

## Kaiser Foundation Health Plan of Washington

# *Clinical Review Criteria* Low Level Laser Therapy for Pain

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## Criteria

#### **For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Laser Procedures (140.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

## For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

#### If requesting this service, please send the following documentation to support medical necessity:

• Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Low level laser therapy (LLLT) is a non-invasive therapeutic option which uses low intensity light at a wavelength ranging from 540 to 830 nm. LLLT produces photochemical reactions and enhance the metabolism of cells. The photochemical reactions change the permeability of cell membrane, increase accumulation of mRNA and result in cell proliferation. After the light is applied, there is activation of photoacceptors, located in the mitochondria, followed by protein synthesis (through several mechanisms). The process reduces pain, causes anti-inflammatory effects, cell proliferation, neovascularization, and balancing immune system. LLLT uses photons at a non-thermal radiation and does not produce heat. In addition, no destruction of the surrounding tissue is reported. Since the density of LLLT is inferior to 5.0 W/cm2, the technique is also called cold laser. (Rayegani, Raeissadat, Heidari, & Moradi-Joo, 2017).

Low-level light with different wavelengths is applied to a specific site. This is followed by absorption of the light by the tissue. The red or infrared light causes the photochemical response and regeneration described above. The wavelengths vary between 600 to 700 nm for small penetration and 780 to 950 nm for more profound penetration. The procedure is short, and no pain, sound, vibration or heat is generated. (https://www.healthline.com/health/cold-laser-therapy#procedure).

The clinical application of low-level laser therapy is broad, but it's mainly used for pain reduction. The current review will focus on knee pain (osteoarthritis/musculoskeletal disorders), painful diabetic neuropathy, and carpal tunnel syndrome.

The incidence and prevalence of osteoarthritis vary and depend on its definition. In the United States, its incidence is lower in African Americans than Caucasians (Nelson, 2018). Based on United States data ranging from 2007 to 2008, 7% of adults over age 25 had symptomatic knee osteoarthritis (Nelson, 2018). Knee osteoarthritis (KOA) is a degenerative disease characterized by gradual loss of cartilage. Symptoms of KOA include pain, limited range of motion, bony swelling, deformity, instability, disability, and reduced quality of life. The diagnosis is clinical; imaging can be performed if the diagnosis is not clear. Conservative therapy includes exercise therapy, non-steroidal anti-inflammatory drugs (NSAIDs), and low-level laser therapy (LLLT) (Stausholm et al., 2019).

Carpal tunnel syndrome is characterized by tingling, pain, even numbness in the wrist/hand. It is the result of compression of the median nerve.

## Medical Technology Assessment Committee (MTAC)

#### 12/20/2010: MTAC Review

#### Lower Level Laser Therapy for Pain

Evidence Conclusion: Back pain - A meta-analysis of 7 RCTs that included 384 participants assessed the effects of LLLT in patients with non-specific low-back. Because the studies included in the meta-analysis were heterogeneous with respect to population, intervention, and comparison group, it is difficult to draw conclusions on the clinical effect of LLLT for low back pain (Yousefi-Nooraie 2008). A double-blind RCT that included 80 participants was conducted after the meta-analysis and compared the effectiveness of LLLT on pain and functional capacity in patients with acute and chronic low back pain caused by lumbar disc herniation (LDH). Patients were randomized to one of four treatment groups: LLLT + hot pack (acute back pain), placebo LLLT + hot pack (acute back pain), LLLT + hot pack (chronic back pain), and placebo LLLT + hot pack (chronic back pain). After treatment, there were statistically significant improvements in pain, range of motion, and disability in all groups with respect to all outcome parameters. However, there was no statistically significant difference between the four treatment groups for any of the treatment parameters. This study had several limitations. The sample size may have been too small to detect between group differences and the follow-up duration was only 3 weeks (Ay 2010). Neck pain - A recent meta-analysis of 16 RCTs that included 820 participants assessed the safety and efficacy of LLLT in treating acute and chronic neck pain. Subjects with acute neck pain who were treated with LLLT were significantly more likely to experience an improvement in pain compared to subjects treated with placebo (RR 1.69, 95% CI 1.22 to 2.33). Patients with chronic neck pain treated with LLLT also experienced greater reductions in pain compared to patients receiving placebo (WMD 19.86, 95% CI 10.04 to 29.68). Results from this analysis also suggest that the effects of treatment may last as long as 22 weeks. Sideeffects included tiredness, nausea, headache, and increased pain. Side-effects were generally mild and did not differ from those in the placebo group. Trials included in the meta-analysis were small RCTs that were heterogeneous with respect to laser parameters, application technique, and intended rationale for treatment (Chow 2009). A small double-blind RCT that included 60 participants investigated the clinical effects of LLLT in patients with acute neck pain with radiculopathy. Results from this study suggest that compared to placebo, patients treated with LLLT experienced significantly greater improvements in arm pain, disability, and neck mobility. There was no significant difference in neck pain between the two groups. All adverse events occurred in the LLLT group and included: transitional worsening of pain (6/30), persistent nausea (1/30), and increased blood pressure (1/30). Results from this study are generalizable to patients with acute neck pain with radiculopathy with severe levels of pain and moderate to severe levels of disability (Konstantinovic 2010). Carpal tunnel syndrome -LLLT vs. placebo A double-blind RCT that included 36 patients with mild to moderate carpal tunnel syndrome (CTS) evaluated the therapeutic effects of LLLT versus placebo for the treatment of CTS. The primary outcome measures included: pain, grip strength, symptom severity, functional status, and motor and sensory peak latency. After treatment there was no significant differences between LLLT and placebo for any of the outcomes except for pain. Patients who were treated with LLLT experienced a greater reduction in pain compared to patients treated with placebo. However, after 2 weeks of follow-up, patients who received LLLT showed significant improvement in pain, symptom severity, functional status, and grip strength. There was no significant difference in sensory peak latency or motor latency between the groups after treatment or after 2 weeks of follow-up. This was a small trial with a short duration of follow-up (Chang 2008). Another RCT that included 81 patients and compared LLLT to placebo found no significant difference with regard to pain and functional capacity between the two treatment groups after 12 weeks of follow-up (Evcik 2007). LLLT vs. ultrasound An RCT that included 50 patients with mild to moderate CTS (90 wrists) compared the efficacy of LLLT and ultrasound for the treatment of CTS. Results from this study suggest that compared to patients treated with LLLT, patients treated with ultrasound showed significant improvements in pain, pinch strength, grip strength, and electroneurographic measurements (Bakhtiary 2004). Splinting vs. splinting + ultrasound vs. splinting + LLLT A recent RCT that included 100 wrists of patients with mild to moderate CTS investigated the effectiveness of splinting, ultrasound, and LLLT for the management of CTS. The primary outcome measures were symptom severity, functional status, pain, median

nerve sensory velocity, and median nerve motor distal latency. For all measurements, the combination of a splint plus ultrasound or LLLT was significantly better than the use of a splint alone. Patients who were treated with a splint plus LLLT experience significantly greater reductions in pain and symptom severity compared to patients treated with a splint plus ultrasound. Results from this study should be interpreted with caution as power was not addressed, it was not stated if an ITT analysis was performed, 4 patients did not finish therapy, 6 patients were lost to follow-up, and splint compliance was not addressed (Dincer 2009). *Conclusion:* There is insufficient evidence to determine the safety and efficacy of LLLT for the treatment of: Low back pain, Neck pain, and Carpal tunnel syndrome

Articles: A meta-analysis of RCT and an RCT published after the meta-analysis were identified that addressed the safety and efficacy of LLLT for the treatment of low back pain. The literature search also revealed a metaanalysis and RCT that looked at LLLT for the treatment of neck pain. Several RCT were identified that addressed the efficacy of LLLT for the treatment of carpal tunnel syndrome. Trials were selected for review if they had more than 25 participants and compared LLLT alone or in combination with another therapy to placebo or another active treatment. The following studies were critically appraised: Ay S, Doğan SK, and Evcik D. Is low-level laser therapy effective in acute or chronic low back pain? Clin Rheumatol 2010; 29:905-910. See Evidence Table. Bakhtiary AH and Rashidy-Pour A. Ultrasound and laser therapy in the treatment of carpal tunnel syndrome. Aust J Physiother 2004; 50:147-151. See Evidence Table. 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; 26:551-557. See Evidence Table. Chow RT, Johnson MI, Lopes-Martins RAB, et al. Efficacy of low-level laser therapy in the management of neck pain: a systematic review and meta-analysis of randomized placebo controlled, or active-treatment controlled trials. Lancet 2009; 374:1894-1908. See Evidence Table. Dincer U, Cakar E, Kiralp MZ, et al. The effectiveness of conservative treatments of carpal tunnel syndrome: splinting, ultrasound, and low-level laser therapies. Photomed Laser Surg 2009: 27:119-125. See Evidence Table. Konstantinovic LM, Cutovic MR, Milovanovic AN, et al. Low-level laser therapy for acute neck pain with radiculopathy: a double-blind placebo-controlled randomized study. Pain Med 2010; 11:1169-1178. See Evidence Table. Yousefi-Nooraie R, Schonstein E, Heidari K, et al. Low-level laser therapy for nonspecific low-back pain. Cochrane Database of Systematic Reviews 2008, Issue 2. Art. No. CD005107.DOI: 10.1002/14651858. CD005107.pub4. See Evidence Table.

The use of low-level laser therapy for pain does not meet the *Kaiser Permanente Medical Technology* Assessment Criteria.

#### 01/13/2020: MTAC Review Lower Level Laser Therapy for Pain Evidence Conclusion:

- Low evidence supports the effectiveness (reduction of pain and disability) of LLLT (with or without exercise therapy) in patients with knee osteoarthritis compared to placebo/sham.
- There is insufficient evidence to assess the safety of LLLT in patients with knee osteoarthritis or musculoskeletal disorders.
- There is also insufficient evidence to compare LLLT versus physical therapy or NSAIDs.
- The evidence is insufficient to assess quality of life.
- There is insufficient evidence to assess the effectiveness and safety of LLLT in patients with painful diabetic neuropathy.
- Low evidence indicates that LLLT may be more effective than placebo on the short-term, but there is insufficient evidence to compare LLLT vs ultrasound or as adjunct to other treatment for patients with carpal tunnel syndrome.

<u>Articles:</u> PubMed was searched through January 3, 2020. Search terms included Low level laser therapy OR LightForce OR Cold laser treatment OR cold laser therapy OR LLLT AND with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Filters included meta-analysis and randomized controlled trials. The search yielded several articles. The following articles (under summary) were reviewed. <u>See Evidence Table</u>.

The use of low-level laser therapy for pain does not meet the *Kaiser Permanente Medical Technology* Assessment Criteria.

# **Applicable Codes**

<u>Medicare</u> - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

#### Non-Medicare - Considered Not Medically Necessary

CPT® or HCPC Codes	Description
97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non- ablative) for post-operative pain reduction
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional

\*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/20/2010	02/10/2011 <sup>MDCRPC</sup> , 12/06/2011 <sup>MDCRPC</sup> , 10/02/2012 <sup>MDCRPC</sup> , 08/06/2013 <sup>MPC</sup> , 06/03/2014 <sup>MPC</sup> , 04/07/2015 <sup>MPC</sup> , 02/02/2016 <sup>MPC</sup> , 12/06/2016 <sup>MPC</sup> , 10/03/2017 <sup>MPC</sup> , 09/04/2018 <sup>MPC</sup> , 09/03/2019 <sup>MPC</sup> , 09/01/2020 <sup>MPC</sup> , 09/07/2021 <sup>MPC</sup> , 09/06/2022 <sup>MPC</sup> , 09/05/2023 <sup>MPC</sup> , 04/02/2024 <sup>MPC</sup> , 04/01/2025 <sup>MPC</sup>	08/09/2024

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee <sup>MPC</sup> Medical Policy Committee

Revision History	Description
06/04/2019	Removed MCG A-0511 for clinical guidelines
03/03/2020	Added January 2020 MTAC review; MPC approved to retain existing non-coverage policy for LLT.
09/01/2020	Added CPT code 0552T
08/09/2024	Added new CPT code 97037, effective 1/1/2024