Low-Level Laser Therapy

Description

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

LLLT is the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and power between 5 and 500 MW. (By comparison, lasers used in surgery typically use 300 W.) 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.

OBJECTIVE

The objective of this evidence review is to evaluate the safety and efficacy of low-level laser therapy for treating patients at increased risk of mucositis and other conditions (eg, soft tissue injuries, myofascial pain, tendinopathies, nerve injuries, joint pain, lymphedema).
POLICY STATEMENT

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 cell transplantation (see Policy Guidelines).

Low-level laser therapy is considered investigational for all other indications including but not limited to:

- Carpal tunnel syndrome
- Neck pain
- Subacromial impingement
- Adhesive capsulitis
- Temporomandibular joint pain
- Low back pain
- Osteoarthritic knee pain
- Heel pain (ie, Achilles tendinopathy, plantar fasciitis)
- Rheumatoid arthritis
- Bell palsy
- Fibromyalgia
- Wound healing
- Lymphedema.

POLICY GUIDELINES

In the meta-analysis of 18 trials comparing low-level laser therapy (LLLT) to chemotherapy or chemoradiation for prevention of oral mucositis (Oberoi et al [2014]), the course of LLLT was generally from day 0 through treatment. In studies of hematopoietic cell transplant, the course of LLLT began between day -7 and day 0 and continued as long as day 14 or 15. In studies that began LLLT at day -7 or day -5 before hematopoietic cell transplant, the course of laser therapy ended at day -1 or day 0.

Other protocols have applied low-level laser energy to acupuncture points on the fingers and hand. This technique may be referred to as laser acupuncture. Laser acupuncture is not reviewed herein.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

MicroLight Laser Corp. has published a list of providers offering low-level laser therapy; most of the providers are chiropractors. Because the therapy typically requires up to 15 treatments, contractual or benefit restrictions on chiropractic visits for an individual diagnosis may apply.
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 more 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.

**Rationale**

**Summary of Evidence**

**Oral Mucositis**

For individuals who have increased risk of oral mucositis due to some cancer treatments (e.g., chemotherapy, radiotherapy) and/or HCT who receive LLLT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. A 2014 systematic review included 18 RCTs and found better outcomes with LLLT used to prevent oral mucositis than with control treatments. RCTs published after the systematic review had similar findings. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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Musculoskeletal and Neurologic Disorders

For individuals who have CTS who receive LLLT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Both a 2016 systematic review and a TEC Assessment (2010) did not find sufficient evidence from RCTs that LLLT improves outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have neck pain who receive LLLT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A 2013 systematic review identified 17 trials, most of which were considered low-quality. Only two trials were considered moderate quality, and they found that LLLT led to better outcomes than placebo for chronic neck pain. A TEC Assessment (2010) found conflicting evidence. Additionally, laser types, application dosages, and treatment schedules vary in the available evidence and require further study. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SANS who receive LLLT, the evidence includes RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Most trials did not show a significant benefit of LLLT compared with sham treatment or with an alternative intervention (eg, exercise). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have adhesive capsulitis who receive LLLT, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A Cochrane review evaluating treatments for adhesive capsulitis identified two RCTs assessing LLLT. Due to the small number of trials and study limitations, reviewers concluded that the evidence was insufficient to permit conclusions about the effectiveness of LLLT for adhesive capsulitis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have TMJ who receive LLLT, the evidence includes RCTs and several systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A 2015 meta-analysis, which included 14 placebo-controlled randomized trials, did not find a statistically significant impact of LLLT on pain but did find that LLLT significantly improved functional outcomes (eg, mouth opening). RCTs have not compared the impact of LLLT with physical therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have low back pain who receive LLLT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Meta-analyses of RCTs found that LLLT resulted in a significantly greater reduction in pain scores and global assessment scores than a placebo control in the immediate post-treatment setting. Meta-analyses also found that other outcomes (eg, disability index, range of motion) were significantly better immediately after treatment with active rather than placebo LLLT but not at longer-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OA knee pain who receive LLLT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A 2015 systematic review, which pooled study findings, did not find that LLLT significantly reduced pain or improved functional outcomes compared with a sham intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heel pain (ie, Achilles tendinopathy, plantar fasciitis) who receive LLLT, the evidence includes RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Findings of two sham-controlled randomized trials were inconsistent, and while an RCT compared LLLT with standard care lacked long-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have RA who receive LLLT, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A systematic review of RCTs found an inconsistent benefit of LLLT for a range of outcomes. A 2010 RCT, published after the systematic review, did not find that LLLT was significantly better than a placebo treatment on most outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Bell palsy who receive LLLT, the evidence includes two RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The RCT found a significant short-term benefit of LLLT over exercise. Longer-term outcomes (>6 weeks) were not available. Because Bell palsy often improves within weeks and may completely resolve

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within months, it is difficult to isolate specific improvements from laser therapy over the natural resolution of the illness. Also, no sham-controlled trials are available. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fibromyalgia who receive LLLT, the evidence includes RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The RCTs evaluating LLLT for treatment of fibromyalgia are small (ie, <25 patients each). One RCT (n=20 patients) found significantly better outcomes with LLLT than with sham, while another (n=20 patients) did not find statistically significant between-group differences for similar outcomes. Additional RCTs with sufficient numbers of patients are needed to establish the efficacy of LLLT for fibromyalgia. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Wound Care and Lymphedema**

For individuals who have chronic nonhealing wounds who receive LLLT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The few existing RCTs tend to have small sample sizes and potential risk of bias. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lymphedema who receive LLLT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Two systematic reviews detected methodologic flaws in the available studies and did not consistently find better outcomes for patients receiving LLLT than those receiving a control condition for the treatment of lymphedema. The evidence is insufficient to determine the effects of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**Mucositis Prevention Guideline Development Group**

The Mucositis Prevention Guideline Development Group (2017) published guidelines on preventing oral and oropharyngeal mucositis in children undergoing hematopoietic cell transplantation. The guidelines were based on an evidence review consisting of randomized controlled trials that evaluated interventions such as cryotherapy and low-level laser therapy (LLLT). The guidelines suggested that LLLT could be offered to children but classified this recommendation as weak.

**Multinational Association of Supportive Care in Cancer et al**

The Multinational Association of Supportive Care in Cancer and the International Society of Oral Oncology (2014) published joint guidelines on the management of mucositis secondary to cancer therapy. For the prevention of oral mucositis, the 2 associations recommended the following treatments, based on strong evidence: LLLT (650 nm, power of 40 mW) in patients receiving hematopoietic cell transplantation conditioned with high-dose chemotherapy with or without total body irradiation; oral cryotherapy in patients receiving bolus 5-fluorouracil chemotherapy; recombinant human keratinocyte growth factor-1 in patients receiving high-dose chemotherapy and total body irradiation, followed by autologous cell transplantation for hematologic malignancy; and benzydamine mouthwash in patients with head and neck cancer receiving moderate-dose radiotherapy without concomitant chemotherapy.

Additionally, the following treatments were recommended for the prevention of oral mucositis based on weaker evidence: LLLT (632.8 nm) in patients undergoing radiotherapy, without concomitant chemotherapy, for head and neck cancer; oral care protocols for patients undergoing any cancer treatment; oral cryotherapy in patients receiving high-dose melphalan as conditioning for hematopoietic cell transplantation; and oral zinc supplements in oral cancer patients receiving radiotherapy or chemoradiation.

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American Physical Therapy Association

The American Physical Therapy Association (2010) published guidelines on the diagnosis and treatment of Achilles tendinitis. LLLT received a level B recommendation (based on moderate evidence) for decreasing pain and stiffness in patients with Achilles tendinopathy. The guidelines concluded that "given the limited number of studies employing LLLT in this population, additional study is warranted." The Association (2014) stated in a press release, based on a Cochrane review, that "it could be that low-level laser therapy (LLLT) is a useful electrotherapy modality for treatment of adhesive capsulitis, but the effects are marginal, and evidence is a long way from conclusive...."

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2009) issued guidance on early management of persistent, nonspecific low back pain and did not recommend laser treatment, citing limited evidence. The 2016 updated guidance does not mention laser therapy. The Institute (2018) released guidance stating that it was considering LLLT and that it would issue and interventional procedures consultation document regarding the safety and efficacy of the treatment; at the time of this writing, the Institute was still in progress of releasing their disclosure.

American College of Physicians and American Pain Society

The joint guidelines by the American College of Physicians and American Pain Society (2007) stated that there is insufficient evidence to recommend LLLT for treatment of low back pain. The 2009 updated guidelines did not mention LLLT. The American College of Physicians (2017) released guidelines relating to noninvasive treatments for chronic low back pain. The guidelines strongly recommended that patients with chronic low back pain should first seek nonpharmacologic treatment such as exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction—all based on moderate quality evidence. The recommendation also stated that patients with chronic low back pain should seek treatments such as tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, LLLT, operant therapy, cognitive behavioral therapy, or spinal manipulation—all based on low-quality evidence. While the College stated that LLLT has a small effect on pain and function, it found the evidence insufficient for the use of LLLT.

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons’ (2016) guidelines on the management of carpal tunnel syndrome indicated that "limited evidence supports that laser therapy might be effective compared to placebo." U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.
REFERENCES


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<td>New policy</td>
<td>Policy updated with literature review through September 2012, references added and reordered, policy statement unchanged.</td>
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<td>March 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 5, 9-11, 15, 17, 25, 35, 37, 48, and 51 added. Statement added that low-level laser therapy may be considered medically necessary for prevention of oral mucositis in selected patients. Not medically necessary statement changed to investigational with added bullet points.</td>
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