Priority Health

MEDICAL POLICY
No. 91486-R4

MONOCHROMATIC PHOTOTHERAPY (ANODYNE THERAPY/MIRE THERAPY/ LOW LEVEL LIGHT THERAPY)

Effective Date: September 1, 2025

Review Dates: 9/04, 9/05, 8/06, 6/07, 6/08, 6/09, 6/10, 6/11, 6/12, 6/13, 8/14, 8/15, 8/16, 8/17, 8/18, 8/19, 8/20, 8/21, 8/22, 8/23, 8/24, 8/25

Date Of Origin: September 21, 2004

Status: Current

Summary of Changes

Addition:

- New sections: Government regulations and Guidelines/Position Statements

I. POLICY/CRITERIA

Monochromatic Phototherapy (skin contact monochromatic infrared energy) or other types of low-level light therapy is considered investigational & experimental as a treatment technique for any indication, including but not limited to

1. Cutaneous ulcers
2. Diabetic neuropathy
3. Lymphedema
4. Peripheral neuropathy
5. Soft tissue pain and musculoskeletal conditions, such as temporomandibular disorders, tendonitis, capsulitis, knee pain and myofascial pain.

II. GOVERNMENT REGULATIONS

The information below is for informational purposes and current as of the review date for this policy. The Centers for Medicare & Medicare Services update and/or revise coverage criteria periodically. For the most current information, an official Medicare source should be consulted.

National Coverage Determinations (NCDs)	270.6 Infrared Therapy Devices
Local Coverage Determinations	
National Government Services, Inc	L33631 - Outpatient Physical and Occupational Therapy Services

III. GUIDELINES/POSITION STATEMENTS

Medical or Professional Society	Recommendation
American Academy of Orthopedic Surgeons (AAOS, 2021) - Management of Osteoarthritis of the Knee (Non-	Laser Treatment FDA-approved laser treatment may be used to improve pain and function in

Arthroplasty)	patients with knee osteoarthritis. Strength of Recommendation: Limited (2/4 stars)

IV. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

V. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern..***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

VI. DESCRIPTION

Low-level infrared therapy uses a type of low-energy laser that uses light in the infrared spectrum.

Monochromatic phototherapy or monochromatic infrared energy (MIRE) therapy is a noninvasive treatment technique that applies infrared light to the skin to

stimulate blood flow, reducing inflammation, and/or promoting healing at the treatment site. MIRE therapy uses a flexible infrared-emitting pad placed over an affected area. The pad contains an array of infrared 60 superluminous gallium aluminum arsenide diodes which emit monochromatic infrared light at or around 890 nanometers (Burke, 2003). The Anodyne Therapy System is a type of low-level infrared therapy or monochromatic phototherapy, developed by Integrated Systems Physiology Inc., that has been promoted for augmenting wound healing, reversing the symptoms of peripheral neuropathy in people with diabetes, and treating lymphedema. The manufacturer states that the Anodyne Therapy System increases circulation and reduces pain by increasing the release of nitric oxide.

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.

A systematic review by Li et al (2008) concluded poor study designs, small sample sizes, limited information regarding treatment volume or intensity, concomitant use of conventional physical therapy modalities, and a lack of long-term follow-up decrease the validity of most studies. In a systematic review by Robinson et al (2017), the authors determined that MIRE resulted in short-term improvement of tactile sensitivity but is not sustained over time. The limited evidence also suggested that MIRE did not provide relief for neuropathic pain. In a double blind, randomized controlled trial, Lavery et al (2007) concluded that anodyne MIRE therapy was no more effective than sham therapy in the treatment of sensory neuropathy in individuals with diabetes. Definitive patient selection criteria have not been established for treatment of diabetic neuropathy with monochromatic phototherapy and there is insufficient evidence to conclude that monochromatic phototherapy reduces the severity of diabetic neuropathy. The only available study using this technology for treatment of patients with diabetic neuropathy was uncontrolled, and therefore, although improvements in sensation were reported after treatment, the contribution of phototherapy to these positive outcomes cannot be determined.

There is no evidence that infrared light therapy or low-level light therapy is any more effective than other heat modalities in the symptomatic relief of musculoskeletal pain. Stausholm et al (2022)

There is no evidence in the published peer-reviewed medical literature on the effectiveness of infrared therapy for the treatment of lymphedema. Stausholm et al (2022) conducted a randomized clinical trial to investigate the short- and long-term effectiveness of LLLT combined with strength training in persons with knee osteoarthritis (KOA). ifty participants were randomly divided in two groups, one with LLLT plus strength training (n = 26) and one with placebo LLLT plus

strength training (n = 24). LLLT and strength training were performed triweekly for 3 and 8 weeks. The authors found that pain was reduced substantially in both groups. LLLT seemed to provide a positive add-on effect in the follow-up period in terms of reduced pain medication usage and increased performance in the sit-to-stand test. A systematic review by Khalilizad et al (2024) examined randomized controlled trial (RCT) studies that investigated the efficiency of High-intensity laser therapy (HILT_ or LLLT plus knee osteoarthritis exercise therapy (ET) in pain and functional improvement of the knee. The review concluded that HILT+ET and LLLT+ET treatments effectively reduced pain and improved function, but HILT+ET showed a more significant improvement in both outcomes compared to LLLT+ET.

VII. CODING INFORMATION

ICD-10 Diagnosis:
None

CPT/HCPCS Codes:

Not Covered

0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional
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
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

VIII. REFERENCES

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Cutaneous ulcers

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