

EFFECTIVE DATE: 10|01|2015

POLICY LAST UPDATED: 05|16|2017

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 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 section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services 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 superluminescent 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

There are no specific codes for skin contact monochromatic infrared energy (MIRE) therapy. However, the following codes may be used but are not medically necessary when used for skin contact monochromatic infrared energy (MIRE) therapy:

97026 Application of modality to 1 or more areas; infrared

E0221 Infrared heating pad system

A4639 Replacement pad for infrared heating pad system, each

RELATED POLICIES

None

PUBLISHED

Provider Update, July 2017

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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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.
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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.
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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=AgAAgAAAAAAAAAAAA%3d%3d&>

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