09-E0000-44

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Subject: Infrared Energy Therapy and Low Level Laser Therapy

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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.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Diagnosis and Treatment of Temporomandibular Joint Disorder, 02-20000-12

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

OTHER:

None applicable.

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COMMITTEE APPROVAL:

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

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.
10/15/25	Annual review: position statements maintained and references updated.
10/15/26	Annual review: Position statements maintained; references updated.