MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Low-Level Laser Therapy (LLLT)**
Policy Number	**8.01.23**
Category	**Technology Assessment**
Effective Date	**01/16/20**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based on our criteria and assessment of the peer-reviewed literature, low-level laser therapy (LLLT) may be considered **medically appropriate** for the prevention of oral mucositis in patients undergoing cancer treatment associated with increased risk of oral mucositis, including chemotherapy, radiotherapy, and/or hematopoietic cell transplantation.

II. Based on our criteria and assessment of the peer-reviewed literature, LLLT is considered **investigational** for all other indications, including, but not limited to:

a. carpal tunnel syndrome;
b. neck pain;
c. temporomandibular joint pain;
d. low back pain; and
e. wound healing

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

POLICY GUIDELINES

I. The number of treatments for prevention of oral mucositis is dependent on the duration of cancer treatment.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests be approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

LLLT, also known as Photobiomodulation (PBM), is the application of light, such as ultraviolet or infrared, to tissues to reduce inflammation and improve healing. It is thought to work by increasing cellular energy and reducing free radicals. A number of low-level lasers have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of pain. Data submitted for the MicroLight 830® Laser consisted of the application of the laser over the carpal tunnel 3 times a week for 5 weeks. The labeling states that the "MicroLight 830 Laser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome." In 2006, GRT LITE™ was cleared for marketing, listing the TUCO Erchonia PL3000, the Excalibur System, the MicroLight 830® Laser, and the Acculaser Pro as predicate devices. Indications of the GRTLITE™ for CTS are similar to the predicate devices: "adjunctive use in providing temporary relief of minor chronic pain." In 2009, the LightStream™ LLL device was cleared for marketing by the FDA through the 510(k) process for adjunctive use in the temporary relief of pain

associated with knee disorders treated in standard chiropractic practice. A number of clinical trials of LLLT are underway in the U.S., including studies of wound healing. Since 2009, many similar LLLT devices have received 510(k) clearance from the FDA; most recently, in 2018, Super Pulsed Laser technology (Multi Radiance Medical) was approved by the FDA through the premarket approval process for use in neck and shoulder pain.

Oral mucositis describes inflammation of the oral mucosa and typically manifests as erythema or ulcerations that appear seven to ten 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 of standard treatment. When uncomplicated by infection, oral mucositis is self-limited and usually heals within two to four weeks after cessation of cytotoxic chemotherapy. LLLT has been used in cancer therapy-induced oral mucositis in patients treated with radiotherapy and/or chemotherapy and hematopoietic cell transplantation. LLLT treatment for oral mucositis is done prophylactically prior to each round of chemoradiotherapy, to prevent oral mucositis and associated symptoms.

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy and the most commonly performed surgery of the hand. The syndrome is related to the bony anatomy of the wrist. The carpal tunnel is bound dorsally and laterally by the carpal bones and ventrally by the transverse carpal ligament. Through this contained space run the nine flexor tendons and the median nerve. Therefore, any space-occupying lesion can compress the median nerve and produce the typical symptoms of CTS-pain, numbness, and tingling in the distribution of the median nerve. Symptoms of more severe cases include hypesthesia, clumsiness, loss of dexterity, and weakness of pinch. In the most severe cases, patients experience marked sensory loss and significant functional impairment with thenar atrophy. Mild-to-moderate cases of CTS are usually first treated conservatively with splinting and cessation of aggravating activities. Other conservative therapies include oral steroids, diuretics, nonsteroidal anti-inflammatory drugs, and steroid injections into the carpal tunnel itself. Patients who do not respond to conservative therapy or who present with severe CTS with thenar atrophy may be considered candidates for surgical release of the carpal ligament, using either an open or endoscopic approach. LLLT is also used to treat CTS.

RATIONALE

A randomized controlled trial was conducted by Gautam A, et al. (2012) to evaluate the prophylactic use of Low Level Helium Neon in the prevention and treatment of oral mucositis (OM) in oral cancer patients receiving chemoradiotherapy treatment (CRT). During the trial, 121 patients were randomized into two groups, laser (n = 60) and placebo (n = 61) group. The laser group received He–Ne Laser, and the placebo group received sham treatment just before radiation for 6.5 weeks. Standard oral care and oral hygiene protocol were administered before and during the entire course of CRT in both groups of patients. The patients were evaluated using the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer (RTOG/EORTC) scoring system (Grade 0–4, 0 = none, 1 = erythema of oral mucosa, 2 = patchy mucositis, 3 = confluent mucositis, 4 = Ulceration, necrosis or hemorrhage), pain using visual analog scale (VAS) and total parenteral nutrition (TPN) need at the end of every week. The results of the study showed that patients experience less severe pain throughout their course of CRT in the laser group. Incidence of severe grades OM and its associated pain and TPN was significantly less in laser than placebo group patients at the end of CRT, and, in the last weeks of CRT, severe grades (>2) were significantly less in laser group than placebo group. One limitation of the study that was identified was that patients were not followed for their long-term outcomes after they had finished their CRT. The authors concluded that low level He–Ne Laser therapy showed better treatment outcomes in preventing and treating the CRT induced severe OM than placebo in oral cancer patients.

A systemic review was conducted by Zadik (2019) et al. to review the literature and update the clinical practice guidelines for the Multinational Association of Supportive Care in Cancer (MASCC) for the use of photobiomodulation (PBM), such as laser light therapies. After reviewing all the abstracts found, a total of 33 papers were included in the systematic review. Authors found that intra-oral PBM was reported to be beneficial for the prevention of oral mucositis (OM) and related pain in hematopoietic stem cell transplantation (HSCT) patients in numerous RCTs. Authors found that the efficacy of intra-oral PBM for prevention of OM and related pain in cancer patients treated with radiotherapy (RT) to the head and neck (without CT) was reported in several studies. The efficacy of intra-oral PBM for the prevention of OM and related

pain in H&N cancer patients treated by RT with CT were reported in several RCTs. The authors concluded that the evidence supports the use of specific settings of PBM therapy for the prevention of OM in specific patient populations. Under these circumstances, PBM is recommended for the prevention of OM. The guidelines are subject to continuous update based on new published data.

The National Comprehensive Cancer Network (NCCN) references the Multinational Association of Supportive Care in Cancer (MASCC) clinical practice guidelines for oral mucositis. The guidelines suggest the use of intra-oral PBM therapy using LLLT for the prevention of OM in adult patients receiving radiotherapy (RT) and chemotherapy (CT) for head and neck cancer, the specific PBM therapy parameters of the selected protocol should be followed for optimal therapy, as well as the use of intra-oral PBM therapy using low-level laser therapy for prevention of OM in adult patients receiving RT to the head and neck (without CT) the specific PBM therapy parameters of the selected protocol should be followed for optimal therapy. The clinical practice guidelines also suggest the use of intra-oral PBM therapy using low-level laser therapy for the prevention of OM in adult patients receiving hematopoietic stem cell transplantation conditioned with high-dose chemotherapy, with or without total body irradiation. The guidelines note that safety considerations unique to patients with oral cancer should be considered.

A meta-analysis by Franke T, et al (2018) was done to systematically review the literature on the effectiveness of low-level laser therapy (LLLT) for patients with carpal tunnel syndrome (CTS). The Cochrane Library, PubMed, Embase, CINAHL, and Physiotherapy Evidence Database were searched for relevant systematic reviews and randomized controlled trials (RCTs) up to April 2016. Systematic reviews and/or RCTs were considered eligible for inclusion if they fulfilled all of the following criteria: (1) the study included patients with CTS; (2) CTS was not caused by an acute trauma or any systemic disease as described in the definition of the complaints of the arm, neck, and/or shoulder model1; (3) LLT used for treating the disorder was evaluated; and (4) results on pain, function, or recovery were reported. After inclusion criteria was applied two Cochrane reviews and 17 RCTs were reviewed comparing LLLT to placebo, LLLT as an adjunctive procedure and LLLT versus other procedures for treatment of carpal tunnel syndrome. Authors found that in the short term, low-level laser therapy is more effective as a single intervention than placebo low-level laser therapy in patients with carpal tunnel syndrome. The positive effects of low-level laser therapy tend to subside. Studies comparing LLLT and ultrasound found that ultrasound was significantly more effective in reducing pain than LLLT. They concluded that more studies were needed to evaluate the long term effectiveness.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional

HCPCS Codes

Code	Description
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

ICD10 Codes

Code	Description
C00-D49	Neoplasms (code range)
K12.30-K12.39	Oral mucositis (ulcerative) (code range)

REFERENCES

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*Key Article

KEY WORDS

Oral Mucositis, THOR, Low-level laser therapy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Physical and Occupational Therapy where Low-Level Laser Therapy is addressed. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33631&ver=43&Date=&DocID=L33631&bc=iAAAABAAAAAA&

There is currently and National Coverage Determination (NDC) addressing Laser Procedures. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=69&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=41&KeyWord=laser&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&