

Anodyne® Therapy (Monochromatic Infrared Energy)

Date of Origin: 09/06

Last Review Date: 06/23/2021

Effective Date: 07/01/2021

Dates Reviewed: 09/07, 09/08, 07/10, 02/11, 01/12, 09/12, 07/13, 06/14, 05/15, 05/16, 05/17, 05/2018, 07/2019, 07/2020, 06/2021

Developed By: Medical Necessity Criteria Committee

I. Description

The Anodyne® Therapy System delivers monochromatic infrared energy (MIRE) through contact with the skin. The light is emitted by an array of 60 super luminous 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.

There is insufficient scientific evidence in peer reviewed medical literature regarding the use, safety, improvement and effectiveness on health outcomes of MIRE devices.

II. Criteria: CWQI HCS-0005

A. Moda Health considers Anodyne® Therapy System or use of other MIRE devices investigational as a treatment technique for any indication, including but not limited to:

- acne
- back (thoracic and lumbar) pain
- bell’s palsy, cancer
- cardiovascular diseases
- central nervous system injuries
- chronic kidney diseases
- chronic non-healing wounds (including pressure ulcers)
- diabetes mellitus (including diabetic macular edema and diabetic peripheral neuropathy)
- disorders of consciousness
- ischemic stroke

- lymphedema
- migraines
- neck pain
- non-diabetic peripheral neuropathy
- onychomycosis
- osteoarthritis
- Parkinson’s disease
- retinal degeneration
- seasonal affective disorder (for prevention)
- spinocerebellar ataxia
- stroke
- traumatic brain injury

B. Moda Health considers infrared coagulation medically necessary for members with grade 1 or grade 2 internal hemorrhoids that are painful or persistently bleeding (CPT Code 46930)

- Infrared coagulation usually requires 2 sessions to eradicate the hemorrhoids.
- Internal hemorrhoids are classified by the following grades:
 - Grade I: Bleeding without prolapse
 - Grade II: Prolapse with spontaneous reduction
 - Grade III: Prolapse with manual reduction
 - Grade IV: Incarcerated, irreducible prolapse

III. Information Submitted with the Prior Authorization Request:

1. Chart notes from the treating physician documenting history of hemorrhoids
2. Record of treatment plan/goals

IV. CPT codes covered if criteria met

Codes	Description
46930	Destruction of internal hemorrhoid(s), by thermal energy (eg, infrared coagulation, cautery, radiofrequency)

V. CPT or HCPC codes NOT covered:

Codes	Description
97026	Application of a modality to one or more areas; infrared
A4639	Replacement pad for infrared heating pad system, each
E0221	Infrared heating pad system

VI. Annual Review History

Review Date	Revisions	Effective Date
07/2013	Annual Review: Added table with review date, revisions, and effective date.	07/2013
06/2014	Annual Review: No change	06/2014
05/2015	Annual Review: No change	05/2015
05/2016	Annual Review: No change	05/2016
05/2017	Annual Review: Updated to new template, updated references	05/24/2017
05/2018	Annual Review: No change	05/23/2018
07/2019	Annual Review: Added coverage for code 46930 if criteria is met	08/01/2019
07/2020	Annual Review: No changes	08/01/2020
06/2021	Annual Review: No content changes	07/01/2021

VII. References

- Centers for Medicare & Medicaid Services. Decision Memo for Infrared Therapy Devices CAG-00291N
- Cliffert 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.
- 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.
- 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.
- Horwitz LR, Burke TJ, Carnegie D. Augmentation of wound healing using monochromatic infrared energy. *Adv Wound Care*. 1999 Jan-Feb; 12:35-40.
- Hsieh RL, Lo MT, Lee WC, Liao WC., Therapeutic effects of short-term monochromatic infrared energy therapy on patients with knee osteoarthritis: a double-blind, randomized, placebo-controlled study. *J Orthop Sports Phys Ther*. 2012 Nov; 42(11):947-56. doi: 10.2519/jospt.2012.3881. Epub 2012 Sep 5.
- 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.
- Prendergast JJ, Miranda G, Sanchez M. Improvement of sensory impairment in patients with peripheral neuropathy. *Endocr Pract*. 2004 Jan-Feb; 10(1):24-30.
- Product information from Anodyne® Therapy
- 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.

12. Centers for Medicare & Medicaid Services; National Coverage Determination (NCD) for Infrared Therapy Devices; publication 270.6; Review date November 2006; Implementation Date 1/16/2007; Revised 02/2017; accessed 5/16/17
13. Physician Advisors
14. MacKay D. Hemorrhoids and varicose veins: A review of treatment options. *Altern Med Rev.* 2001; 6(2):126-140.
15. Linares Santiago E, Gomez Parra M, et al. Effectiveness of hemorrhoidal treatment by rubber band ligation and infrared photocoagulation. *Rev Esp Enferm Dig.* 2001; 93(4):238-247.
16. Accarpio G, Ballari F, Puglisi R, e al. Outpatient treatment of hemorrhoids with a combined technique: Results in 7850 cases. *Tech Coloproctol.* 2002; 6(3):195-196.
17. Gupta PJ. Infrared coagulation versus rubber band ligation in early stage hemorrhoids. *Braz J Med Biol Res.* 2003; 36(10):1433-1439.
18. Madoff RD, Fleshman JW; Clinical Practice Committee, American Gastroenterological Association. American Gastroenterological Association technical review on the diagnosis and treatment of hemorrhoids. *Gastroenterology.* 2004; 126(5):1463-1473.

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
	NCD Infrared Heating Devices 270.6 and Decision Memo for Infrared Therapy Devices (CAG-00281N)
	Noridian LCD Infrared Heating Pad Systems L33825

NCD/LCD Document (s):
Noridian Infrared Heating Pad Systems Policy Article A52477

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC