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: 09|06|2016

OVERVIEW
The 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and 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. There are insufficient peer reviewed, scientifically controlled studies in the literature that demonstrate superior health outcomes over other techniques.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for limitations of benefits/coverage when services are not medically necessary.

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

BlueCHiP for Medicare and Commercial Products

The following HCPCS codes are considered not medically necessary for the diagnosis codes indicated:

E0221 A4639

ICD-10 Codes:

ICD-10 Codes Skin Contact Monochroma

RELATED POLICIES

None

PUBLISHED

Provider Update, November 2016
Provider Update, August 2015
Provider Update, June 2014
Provider Update, January 2013
Provider Update, February 2012
Provider Update, December 2010
Provider Update, October 2009
Policy Update, October 2008

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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.

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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.

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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.

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11. CMS.gov Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Infrared Therapy Devices (270.6)
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=315&ncdver=1&bc=AgAAgAAAAAAAAA%3d%3d&