy: a systematic review and meta-analysis of randomized controlled trials. *Braz J Phys Ther* 2017; 21(4):233-243. doi: 10.1016/j.bjpt.2017.05.008. Epub 2017 May 20
4. 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.
5. Clift JK, Kasser RJ, Newton TS et al. The effect of monochromatic infrared energy on sensation in patients with diabetic peripheral neuropathy: a double-blind, placebo-controlled study. *Diabetes Care* 2005; 28(12):2896-900.
6. Nawfar SA, Yacob NB. Effects of monochromatic infrared energy therapy on diabetic feet with peripheral sensory neuropathy: a randomised controlled trial. *Singapore Med J* 2011; 52(9):669-72.
7. 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.
8. Leonard DR, Farooqi MH, Myers S. Restoration of sensation, reduced pain and improved balance in subjects with diabetic peripheral neuropathy: a double-blind, randomized, placebo-controlled study with monochromatic near-infrared treatment. *Diabetes Care* 2004; 27(1):168-72.
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12. Thomasson T. Effects of skin-contact monochromatic infrared irradiation on tendonitis, capsulitis, and myofascial pain. *J Neurol Orthop Med Surg* 1996; 16:242-5.
13. Kochman AB, Carnegie DH, Burke TJ. Symptomatic reversal of peripheral neuropathy in patients with diabetes. *J Am Podiatr Med Assoc* 2002; 92(3):125-30.

14. 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.
15. Hsieh RL, Lo MT, Lee WC et al. Therapeutic effects of short-term monochromatic infrared energy therapy on patients with knee osteoarthritis: a double-blind, randomized, placebo-controlled study. *J Orthop Sports Phys Ther* 2012; 42(11):947-56.
16. Bolton L, Girolami S, Corbett L et al. The Association for the Advancement of Wound Care (AAWC) Venous and Pressure Ulcer Guidelines. *Ostomy Wound Management*, November 2014; 60(11), pp. 24-66.
17. Centers for Medicare and Medicaid, National Coverage Determination for Infrared Therapy Devices (270.6), Effective date 10/24/2006, Implementation date 1/16/2007. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=315&ncdver=1&bc=AgAAQAAAAAAAAAA%3d%3d&> Accessed 1/3/22).
18. CGS Administrators, LLC, 17013-DME MAC, J-B, Local Coverage Determination (LCD): Infrared Heating Pad Systems (L33825), Original Effective Date: For services performed on or after 10/01/2015, Revision Effective Date: For services performed on or after 01/01/2020.
19. CGS Administrators, LLC, 17013-DME MAC, J-B, Local Coverage Article: Infrared Heating Pad Systems – Policy Article (A52477). Original Effective Date: 10/01/2015; Revision Effective Date: 01/01/2020.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/3/21, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
12/9/05	12/9/05	12/1/05	Joint policy established
9/1/07	8/19/08	7/1/07	Policy updated
3/1/09	12/21/08	12/21/08	Routine maintenance
9/1/11	6/21/11	6/21/11	Routine maintenance. HCPCS codes A4639 and E0221 added to policy; removed HCPCS code E1399.
11/1/12	8/21/12	8/21/12	Routine maintenance
7/1/14	4/10/14	4/15/14	Routine maintenance
5/1/16	2/16/16	2/16/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance Updated local Medicare information
5/1/18	2/20/18	2/20/18	Routine maintenance
5/1/19	2/19/19		Routine maintenance
5/1/20	2/18/20		Routine maintenance
5/1/21	2/16/21		Routine maintenance
5/1/22	2/15/22		Routine maintenance

Next Review Date: 1st Qtr, 2023

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MONOCHROMATIC INFRARED ENERGY (MIRE) AS A TECHNIQUE TO TREAT
CUTANEOUS ULCERS, DIABETIC NEUROPATHY AND MISCELLANEOUS
MUSCULOSKELETAL CONDITIONS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.