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: 05|04|2022

OVERVIEW
Monochromatic infrared energy (MIRE™) is a therapy that uses pulsed infrared light at a wavelength of 880 nm through pads that contain an array of 60 superluminous infrared diodes. Use of MIRE™ has been proposed as a therapy for multiple conditions including cutaneous ulcers, diabetic neuropathy, and musculoskeletal and soft tissue injuries.

This policy is applicable to Commercial Products only; For Medicare Advantage Plans, see related policy for Medicare Advantage Plans 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 monochromatic infrared energy (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 not medically necessary.

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

Medicare Advantage Plans National and Local Coverage Determinations Policy

PUBLISHED

Provider Update, July 2022
Provider Update, Sept 2021
Provider Update, Sept 2020
Provider Update, December 2019
Provider Update, Sept 2018
Provider Update, July 2017

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