09-E0000-44

Original Effective Date: 08/15/03

Reviewed: 09/26/24

Revised: 10/15/24

Subject: Infrared Energy Therapy and Low Level Laser Therapy

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Infrared Energy Therapy

Monochromatic infrared energy (MIRE™) is a therapy that uses pulsed infrared light at a wavelength of 880 nm through pads that contain an array of 60 superluminous infrared diodes. Use of skin contact MIRE has been proposed as a therapy for multiple conditions including cutaneous ulcers, diabetic neuropathy, and musculoskeletal and soft tissue injuries. The proposed mechanism of action is not known, although some sort of photobiostimulation has been proposed, as well as increased circulation related to an increase in plasma of the potent vasodilator nitric oxide.

Low-level laser Therapy

Low-level laser therapy (LLLT), also called photobiomodulation, is the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and power between 5 and 500 MW. By comparison, lasers used in surgery typically use 300 W. When applied to the skin, LLLT produces no sensation and does not burn the skin. Because of the low absorption by human skin, it is hypothesized that the laser light can penetrate deeply into the tissues where it has a photobiostimulative effect. The exact mechanism of its effect on tissue healing is unknown; hypotheses have included improved cellular repair and stimulation of the immune, lymphatic,and vascular systems. LLLT is being evaluated to treat a wide variety of conditions, including, among others, soft tissue injuries, myofascial pain, tendinopathies, nerve injuries, joint pain, and lymphedema.

A number of MIRE devices and low-level lasers have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process.

Summary and Analysis of Evidence: The evidence for the use of low level laser therapy (LLLT) for individuals who have an increased risk of oral mucositis due to cancer treatments (eg,chemotherapy, radiotherapy) or hematopoietic cell transplantation (HCT) includes systematic reviews and random control trials (RCTs). Several systematic reviews have found better outcomes with LLLT used to prevent oral mucositis than with control treatments. Results have consistently supported a reduction in severe oral mucositis in patients undergoing chemotherapy, HCT, radiotherapy, and chemoradiotherapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Treatment of carpal tunnel syndrome with LLLT, the evidence includes RCTs and systematic reviews however, the reviews did not find sufficient evidence that LLLT improves outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. LLLT for treatment of neck pain, the evidence includes RCTs and systematic reviews. A 2013 systematic review identified 17 trials, most of which were considered low-quality. Only 2 trials were considered moderate quality, and they found that LLLT led to better outcomes than placebo for chronic neck pain. Additionally, laser types, application dosages, and treatment schedules vary in the available evidence and require further study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Individuals with subacromial impingement syndrome treated with LLLT, the evidence includes RCTs.Most trials did not show a significant benefit of LLLT compared with sham treatment or with an alternative intervention (eg,exercise). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Adhesive capsulitis treated with LLLT, the evidence includes RCTs and a systematic review. A review evaluating treatments for adhesive capsulitis identified 2 RCTs assessing LLLT. Due to the small number of trials and study limitations, reviewers concluded that the evidence was insufficient to permit conclusions about the effectiveness of LLLT for adhesive capsulitis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Temporomandibular joint (TMJ) pain treated with LLLT, the evidence includes RCTs and systematic reviews. Meta-analyses of RCTs had mixed findings. A meta-analysis, which included 33 placebo-controlled randomized trials, found a statistically significant impact of LLLT on pain scores and improved functional outcomes (eg, mouth opening); however, heterogeneity was high among included trials. Furthermore, RCTs have not compared the impact of LLLT with physical therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. For individuals with low back pain treated with LLLT, the evidence includes RCTs and systematic reviews. Meta-analyses of RCTs found that LLLT resulted in a significantly greater reduction in pain scores and global assessment scores than a placebo control in the immediate posttreatment setting. Meta-analyses have found conflicting evidence regarding other outcomes (eg, disability index, range of motion). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Osteoarthritis knee pain treated with LLLT, the evidence includes RCTs and systematic reviews. A systematic review, which pooled study findings, did find that LLLT significantly reduced pain or improved functional outcomes compared with a sham intervention; however, the study was limited by high heterogeneity and inconsistency between regimens and follow-up duration. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Heel pain (ie, Achilles tendinopathy, plantar fasciitis) treated with LLLT, the evidence includes RCTs and systematic reviews. Findings of sham-controlled randomized trials were inconsistent, and RCTs lacked long term follow up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. For individuals with rheumatoid arthritis treated with LLLT, the

evidence includes RCTs and a systematic review. The review of RCTs found an inconsistent benefit of LLLT for a range of outcomes. An RCT, published after the systematic review, did not find that LLLT was significantly better than a placebo treatment on most outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Individuals with Bell palsy treated with LLLT, the evidence includes RCTs and nonrandomized controlled trial. One RCT found a significant short-term benefit of LLLT over exercise. Longer-term outcomes (>6 weeks) were not available. Because Bell palsy often improves within weeks and may completely resolve within months, it is difficult to isolate specific improvements from laser therapy over the natural resolution of the illness. No sham-controlled trials are available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Fibromyalgia treated with LLLT, the evidence includes RCTs and systematic reviews.The RCTs evaluating LLLT for treatment of fibromyalgia are small. One RCT (N=20 patients) found significantly better outcomes with LLLT than with sham, while another (N=20 patients) did not find statistically significant between-group differences for similar outcomes. A larger (N=42) study found improved pain and QOL with LLLT; however, the trial was conducted at a single center with strict inclusion criteria. Additional RCTs with sufficient numbers of patients are needed to establish the efficacy of LLLT for fibromyalgia. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Chronic nonhealing wounds treated with LLLT, the evidence includes RCTs and systematic reviews. The few existing RCTs tend to have small sample sizes and potential risk of bias. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. For individuals with lymphedema treated with LLLT, the evidence includes RCTs and systematic reviews. Multiple systematic reviews detected methodologic flaws in the available studies and did not consistently find better outcomes for patients receiving LLLT than those receiving a control condition for the treatment of lymphedema. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. There is a lack of data to support the use of skin contact MIRE for all indications. There are small controlled trials and observational studies but no improvement was reported for individuals treated with MIRE. The evidence is insufficient to determine the effects of the technology on health outcomes.

POSITION STATEMENT:

Low-level laser therapy **meets the definition of medical necessity** for prevention of oral mucositis in members undergoing cancer treatment associated with increased risk of oral mucositis, including chemotherapy and/or radiotherapy, and/or hematopoietic stem cell transplantation.

Low-level laser therapy is considered **experimental or investigational** for all other indications including but not limited to:

- Adhesive capsulitis
- Bell palsy
- Carpal tunnel syndrome
- Fibromyalgia
- Heel pain (ie, Achilles tendinopathy, plantar fasciitis)
- Low back pain

- Lymphedema
- Neck pain
- Osteoarthritic knee pain
- Rheumatoid arthritis
- Subacromial impingement
- Temporomandibular joint pain
- Wound healing.

The evidence is insufficient to determine the effects of the technology on health outcomes.

Skin contact monochromatic infrared energy (MIRE) therapy is considered **experimental or investigational** for all indications. The evidence is insufficient to determine the effects of the technology on health outcomes. (This includes the use of a home device.)

BILLING/CODING INFORMATION:

CPT Coding

97026	Application of a modality to 1 or more areas; infrared **(Investigational)**
97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non-ablative) for post-operative pain reduction (**Investigational**)
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional

HCPCS Coding

A4639	Replacement pad for infrared heating system, each (**Investigational**)
E0221	Infrared heating pad system (**Investigational**)
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Infrared Therapy Devices (270.6) and Laser Procedures (140.5) located at cms.gov.

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Infrared Heating Pad Systems (L33825) located at cgsmedicare.com.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Physical Therapy (PT) and Occupational Therapy (OT), 01-97000-01

OTHER:

None applicable.

REFERENCES:

1. American Academy of Orthopaedic Surgeons. Management of Carpal Tunnel Syndrome Evidence-Based Clinical Practice Guideline. Published 05/18/2024; located at aaos.org.
2. Blue Cross Blue Shield Association Evidence Positioning System®. 2.01.56 Low Level Laser Therapy, 07/24.
3. Centers for Medicare & Medicaid (CMS), National Coverage Determination (NCD) for Infrared Therapy Devices (270.6), accessed at cms.gov.
4. Centers for Medicare & Medicaid (CMS), National Coverage Determination (NCD) Laser Procedures (140.5), accessed at cms.gov.
5. CGS Administrators, LLC. Local Coverage Determination (LCD):Infrared Heating Pad Systems (L33825), accessed at cgsmedicare.com.
6. ClinicalTrials.gov. To Evaluate the Efficacy Treatment of Lower Extremity Pathologies Derived From Neurological Ischemia Disorders; accessed August 2024.
7. ClinicalTrials.gov. Evaluating the Effectiveness of Photobiomodulation Therapy in the Management of Breast Cancer-Related Lymphedema: a Randomized Controlled Trial; accessed August 2024.
8. ClinicalTrials.gov. Photobiomodulation Therapy for Plantar Fasciitis: A Single-Blind Randomized Control Trial; accessed August 2024.
9. Cruz AR, Minicucci EM, et al. Efficacy of photobiomodulation in the treatment of oral mucositis in patients undergoing antineoplastic therapy: systematic review and meta-analysis. Support Care Cancer. 2023 Oct 19;31(12):645. PMID: 37853254.
10. Elad S, Cheng KKF, et al. MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. Cancer. 2020 Jul 28;126(19):4423-4431.
11. Ferlito JV, Silva CF, et al. Effects of photobiomodulation therapy (PBMT) on the management of pain intensity and disability in plantar fasciitis: systematic review and meta-analysis. Lasers Med Sci. 2023 Jul 18;38(1):163. PMID: 37464155.

12. Glazov G, Yelland M, Emery J. Low-level laser therapy for chronic non-specific low back pain: a meta-analysis of randomised controlled trials. Acupunct Med. Oct 2016;34(5):328-341.
13. Guimaraes JS, Arcanjo FL, et al. Effect of low-level laser therapy on pain and disability in patients with plantar fasciitis: A systematic review and meta-analysis. Musculoskelet Sci Pract. 2022 Feb;57:102478. PMID: 34847470.
14. Kiritsi O, Tsitas K, Malliaropoulos N, Mikroulis G, Ultrasonographic Evaluation of Plantar Fasciitis After Low-Level Laser Therapy: Results of a Double-Blind, Randomized, Placebo-Controlled Trial, Lasers Med Sci, 2010 Mar; 25(2): 275-81.
15. Konstantinovic LM, Kanjuh ZM, Milovanovic AN et al. Acute low back pain with radiculophaty: a double-blind, randomized, placebo-controlled study. Photomedicine and Laser Surgery 2010; 28(4): 553-560.
16. Li ZJ, Wang Y, Zhang HF, et al. Effectiveness of low-level laser on carpal tunnel syndrome: A meta-analysis of previously reported randomized trials. Medicine (Baltimore). Aug 2016;95(31):e4424.
17. Lourinho I, Sousa T, et al. Effects of low-level laser therapy in adults with rheumatoid arthritis: A systematic review and meta-analysis of controlled trials. PLoS One. 2023 Sep 8;18(9):e0291345. PMID: 37683021.
18. Martin RL, Chimenti R, et al. Achilles Pain, Stiffness, and Muscle Power Deficits: Midportion Achilles Tendinopathy Revision 2018. J Orthop Sports Phys Ther. 2018 May;48(5):A1-A38.
19. Meireles SM, Jones A, Jennings F, et al. Assessment of the Effectiveness of Low-Level Laser Therapy on the Hands of Patients with Rheumatoid Arthritis: A Randomized Double-Blind Controlled Trial, Clin Rheumatology, 01/16/10.
20. Nawfar SA, Yacob NBM. Effects of monochromatic infrared energy therapy on diabetic feet with peripheral sensory neuropathy: a andomized controlled trial. Singapore Med J. 2011 Sep;52(9):669-72.
21. Naterstad IF, Joensen J, et al. Efficacy of low-level laser therapy in patients with lower extremity tendinopathy or plantar fasciitis: systematic review and meta-analysis of randomised controlled trials. BMJ Open. 2022 Sep 28;12(9):e059479. PMID: 3671024.
22. National Institute for Health and Care Excellence (NICE) Low-level laser therapy for preventing or treating oral mucositis caused by radiotherapy or chemotherapy. Interventional procedures guidance [IPG615] Published date: May 2018; accessed at nice.org.
23. Navarro-Ledesma S, Carroll J, et al. Short-Term Effects of Whole-Body Photobiomodulation on Pain, Quality of Life and Psychological Factors in a Population Suffering from Fibromyalgia: A Triple-Blinded Randomised Clinical Trial. Pain Ther. 2023 Feb;12(1):225-239.
24. North American Spine Society. Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis & Treatment of Low Back Pain, 2020; accessed at spine.org.
25. Oberoi S, Zamperlini-Netto G, Beyene J, et al. Effect of prophylactic low level laser therapy on oral mucositis: a systematic review and meta-analysis. PloS One. 2014;9(9):e107418.
26. Peng J, Shi Y, et al. Low-level laser therapy in the prevention and treatment of oral mucositis: a systematicreview and meta-analysis. Oral Surg Oral Med Oral Pathol Oral Radiol. Oct 2020; 130(4): 387-397.PMID:32624448.

27. Qaseem A, McLean RM, et al. Nonpharmacologic and Pharmacologic Management of Acute PainFrom Non-Low Back, Musculoskeletal Injuries in Adults: A Clinical Guideline From the American College ofPhysicians and American Academy of Family Physicians. Ann Intern Med. Aug 18 2020. PMID: 32805126.
28. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. Ann Intern Med. Apr 4 2017;166(7):514-530.
29. Robinson CC, Klahr PDS, et al. Effects of monochromatic infrared phototherapy in patients with diabetic peripheral neuropathy: a systematic review and meta-analysis of randomized controlled trials. Braz J Phys Ther. 2017 Jul-Aug;21(4):233-243.
30. Shobha R, Narayanan VS, Jagadish Pai BS, et al. Low-level laser therapy: A novel therapeutic approach to temporomandibular disorder – A randomized, double-blinded, placebo-controlled trial. Indian J Dent Res. Jul-Aug 2017;28(4):380-387.
31. Stausholm MB, Naterstad IF, et al. Efficacy of low-level laser therapy on pain and disability in kneeosteoarthritis: systematic review and meta-analysis of randomised placebo-controlled trials. BMJ Open. Oct 282019; 9(10): e031142.
32. Sung L, Robinson P, Treister N, et al. Guideline for the prevention of oral and oropharyngeal mucositis in children receiving treatment for cancer or undergoing haematopoietic stem cell transplantation. BMJ Support Palliat Care. Mar 2017;7(1):7-16.
33. U.S. Food and Drug Administration (FDA); accessed at fda.gov.
34. Wang W, Jiang W, et al. Clinical efficacy of low-level laser therapy in plantar fasciitis: A systematic reviewand meta-analysis. Medicine (Baltimore). Jan 2019; 98(3):e14088.
35. Wu D, Zhao YL, et al. A Nonrandomized Trial of the Effects of Near-Infrared Photobiomodulation Therapy on Bell's Palsy with a Duration of Greater Than 8 Weeks. Photobiomodul Photomed Laser Surg. 2023 Sep;41(9):490-500. PMID: 37738368.
36. Zhang Y, Qian Y, et al. Efficacy of laser therapy for temporomandibular disorders: A systematic review and meta-analysis. Complement Ther Med. 2023 Jun:74:102945. PMID: 36997006.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

08/15/03	New Medical Coverage Guideline.
08/15/04	Scheduled annual review; S8948 added; no change in investigational status.
08/15/05	Scheduled annual review; no change in investigational status.
09/15/06	Scheduled annual review; no change in investigational status.
07/15/07	Scheduled review; investigational status maintained, added CPT code 97026; reformatted guideline, references updated.
09/15/08	Annual review: position statements maintained, description section and references updated.

08/15/09	Annual review: position statements maintained, description section and references updated.
06/15/10	Annual review: position statements maintained and references updated.
11/15/11	Revision; added laser therapy position statement and update references.
05/11/14	Revision: Program Exceptions section updated.
05/15/17	Revision: Guideline title, description, position statements, coding, and references updated.
10/15/18	Review; position maintained; investigational position statement updated; coding and references updated.
07/01/19	Quarterly CPT/HCPCS update. Added code 0552T.
12/15/20	Review; Position statements maintained and references updated.
11/15/22	Review: Position statements maintained; coding and references updated.
12/15/23	Program exception and references updated.
01/01/24	Annual CPT/HCPCS coding update. Code 97037 added.
10/15/24	Review: MIRE positon statement, description, and references updated.