Clinical Review Criteria
Low Level Laser Therapy for Pain

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
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<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Laser Procedures (140.5)</td>
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<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<td>Local Coverage Article</td>
<td>None</td>
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</tbody>
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For Non-Medicare Members

Kaiser Permanente has elected to use the Laser Therapy (A-0511) MCG* for medical necessity determinations.

*The MCG are proprietary and cannot be published and/or distributed.* However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

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, KPWA 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 light source treatment that generates light of a single wavelength and is thought to promote tissue regeneration, reduced inflammation, and relieve pain. Unlike many other medical laser procedures, LLLT emits no heat, sound, or vibration. Instead of producing a thermal effect, it is thought that LLLT works by eliciting photochemical reactions in cells. Although the exact mechanism of biological action is unknown, several theories have been proposed and include: increased mitochondrial ATP production, enhanced cellular proliferation, increased cellular oxygenation, increased serotonin and endorphin production, stimulation of angiogenesis, and suppression of inflammatory cytokines (Huang 2009, Lin 2010).

Ideal treatment characteristics are unknown; however, LLLT is defined by several parameters (Posten 2005):

- Power with a range of $10^{-3}$ to $10^1$ Watts
- Wavelength between 300 and 10,600 nm
- Pulse rate of 0 (continuous) to 5,000 Hz
- Pulse duration of 1 to 500 milliseconds
- Total irradiation time to 10 to 3,000 seconds
- Intensity (power/area) of $10^{-2}$ to $10^0$ W/cm²
- Dose (power x irradiation time/area irradiated) of $10^{-2}$ to $10^2$ J/cm²

There are a variety of lasers used for administering LLLT. Different types of lasers emit light at different wavelengths. Common lasers used include: ruby, argon, helium-neon, krypton, gallium-aluminum-arsenide, and gallium-arsenide (Lin 2010). Several low level laser devices have received FDA approval.
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. Side-effects 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 patient 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 A 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 (Bakhtiyari 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 a 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 meta-analysis 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

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