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.

PRIOR AUTHORIZATION
Not Applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial products:
MIRE 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 which demonstrate superior health outcomes over other techniques.

MEDICAL CRITERIA
Not Applicable

BACKGROUND
Monochromatic infrared energy (MIRE) refers to light at a wavelength of 880 nanometers. MIRE can be delivered through pads containing a range 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 uniform manner in sessions lasting from 30 to 45 minutes.

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.

**COVERAGE**
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable "not medically necessary" benefits/coverage.

**CODING**
**Blue CHiP for Medicare and Commercial**
There is no CPT code that specifically describes the use of skin contact MIRE therapy. Report the unlisted CPT code for the procedure.

**RELATED POLICIES**
None

**PUBLISHED**
- Provider Update June 2014
- Provider Update Jan 2013
- Provider Update Feb 2012
- Provider Update Dec 2010
- Provider Update Oct 2009
- Policy Update Oct 2008

**REFERENCES**


Centers for Medicare and Medicaid (CMS): National Coverage Determination (NCD) for INFRARED THERAPY Devices (270.6) http://www.cms.gov/medicare-coverage-database

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