



Cigna Medical Coverage Policy

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Subject **Low-Level Laser Therapy**

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Coverage Policy

In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna does not cover low-level laser therapy (LLLT) for any indication because it is considered experimental, investigational or unproven.

General Background

Low-level laser therapy (LLLT) refers to the use of red-beam or near-infrared lasers with a wave-length between 600 and 1000nm, power from 5–500 milliwatts. In contrast, lasers used in surgery typically use 300 watts. These lasers are nonthermal. While the exact mechanism of its effect is unknown, it is theorized that due to the low absorption by human skin the laser light can penetrate deeply into the tissues where it may have a photobiostimulation effect. These types of lasers have been advocated for use in a wide range of medical conditions encompassing: wound healing; smoking cessation; tuberculosis; temporomandibular joint (TMJ) disorders; and a variety of musculoskeletal conditions that includes carpal tunnel syndrome, fibromyalgia, osteoarthritis, and rheumatoid arthritis. LLLT may be administered by several different types of providers, including physicians, chiropractors, physical therapists, or occupational therapists. It is generally provided in an office or other outpatient setting with no anesthesia or sedation needed.

LLLT is also referred to as cold laser therapy, low-power laser therapy (LPLT), low-intensity laser and low-energy laser therapy. When LLLT is administered to the acupuncture pressure points, it may be referred to as laser acupuncture. LLLT includes an extensive variety of procedures involving several laser types and treatment methods. There does not appear to be standards regarding the laser dose, number of treatments or the length

of treatment. This results in difficulties with the consistency of the literature. Several randomized controlled trials involving patients with venous ulcers, rheumatoid arthritis, and other musculoskeletal disorders have failed to demonstrate any significant benefits of LLLT when compared to standard treatment methods or placebos for these conditions.

Literature Review—Musculoskeletal Conditions

Peters et al. (2013) reported on a Cochrane review that examined the effectiveness of rehabilitation following carpal tunnel syndrome (CTS) surgery compared with no treatment, placebo, or another intervention. The review found limited and low quality evidence for the benefit of the reviewed treatments, including laser therapy. The review included one quasi-randomized trial which compared LLLT to a placebo laser. This study found that there was no statistically significant difference in CTS symptoms with low-level laser therapy compared with a placebo.

Gross et al. (2013) conducted a systematic review to evaluate low level laser therapy (LLLT) for adults with neck pain. The review included 17 randomized controlled trials, with 10 found to have high risk of bias. For chronic neck pain, there was moderate quality evidence (in two trials, 109 participants) supporting LLLT over placebo to improve pain/disability/quality of life (QoL)/GPE up to intermediate-term (IT). For acute radiculopathy, cervical osteoarthritis or acute neck pain, low quality evidence indicated that LLLT improves ST pain/function/QoL over a placebo. For chronic myofascial neck pain (five trials, 188 participants) the evidence was conflicting. Studies with larger sample sizes are needed to investigate the functional outcomes of LLLT in the treatment of neck pain, to compare different types of laser, and to increase the understanding of the dosage parameters of LLLT in the treatment of neck pain.

Blue Cross Blue Shield Technology Assessment Center (TEC) conducted a review of the evidence to determine if low-level laser therapy is effective treatment for carpal tunnel syndrome and chronic neck pain (2010). For the indication of carpal tunnel syndrome, four randomized, sham-controlled clinical trials of low-level laser therapy with 151 patients were included. The studies had serious limitations including the small sample size and limited follow-up. The review concluded that for both clinical indications of carpal tunnel syndrome and chronic neck pain, the existing randomized clinical trials are insufficient to make conclusions regarding the effect of low-level laser therapy.

Several studies have been published regarding LLLT for musculoskeletal conditions. Limitations of the studies included small study size, short follow-up time periods, and heterogeneity in terms of laser, dose, duration and frequency of treatments (Dakowicz, et al., 2011; Tascioglu, et al., 2012; Konstantinovic, et al., 2010; Ay, et al., 2010; Oken, et al., 2008; and Djavid, et al., 2007).

There are several systematic and technical reviews published regarding the use of LLLT for musculoskeletal conditions. A systematic review of rehabilitative interventions was conducted to assess various rehabilitative interventions on pain, function and physical impairments in hand osteoarthritis (Ye, et al., 2011). There were two studies included in the review that addressed LLLT. It was that there was no effect on pain with LLLT, but it may be useful for improving range of motion.

Bjordal et al. conducted a systematic review with meta-analysis of LLLT in lateral elbow tendinopathy, with primary outcome measures of pain relief and/or global improvement and subgroup analyses of methodological quality, wavelengths and treatment procedures. The review included 13 randomized controlled trials (730 patients). The weighted mean difference for pain relief was 10.2 mm (95% CI: 3.0 to 17.5). Trials which targeted acupuncture points reported negative results, as did trials with wavelengths 820, 830 and 1064 nm. In a subgroup of five trials with 904 nm lasers and one trial with 632 nm wavelength where the lateral elbow tendon insertions were directly irradiated, the weighted mean difference for pain relief was 17.2 mm (95% CI: 8.5 to 25.9) and 14.0 mm (95% CI: 7.4 to 20.6) respectively. The LLLT doses in this subgroup ranged between 0.5 and 7.2 Joules. In the secondary outcome measures of pain free grip strength, pain pressure threshold, sick leave, the follow-up data from 3 to 8 weeks after the end of treatment showed consistently significant results in favor of the same LLLT subgroup ($p < 0.02$).

Yousefi-Nooraie et al. (2008) conducted a Cochrane review that included seven studies and examined LLLT for nonspecific low-back pain. The authors concluded that based on the heterogeneity of the populations, interventions and comparison groups, "that there are insufficient data to draw firm conclusion on the clinical effect of LLLT for low-back pain." In addition the authors note that there is a need for further methodologically

rigorous randomized, controlled trials to evaluate the effects of LLLT compared to other treatments, different lengths of treatment, wavelengths and dosage.

A review of evidence was conducted for the development of an American Pain Society /American College of Physicians clinical practice guideline for diagnosis and treatment of low back pain (Chou and Huffman, 2007). The review examined nonpharmacologic therapies for acute and chronic low back pain and included only systematic reviews and randomized trials, with seven trials that included LLLT. Four trials found laser therapy superior to sham for pain or functional status up to one year after treatment, but another higher-quality trial found no differences between laser and sham in patients receiving exercise. One lower-quality study reported found similar results for laser, exercise and the combination of laser plus exercise for pain and back-specific functional status. It was noted that optimal treatment parameters, wavelength, dosage, dose intensity are uncertain.

A Cochrane systematic review (Brosseau, et al., 2005) was performed for the purpose of reviewing literature regarding the use of LLLT as treatment for rheumatoid arthritis (RA). Six studies with 220 patients with rheumatoid arthritis were included in the review. The main limitation with the studies is the heterogeneity of clinical application. In addition, the results are subject to publication bias, if negative trials have not been published. It was concluded in this review that “this meta-analysis found that pooled data gave some evidence of a clinical effect, but the outcomes were in conflict, and it must therefore be concluded that firm documentation of the application of LLLT in RA is not possible. Conversely, a possible clinical benefit in certain subgroups cannot be ruled out from the present meta-analysis and further large scaled studies are recommended with special attention to the findings in this meta-analysis (e.g., low versus high dose wavelength, nerve versus joint application, and treatment duration).”

Literature Review—Wound Healing

There are several systematic technical reviews published regarding the use of low level laser for wound healing. The Agency for Healthcare Research and Quality (AHRQ) published a review of the comparative effectiveness and harms of different therapies and approaches to treating pressure ulcers (Saha, et al., 2013). Regarding low-level laser therapy, the review found low strength of evidence for laser therapy and that wound improvement was similar with laser therapy compared with sham treatment or standard care (four studies).

Literature Review—Oral Mucositis

A systematic review and meta-analysis was conducted to examine the effect of LLLT in cancer therapy-induced oral mucositis (OM). The review included 11 randomized, placebo-controlled trials with 415 patients (Bjordal, et al., 2011). The study found consistent evidence from small high-quality studies that red and infrared LLLT can partially prevent development of cancer therapy-induced OM. LLLT also significantly reduced pain, severity and duration of symptoms in patients with cancer therapy-induced OM. The limitation of the study included the small sample size of the included trials and the heterogeneity of the treatment procedures and dosing.

Clarkson et al. (2010) reported on a Cochrane review to assess the effectiveness of interventions for treating oral mucositis or its associated pain in patients with cancer receiving chemotherapy or radiotherapy or both. The review found that there is limited evidence from two small trials that low level laser treatment reduces the severity of the mucositis. The authors concluded that there is weak and unreliable evidence that low level laser treatment reduces the severity of the mucositis with a need for further, well designed, placebo or no treatment controlled trials assessing the effectiveness of interventions for mucositis.

Kuhn et al. (2009) conducted a placebo-controlled randomized trial of 21 children that used LLLT or placebo (sham treatment). Both groups of patients had daily oral mucositis grading assessments before treatment and thereafter until there was healing of the lesions. At day seven after the oral mucositis diagnosis, there were one of nine patients that remained with lesions in the laser group and in the placebo group there was nine of the 12 patients ($p=0.029$). The mean of oral mucositis duration was 5.8 ± 2 days in the laser group and in placebo group it was 8.9 ± 2.4 days ($p=0.004$). In 2008, Arora et al. reported on a prospective, controlled study that evaluated the efficacy of LLLT for the prevention and treatment of radiotherapy-induced oral mucositis in oral cancer patients. The study included 24 patients who were assigned to either group treated with laser daily before radiotherapy ($n=11$) or Group 2, the control group ($n=13$). Pain increased gradually and was the greatest at the end of seven weeks with the difference between the laser and control groups noted to be statistically significant ($p=.033$). The authors noted that additional studies using different laser energies and application

schedules are needed to define optimal treatment variables along with cellular and molecular studies to define mechanisms of laser effect.

Literature Review—Various Medical Conditions Systematic and Technical Reviews:

There are several Cochrane reviews that are not specifically focused on LLLT, but rather examine a range of interventions, including LLLT, for various medical conditions. These reviews include White et al. (2011) who conducted a review of effectiveness of various interventions for smoking cessation including laser treatment. It was found that the evidence on acupressure and laser stimulation was insufficient and could not be combined and the evidence suggests that electrostimulation is not superior to sham electrostimulation.

Maia reported on a systematic review of LLLT on pain levels in patients with temporomandibular disorders (TMD). The review included 14 studies, with 12 studies utilizing a placebo group. The number of sessions varied along with the frequency of applications. There was a range in the energy density and power density used. It was found that there was a reduction in pain levels reported in 13 studies, with nine of these occurring only in the experimental group and four studies reporting pain relief for both experimental and placebo group. The authors concluded that while LLLT appeared to be effective in reducing pain, due to the heterogeneity in standardization of parameters of laser there should be caution in interpretation of the results. Further research is needed regarding appropriate application laser protocol.

McNeely et al. (2006) conducted a systematic review that assessed the evidence concerning the effectiveness of physical therapy interventions, including LLLT, in the management of TMD. Of the six studies in the review, there was one that compared LLLT to sham laser. No significant difference was found in pain reduction between these two groups. No evidence was found to support the use of any of the electrophysical modalities to reduce pain. The authors concluded that there is a clear need for well-designed, randomized controlled clinical trials to examine physical therapy interventions for TMD. A systematic review and meta-analysis assessed the evidence for LLLT for Temporomandibular Disorders (TMD) (Petrucci, et al., 2011). Six randomized clinical trials were included in the review. The primary outcome was the change in pain from baseline to endpoint. The pooled effect of LLLT on pain, measured through a visual analog scale was not statistically significant from placebo. The authors concluded that there is no evidence to support the effectiveness of LLLT in the treatment of TMD.

U.S. Food and Drug Administration (FDA)

Since 2002, the U.S. Food and Drug Administration (FDA) granted 510(k) approval to several companies to market lasers that provide LLLT. The LLLT lasers are classified as class II devices under the physical medicine devices section as “Lamp, Non-heating, for Adjunctive Use in Pain Therapy.”

Several devices that provide LLLT have been approved under the 501(k) approval process for various indications. These devices include but are not limited to:

- MicroLight 830™ (MicroLight Corporation of America, Missouri City, TX)
- Thor Laser System (Thor International Ltd, Amersham, UK)
- Luminex LL Laser System® (Medical Laser Systems, Inc, Branford CT)
- Vectra Genisys Laser System® (Chattanooga Group, Hixson, TN)

In the data submitted to the FDA as part of the FDA 510(k) approval process in 2002, the manufacturer of the MicroLight device conducted a double-blind, placebo-controlled study of 135 patients with moderate to severe symptoms of carpal tunnel syndrome who had failed conservative therapy for at least a month. However, the results of this study have not been published in the peer-reviewed literature, and only a short summary is available in the FDA Summary of Safety and Effectiveness, which does not permit scientific conclusions.

Professional Societies/Organizations

The evidence-based guidelines published by the American Pain Society /American College of Physicians found that there is insufficient evidence to recommend LLLT for treatment of low back pain (Chou, et al., 2007).

The American Academy of Orthopaedic Surgeons (AAOS) published clinical practice guidelines on the treatment of carpal tunnel syndrome (AAOS, 2008; 2011). In the guidelines, laser treatment was included in treatments that carry no recommendation for or against their use and notes that there is insufficient evidence to

recommend the use of the treatment. It was noted that the modality requires further investigation in appropriately designed studies to determine the efficacy in treatment of carpal tunnel syndrome.

An evidence-based guideline for the treatment of painful diabetic neuropathy published by American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation (Bril, et al., 2011). The guideline notes LLLT is probably not effective for the treatment of this condition and is not recommended.

The Orthopaedic Section of the American Physical Therapy Association (APTA) published clinical practice guidelines for Achilles pain, stiffness, and muscle power deficits (Carcia, et al., 2010). The guidelines note that based on limited works, the future of LLLT is promising for patients suffering from Achilles tendon pain. Given the limited number of studies employing LLLT in this population, additional study is warranted. Clinicians should consider the use of low-level laser therapy to decrease pain and stiffness in patients with Achilles tendinopathy. (Level B).

*Level B: Moderate evidence - A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation

Use Outside of the US

National Institute for Health and Care Excellence (NICE): NICE published guidelines for management of low back pain (2009). Regarding LLLT, the guidelines note, "Do not offer laser therapy".

Summary

Low-level laser therapy (LLLT) has been proposed for a wide variety of uses, including wound healing, tuberculosis, and musculoskeletal conditions such as osteoarthritis, rheumatoid arthritis, fibromyalgia and carpal tunnel syndrome. There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that LLLT is effective for these conditions or other medical conditions. Large, well-designed clinical trials are needed to demonstrate the effectiveness of LLLT for the proposed conditions.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Experimental/Investigational/Unproven/Not Covered when used to report low-level laser therapy (LLLT):

CPT ^{®*} Codes	Description
97039	Unlisted modality (specify type and time if constant attendance)

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

*Current Procedural Terminology (CPT[®]) ©2013 American Medical Association: Chicago, IL.

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