EFFECTIVE DATE: 05|01|2017
POLICY LAST UPDATED: 11|01|2016

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

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Low-level laser therapy may be considered **medically necessary** for prevention of oral mucositis in patients undergoing cancer treatment associated with increased risk of oral mucositis, including chemotherapy and/or radiotherapy, and/or hematopoietic stem cell transplantation.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
Low-level laser therapy (LLLT) refers to the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and power between 5 and 500 MW. In contrast, lasers used in surgery typically use 300 Watts. 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 soft tissue injuries, myofascial pain, tendinopathies, nerve injuries, and joint pain. LLLT has also been evaluated for lymphedema.

One of the primary disorders for which LLLT has been used is carpal tunnel syndrome. Carpal tunnel syndrome 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 9 flexor tendons and the median nerve. Therefore, any space-occupying lesion can compress the median nerve and produce the typical symptoms of carpal tunnel syndrome—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 carpal tunnel syndrome 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 carpal tunnel syndrome with thenar atrophy may be considered candidates for surgical release of the carpal ligament, using either an open or endoscopic approach.

Another key disorder for which LLLT is being evaluated is cancer therapy-induced oral mucositis in patients treated by radiotherapy and/or chemotherapy and hematopoietic stem 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 are 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.

A number of low-level lasers have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for the treatment of pain. Data submitted for the MicroLight 830® Laser consisted of 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 Tuco Erchonia PL3000, the Excalibur System, the Microlight 830 Laser, and the Acculaser Pro as predicate devices. Indications of the GRT LITE for carpal tunnel syndrome 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 FDA through the 510(k) process for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice. A number of clinical trials of LLLT are underway in the United States, including studies of wound healing.

The evidence for low-level laser therapy (LLLT) in individuals who have increased risk of oral mucositis due to some cancer treatments (eg, chemotherapy, radiotherapy) and/or hematopoietic stem cell transplantation is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for LLLT is insufficient to determine the effects of the technology on health outcomes in individuals who have the following conditions:

- orthopedic pain (ie, neck pain, osteoarthritis knee pain, low back pain, carpal tunnel syndrome)
- shoulder conditions, heel pain, or temporomandibular joint pain
- bone, ligament, and joint conditions (eg, rheumatoid arthritis, fibromyalgia)
- Bell palsy
- lymphedema
- chronic wounds

CODING

BlueCHiP for Medicare and Commercial Products

Providers should file the following HCPCS code, as there isn't a specific CPT code for the service. It is considered not medically necessary, unless it is filed with the ICD-10 diagnosis code range below.

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

ICD-10 CM: C00 - D49

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, January 2017
Provider Update, February 2016
Provider Update, May 2014
Provider Update, April 2013
Provider Update, March 2012
Provider Update, February 2010

REFERENCES

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2. Jang H, Lee H. Meta-analysis of pain relief effects by laser irradiation on joint areas. Photomed Laser Surg 2012; 30(8):405-17.

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4. U.S. Food and Drug Administration. 4. 510(k) Summary: MicroLight 830. 2002.

5. Blue Cross and Blue Shield Technology Evaluation Center (TEC). Low-level laser therapy for carpal tunnel syndrome and chronic neck pain. TEC Assessment 2010; Volume 25, Tab 4.

6. Chang WD, Wu JH, Jiang JA et al. Carpal tunnel syndrome treated with a diode laser: a controlled treatment of the transverse carpal ligament. Photomed Laser Surg 2008; 26(6):551-7.

7. Ekim A, Armagan O, Tascioglu F et al. Effect of low level laser therapy in rheumatoid arthritis patients with carpal tunnel syndrome. Swiss Med Wkly 2007; 137(23-24):347-52.

8. Evcik D, Kavuncu V, Cakir T et al. Laser therapy in the treatment of carpal tunnel syndrome: a randomized controlled trial. Photomed Laser Surg 2007; 25(1):34-9.

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