



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Monochromatic Infrared Energy Therapy (Anodyne® Therapy)

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA does not cover monochromatic infrared energy therapy or monochromatic, near-infrared photo energy (MIRE™) (e.g., Anodyne® Therapy or Anodyne® Therapy System) because each is considered experimental, investigational or unproven.

Note: This Coverage Policy does not address standard infrared treatment when used as one modality of a physical therapy treatment plan.

General Background

Monochromatic infrared energy therapy is a therapy that utilizes infrared light therapy through contact with the skin. This therapy may also be referred to as infrared therapy, near-infrared light therapy, and infrared light treatment. It is also known as monochromatic, near-infrared photo energy (MIRE™) (Anodyne Therapy LLC, Tampa, FL). The Anodyne® Therapy System (ATS) (Anodyne Therapy LLC, Tampa, FL) is one type of devices that utilizes MIRE. With Anodyne devices, light is emitted by an array of 60 superluminous gallium aluminum diodes located on a flexible pad. The manufacturer theorizes that phototherapy exposure effects guanylate cyclase (GC) and nitrous oxide (NO) release, which stimulates vasodilation and relaxes smooth muscle cells in blood vessels. According to Anodyne company literature, "intense illumination of the skin may non-invasively increase the localized release of NO from hemoglobin" (Burke, 2005). The company states that this results in "better blood flow via stimulation of GC, acute delivery of growth factors and white blood cells, fibroblastic

differentiation and proliferation, angiogenesis, reduced edema, and mediation of pain” (Burke, 2005). According to the manufacturer, ATS is a non-invasive, drug-free way to increase local circulation to nerves and tissues and reduce neuropathic pain.

An eight-pad MIRE device is available for professional/office use and a four-pad model is available for home use. In the office setting, MIRE may be provided by several different types of providers, including physicians, chiropractors, podiatrists, physical therapists, or occupational therapists. In addition to the Anodyne device, other devices that deliver monochromatic infrared energy include:

- Dermillume Red Lamp (Care Electronics, Inc, Boulder, CO)
- BioBeam[®] (Life Without Pain, LLC, Pompano Beach, FL)

MIRE has been proposed as a treatment modality for several indications, including peripheral neuropathy, pain management, and wound healing. However, there is insufficient evidence in the published peer-reviewed scientific literature to support the use of MIRE for these proposed indications.

U.S. Food and Drug Administration (FDA)

Devices that deliver monochromatic near-infrared photo energy (MIRE) are classified by the FDA as a Class II device as an infrared lamp. The FDA notes that, “an infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical healing.” The Anodyne[®] Therapy System received approval by the FDA in 1994, with the name Spectropad System through the premarket 510(k) process.

Literature Review

Lavery et al. (2008) conducted a double-blind, randomized, sham-controlled clinical trial to determine the efficacy of anodyne MIRE in-home treatments over a 90 day period to improve peripheral sensation and self-reported quality of life in patients with diabetes. Sixty-nine patients with diabetes and a vibration perception threshold (VPT) between 20 and 45V were randomized to an active or sham treatment group. Sixty patients completed the study. The Anodyne units were used at home every day for 40 minutes over 90 days. No significant differences in measures for were found in quality of life, the Michigan Neuropathy Screening Instrument (MNSI), VPT, SWM, or nerve conduction velocities in the active or sham groups ($p>0.05$).

Franzen-Korzendorfer et al. (2008) reported on a controlled, double-blind, randomized clinical study that examined the effect of MIRE on transcutaneous oxygen measurements and protective sensation. The study included 18 patients with diabetes and loss of protective sensation. Patients served as their own control by having each leg randomly assigned to either the sham or active treatment group. Sensation, pain, and transcutaneous oxygen measurements were taken on two sites per foot pre- and post treatment. A series of 30-minute monochromatic infrared energy treatments (one foot active treatment, one foot sham) were delivered. Monochromatic infrared energy was provided at the manufacturer pre-set level of energy of 1.5 J/cm²/min at a wavelength of 890 nm; sham units delivered no energy. There were no significant differences observed between the active and sham treatments for transcutaneous oxygen values, pain, or sensation. Significantly improved sensation when compared to pretest baseline scores ($p<0.05$) was noted in both active and sham MIRE-treated feet. There was no statistical relationship found between transcutaneous oxygen and sensation. MIRE treatment did not appear to have an effect on transcutaneous oxygen measurements, pain, or sensation in adults with diabetes and loss of protective sensation.

Leonard et al. (2004) conducted a double-blind, randomized, placebo-controlled study of 27 participants with diabetes and peripheral neuropathy. The participants were stratified into two groups, based on their ability to sense SWM 6.65 at all tested sites (group 1: n=18) or inability to sense the SWM 6.65 (group 2: n=9). All subjects initially received treatment with both active and sham ATS therapy for 40 minutes, three times per week for two weeks. This was followed by six active treatments of the same duration administered to both limbs during the following two weeks. Group 1 subjects receiving active treatment reduced the number of insensitive sites to the SWM. No decrease was noted with the sham device. In group 2, there was no significant difference with active treatment following the six or 12 treatments. Pain was reported decreased in group 1 subjects but was not significantly reduced in group 2 subjects. Balance was reported as improved following both the sixth and twelfth treatments in group 1 subjects. Group 2 subjects reported improvement after six treatments in four of the nine patients; thereafter, no further change was noted. The authors concluded that, for diabetics with LOPS who have not progressed to profound sensory loss, there can be a temporary improvement in sensation with the use of ATS. Limitations included small study size and the design did not measure pain reduction or balance

improvement in active compared to sham treatment of individual limbs. There was a lack of objective measurement for balance impairment, and follow-up was limited to evaluation after 12 treatments, with no analysis of long-term durability.

Cliff et al. (2005) conducted a randomized, double-blinded, placebo-controlled study of 39 subjects with diabetic peripheral neuropathy (defined as the inability to detect the 5.07 monofilament at any of the four test sites on the plantar surface of the foot). The purpose of the study was to determine if the number of sites that could sense the 5.07 monofilament on the plantar region of the foot would increase after treatments with MIRE. Subjects were assigned randomly to an active MIRE group or a placebo group. Subjects received 30 minutes of active MIRE or placebo three times a week for four weeks. The subjects' plantar sensation was tested before treatment, after four weeks of treatment/placebo and again after four weeks of nontreatment. The average number of sites with increased sensation increased in both groups during the treatment phase, but neither group demonstrated any improvement during the nontreatment phase. There were no significant differences reported between the active and placebo groups at any measurement. The authors concluded that the active MIRE treatment was no more effective than the placebo MIRE.

There have been small case studies published that examined ATS for various uses (Kochman, et al., 2002) and Kochman (2004). These studies have been limited by small size, as well as by a lack of control group, randomization, blinding and long-term follow-up. DeLessis et al. (2005) and Harkless et al. (2006) reported on larger case series that examined MIRE for peripheral neuropathy. These studies were limited by lack of randomization, a control group and blinding. In addition, Harkless et al. (2006) a retrospective review of 2239 patient records, utilized the records of patients who, after being treated with MIRE, had all exhibited improvement in their symptoms.

Professional Societies/Organizations

MIRE for the treatment of peripheral neuropathy is not recognized as a standard of care by the American Association of Clinical Endocrinologists, the American Diabetes Association, the American Academy of Neurology, the American Medical Association, the American Orthopedic Foot and Ankle Society, or the American Podiatric Medical Association.

Summary

Monochromatic infrared energy therapy or monochromatic, near-infrared photo energy (MIRE™) (e.g., Anodyne® Therapy or Anodyne® Therapy System) remain unproven for all conditions, due to the lack of well-designed, controlled, randomized, double-blind trials. In addition, there is lack of evidence of long-term health outcomes supporting the efficacy of this treatment.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT®* Codes	Description
97026†	Application of a modality to one or more areas; infrared

†Note: Experimental/Investigational/Unproven/Not Covered when used to report monochromatic infrared energy therapy or monochromatic near-infrared photo energy.

HCPCS Codes	Description
A4693	Replacement pad for infrared heating pad system, each
E0221	Infrared heating pad system

ICD-9-CM Diagnosis Codes	Description
	All codes

***Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2007	0077	Anodyne Therapy
Great-West Healthcare	8/29/2006	04.262.02	Anodyne Infrared Therapy

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.