



**LOW-LEVEL LIGHT THERAPY
(INFRARED THERAPY,
ANONDYNE® THERAPY SYSTEM
HS-072**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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WellCare Health Insurance of Arizona, Inc.*

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WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

**Low-Level Light Therapy
(Infrared Therapy,
Anodyne® Therapy System)**

Policy Number: HS-072

Original Effective Date: 12/18/2008

**Revised Date(s): 12/22/2009;
12/28/2010; 12/1/2011**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Low level light therapy (LLLT) has been available for over 10 years as one of several physical agents used in physiotherapy. It involves the treatment of inflamed or damaged tissues with very pure light of low intensity and a single wavelength. LLLT is a noninvasive treatment; the applied light travels through the skin and any other overlying tissues and is absorbed by the target tissues. LLLT may be delivered by two different types of devices—lasers or therapy pads imbedded with light-emitting diodes (LEDs). The most common LED-based device is the Anodyne® Therapy System (Anodyne Therapy, LLC), with the trademarked acronym of MIRE™ (monochromatic infrared photo energy) to describe the device's emissions.

In contrast to more powerful surgical lasers, low level laser light is low power, usually 5-500 milliwatts with wavelengths of 600-1000 nm. Infrared light therapy treatment protocols vary in many respects. One significant aspect of variation is the light source, which is usually a single-beam infrared laser. The light source could also be a cluster of laser sources or an array of infrared light-emitting diodes. When performed with an array of light-emitting diodes, this procedure has been referred to as monochromatic near-infrared photoenergy (MIRE) therapy. These light sources usually emit light at a single wavelength. An example of MIRE therapy is the Anodyne Therapy System. Proponents of infrared light therapy suggest that this therapy may stimulate nitric oxide release, cause local vasodilation, improve circulation, and heal damaged nerves.

The Anodyne® Therapy System (Anodyne® Therapy LLC, Tampa, FL) (ATS) delivers monochromatic, near-infrared photo energy through contact with the skin. The light is emitted by an array of 60 superluminous gallium aluminum diodes located on a flexible pad. The manufacturer proposes 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 company literature, the "intense illumination of the skin may non-invasively increase the localized release of NO from hemoglobin". 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". According to the manufacturer, ATS is a non-invasive, drug-free way to increase local circulation to nerves and tissues and reduce neuropathic pain.

ATS 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 ATS for these proposed indications. ATS for the treatment of peripheral neuropathy (PN) 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.

The use of Anodyne® therapy (ATS) or monochromatic near-infrared photo energy (MIRE) remains 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 Anodyne® therapy at this time.

POSITION STATEMENT

Low-Level Light, or Infrared, Therapy, including use of the Anodyne® Therapy **System is considered experimental and investigational and NOT a covered benefit for the treatment of a variety of disorders.** These disorders include, but are not limited to: diabetic neuropathy, carpal tunnel syndrome, lymphedema, skin ulcers and wounds, joint pain, and soft tissue pain.



CLINICAL EVIDENCE

Several meta-analyses have examined the evidence supporting the use of low-level (cold) lasers, including low-level infrared lasers, for treatment of chronic non-healing wounds. These meta-analyses are unanimous in concluding that there is insufficient evidence to support low-level laser in the treatment of chronic venous ulcers or other chronic non-healing wounds.

There is no evidence that infrared light therapy is any more effective than other heat modalities in the symptomatic relief of musculoskeletal pain. Glasgow (2001) reported on the results of a randomized controlled clinical trial of low-level infrared therapy in 24 subjects with experimentally induced muscle soreness, and found no significant differences between treatment and placebo groups.

There are no published studies of the effectiveness of low-level infrared therapy for treatment of diabetic peripheral neuropathy. The case series presented by the manufacturer of the Anodyne System on its web site have not been published in a peer-reviewed medical journal.

Finally, there is no evidence in the published peer-reviewed medical literature on the effectiveness of infrared therapy for the treatment of lymphedema.

CODING

Non-Covered CPT* Codes

97026 Application of a modality to one or more areas; Infrared
97039 Unlisted modality (specify type and time if constant attendance)

Non-Covered ICD-9-CM Procedure Codes

93.35 Other Heat Therapy, Infrared Irradiation

Non-Covered HCPCS Codes

A4639 Replacement pad for infrared heating pad system, each
E0221 Infrared Heating Pad System
S8948* Application of modality (requiring constant provider attendance) to one or more areas, low-level laser, each 15 minutes.
*S-Codes are NON COVERED FOR MEDICARE –For Medicare, bill the appropriate CPT code

Non-Covered ICD-9-CM Diagnosis Codes

All diagnosis codes

*Current Procedural Terminology (CPT®) ©2011 American Medical Association: Chicago, IL.

REFERENCES

Peer Reviewed

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preliminary study of the effects of a novel treatment unit upon experimental muscle soreness. *Lasers in Surgery and Medicine*, 28(1), 33-39.

2. Hayes Directory. (2008, May 12). Low level light therapy for temporomandibular joint pain. Retrieved from <http://www.hayesinc.com>
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6. Hayes Directory. (2008, February 25). Anodyne® therapy system (Anodyne Therapy LLC) for peripheral neuropathy. Retrieved from <http://www.hayesinc.com>

Government Agencies, Professional and Medical Organizations

1. Centers for Medicare and Medicaid Services. (2006, October 24). National Coverage Determination (NCD) for infrared therapy devices (270.6). Retrieved from <http://www.cms.hhs.gov/mcd/search.asp>
2. UnitedHealthcare Technology Assessment. (2006, September 21). Infrared light therapy for treatment of neuropathy and pain.

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• Approved by MPC.• Reformatted references. No changes.• New template design approved by MPC.