

Origination Date: 9/06	Revision Date(s): 9/07, 9/08
Developed By: Medical Criteria Committee	

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Approved: Csaba Mera, MD Date: 09/25/08

Description:

The Anodyne® Therapy System delivers monochromatic infrared energy (MIRE) through contact with the skin. The light is emitted by an array of 60 superluminous infrared diodes located on a flexible pad. The pads can be placed on the skin and the infrared energy is delivered in sessions lasting from 30-45 minutes. The Anodyne® Therapy System is a MIRE device that received FDA approval in 1994. The labeled indication for Anodyne® is for “increasing circulation and decreasing pain.” MIRE devices have been proposed for use in the treatment of conditions such as peripheral neuropathy, pain management, wound healing and musculoskeletal and soft tissue injuries. The proposed mechanism of action is based on the premise that MIRE therapies may cause an increase in nitric oxide concentration that may lead to increased blood flow and promote vasodilation. MIRE therapy may also be referred to as light emitting diode (LED) therapy, infrared light therapy or infrared heating pad system. Examples of MIRE devices are Anodyne® Therapy System, Pain-X 2000, BioScan, and Light Force Therapy. Treatment with a MIRE device is administered several times a week over a period of weeks to months. Treatment may be performed in the home or office setting.

Criteria:

ODS considers Anodyne® Therapy System or use of other MIRE devices investigational as a treatment technique for any indication, including but not limited to diabetic peripheral neuropathy, pain management, wound healing, or musculoskeletal or soft tissue injuries. There is inadequate scientific evidence in peer reviewed medical literature regarding the use, safety and improvement and effectiveness on health outcomes of MIRE devices.

Information to be Submitted with Pre-Authorization Request:

None. This treatment is considered investigational by ODS.

References:

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- Harkless LB, DeLellis S, Carnegie DH, Burke TJ. Improved foot sensitivity and pain reduction in patients with peripheral neuropathy after treatment with monochromatic infrared photo energy—MIRE. *J. Diabetes Complications.* 2006 Mar-Apr;20(2):81-7.
- Clift JK, Kasser RJ, Newton TS, Bush AJ. The effect of monochromatic infrared energy on sensation in patients with diabetic peripheral neuropathy: a double-blind, placebo-controlled study. *Diabetes Care.* 2005 Dec;28(12):2896-900.
- Horwitz LR, Burke TJ, Carnegie D. Augmentation of wound healing using monochromatic infrared energy. *Adv Wound Care.* 1999 Jan-Feb;12:35-40.
- Kochman AB, Carnegie DH, Burke TJ. Symptomatic reversal of peripheral neuropathy in patients with diabetes. *J Am Podiatr Med Assoc.* 2002 Mar;92(3):125-130.
- Kochman AB. Monochromatic infrared photo energy and physical therapy for peripheral neuropathy: influence on sensation, balance, and falls. *J Geriatr Phys Thera.* 2004;27(1):16-19.
- DeLellis S, Carnegie D, Burke T. Improved sensitivity in patients with peripheral neuropathy effects of monochromatic infrared photo energy. *J Am Podiatr Med Assoc.* 2005Mar/Apr; 95(2):143-147.
- Volkert W, Hassan A, Hassan M, et al. Effectiveness of monochromatic infrared photo energy and physical therapy for peripheral neuropathy: changes in sensation, pain, and balance—a preliminary, multi-center study. *Physical & Occupational Therapy in Geriatrics.* 2006 Mar/Apr;24(2):1-17.

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- Product information from Anodyne® Therapy
- Physician Advisors