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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.Several devices have received clearance for marketing from the U.S. Food and Drug Administration (FDA).

Low-level laser Therapy

Low-level lasers are also known as cold lasers, soft lasers, non-thermals, or laser acupuncture. Low-level lasers refer to the use of red-beam or near-infrared lasers with a wavelength between 600 and 1,000 nm and Watts from 5 – 500 milliWatts (MW). When applied to the skin, these lasers produce no sensation and do 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 may have 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. Numerous devices have received clearance for marketing from the FDA.

Low-level laser therapy (LLLT), also called photobiomodulation, is being evaluated to treat various conditions, including, among others, oral mucositis, myofascial pain, joint pain, lymphedema, and chronic

wounds. One of the primary disorders for which LLLT has been used is cancer therapy–induced oral mucositis in patients treated by radiotherapy and/or chemotherapy and hematopoietic cell transplantation. Oral mucositis describes inflammation of the oral mucosa and typically manifests as erythema or ulcerations that appear 7 to 10 days after initiation of high-dose cancer therapy. Oral mucositis can cause significant pain and increased risk of systemic infection, dependency on total parenteral nutrition, and use of narcotic analgesics. Treatment planning may also need to be modified due to dose-limiting toxicity. There are a number of interventions for oral mucositis that may partially control symptoms, but none is considered a criterion standard treatment. When uncomplicated by infection, oral mucositis is self-limited and usually heals within 2 to 4 weeks after cessation of cytotoxic chemotherapy.

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 including, but not limited to, treatment of cutaneous ulcers, diabetic neuropathy, and musculoskeletal conditions such as temporomandibular disorders, tendonitis, capsulitis and myofascial pain. 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**)
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional (**Investigational**)

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 Determination (NCD) was reviewed on the last guideline reviewed date: Infrared Therapy Devices (270.6) 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.

The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Therapy and Rehabilitation Services (L33413) located at fcso.com.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

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

OTHER:

None applicable.

REFERENCES:

1. Blue Cross Blue Shield Association Medical Policy Reference Manual: Low-Level Laser Therapy, June 2018.
2. Centers for Medicare & Medicaid (CMS), National Coverage Determination (NCD) for Infrared Therapy Devices (270.6), accessed at cms.gov.
3. Centers for Medicare and Medicaid Services (CMS) Region C DMERC Local Coverage Determination (LCD) for Infrared Heating Pad Systems (L33825), accessed at cgsmedicare.com.
4. ClinicalTrials.gov, A Phase II Prospective Trial of Low-Level Laser Therapy for Prevention of Oral Mucositis in Patients Receiving Chemotherapy and Radiation for Head and Neck Cancer, sponsored by David A. Clump, MD, PhD, accessed 08/16/18.

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6. ClinicalTrials.gov, A Single-center, Sham-controlled, Single Attack Study of Laser Therapy to the Sphenopalatine Ganglion (SPG) in the Acute Treatment of Migraine, sponsored by The San Francisco Clinical Research Center, accessed 08/16/18.
7. ClinicalTrials.gov, Utilization of Low Level Laser Therapy for Radiation Induced Dermatitis in Patients With Head and Neck Squamous Cell Carcinoma, sponsored by David A. Clump, MD, PhD, University of Pittsburgh, accessed 08/16/18.
8. First Coast Service Options, Inc.(FCSO), Local Coverage Determination (LCD) for Therapy and Rehabilitation Services (L33413), accessed at fcso.com.
9. 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.
10. 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.
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12. 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.
13. 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.
14. 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.
15. 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.
16. 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.
17. 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.
18. 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.
19. U.S. Food and Drug Administration (FDA); accessed at fda.gov.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 09/27/18.

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.