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

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 10|15|2019

OVERVIEW

This medical policy documents the coverage determination for Monochromatic Infrared Energy (MIRE). 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.

This policy is applicable to Commercial Products only; For BlueCHiP for Medicare, see related policy for BlueCHiP for Medicare National and Local Coverage Determinations.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

Skin contact monochromatic infrared energy is considered not medically necessary as a technique to treat cutaneous ulcers, diabetic neuropathy, and musculoskeletal conditions and any other conditions including, but not limited to, temporomandibular disorders, tendonitis, capsulitis, and myofascial pain as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

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 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 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." 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. 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, i.e., temporarily relieves minor pain, stiffness, and muscle spasm and temporarily increases local blood circulation.

The available literature regarding skin contact MIRE as a technique to treat cutaneous conditions is inadequate to draw clinical conclusions. The evidence does not support the efficacy of this technology.

CODING

Commercial Products

The following codes are not medically necessary:

E0221 Infrared heating pad system

A4639 Replacement pad for infrared heating pad system, each

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations Policy

PUBLISHED

Provider Update, December 2019
Provider Update, Sep 2018
Provider Update, July 2017
Provider Update, November 2016
Provider Update, August 2015
Provider Update, June 2014
Provider Update, January 2013

REFERENCES

1. Li H, Nyland J, Shelton T. Effectiveness of the anodyne therapy system in treating diabetic peripheral neuropathy: a systematic review. Physical Therapy Reviews 2008; 13(6):395-404.
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. 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.
4. Clifft 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.
5. Nawfar SA, Yacob NB. Effects of monochromatic infrared energy therapy on diabetic feet with peripheral sensory neuropathy: a randomized controlled trial. Singapore Med J 2011; 52(9):669-72.
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.
7. 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.
8. DeLellis SL, Carnegie DH, Burke TJ. Improved sensitivity in patients with peripheral neuropathy: effects of monochromatic infrared photo energy. J Am Podiatr Med Assoc 2005; 95(2):143-7.

9. Powell MW, Carnegie DE, Burke TJ. Reversal of diabetic peripheral neuropathy and new wound incidence: the role of MIRE. Adv Skin Wound Care 2004; 17(6):295-300.
10. Prendergast JJ, Miranda G, Sanchez M. Improvement of sensory impairment in patients with peripheral neuropathy. Endocr Pract. 2004;10(1):24-30.
11. Thomasson T. Effects of skin-contact monochromatic infrared irradiation on tendonitis, capsulitis, and myofascial pain. J Neurol Orthop Med Surg 1996;16:242-245.
12. Kochman AB, Carnegie DH, Burke TJ. Symptomatic reversal of peripheral neuropathy in patients with diabetes. J Am Podiatr Med Assoc. 2002;92(3):125-130.
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. 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):947-956. PMID 22960644
15. Association for the Advancement of Wound Care. Association for the Advancement of Wound Care Guideline of Pressure Ulcer Guidlines. 2010; http://aawconline.org/wpcontent/uploads/2011/08/AAWCPressureUlcerGuidelineofGuidelinesAug11.pdf. Accessed November 11, 2014.
16. Centers for Medicare and Medicaid Services. Decision memo for infrared therapy devices (CAG-00291N). 2006; http://www.cms.gov/medicare-coverage-database/details/nca-decisionmemo.aspx?NCAId=176&ver=22&NcaName=Infrared+Therapy+Devices

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS