



FEP Medical Policy Manual

FEP 2.01.56 Low Level Laser Therapy

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Related Policies:

2.01.21 - Temporomandibular Joint Disorder

Low Level Laser Therapy

Description

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.

OBJECTIVE

The objective of this evidence review is to evaluate net health outcomes 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 the 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 (LLL) 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.

FDA REGULATORY STATUS

Table 1. Selected Low-Level Laser Therapy Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
FX-635	Erchonia Corporation	6/01/2019	K190572	For adjunctive use in whole body musculoskeletal pain therapy
Super Pulsed Laser Technology	Multi Radiance Medical	01/13/2018	K171354	Providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin
Lightstream Low-Level Laser	SOLICA CORPORATION	04/03/2009	K081166	For adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice
GRT LITE, MODEL 8-A	GRT SOLUTIONS, INC.	02/03/2006	K050668	Use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin
MICROLIGHT 830 LASER SYSTEM	MICROLIGHT CORPORATION OF AMERICA	02/06/2002	K010175	Use in pain therapy or related indication

A number of low-level lasers have been cleared for marketing by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration (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.

RATIONALE

Summary of Evidence

Oral Mucositis

For individuals who have an increased risk of oral mucositis due to some cancer treatments (eg, chemotherapy, radiotherapy) and/or hematopoietic cell transplantation who receive low-level laser therapy (LLL), the evidence includes systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life (QOL), and treatment-related morbidity. Several systematic reviews of randomized controlled trials (RCTs) have found better outcomes with LLLT used to prevent oral mucositis than with control treatments. Results have consistently supported a reduction in severe oral mucositis in patients undergoing chemotherapy, HCT, radiotherapy, and chemoradiotherapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Musculoskeletal and Neurologic Disorders

For individuals who have carpal tunnel syndrome who receive LLLT, the evidence includes RCTs and systematic reviews. 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 that the technology results in an improvement in the net health outcome.

For individuals who have neck pain who receive LLLT, the evidence includes RCTs and systematic reviews. 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 2 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 that the technology results in an improvement in the net health outcome.

For individuals who have subacromial impingement syndrome who receive LLLT, the evidence includes RCTs. 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 that the technology results in an improvement in the net health outcome.

For individuals who have adhesive capsulitis who receive LLLT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A Cochrane review evaluating treatments for adhesive capsulitis identified 2 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 that the technology results in an improvement in the net health outcome.

For individuals who have TMJ pain who receive LLLT, the evidence includes RCTs and several systematic reviews. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Meta-analyses of RCTs had mixed findings. 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). Furthermore, RCTs have not compared the impact of LLLT with physical therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have low back pain who receive LLLT, the evidence includes RCTs and systematic reviews. 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 posttreatment 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 that the technology results in an improvement in the net health outcome.

For individuals who have osteoarthritic (OA) knee pain who receive LLLT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A 2020 systematic review, which pooled study findings, did find that LLLT significantly reduced pain or improved functional outcomes compared with a sham intervention; however, the study was limited by high heterogeneity and inconsistency between regimens and follow-up duration. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heel pain (ie, Achilles tendinopathy, plantar fasciitis) who receive LLLT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Findings of sham-controlled randomized trials were inconsistent, and RCTs lacked long term follow up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have rheumatoid arthritis who receive LLLT, the evidence includes RCTs and a systematic review. 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 that the technology results in an improvement in the net health outcome.

For individuals who have Bell palsy who receive LLLT, the evidence includes a systematic review of 4 RCTs, with 2 RCTs reported in English. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. One 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 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 that the technology results in an improvement in the net health outcome.

For individuals who have fibromyalgia who receive LLLT, the evidence includes RCTs and SR. 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 that the technology results in an improvement in the net health outcome.

Wound Care and Lymphedema

For individuals who have chronic nonhealing wounds who receive LLLT, the evidence includes RCTs and systematic reviews. 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 that the technology results in an improvement in the net health outcome.

For individuals who have lymphedema who receive LLLT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Multiple 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology

In 2017, the Mucositis Prevention Guideline Development Group published guidelines on preventing oral and oropharyngeal mucositis in children undergoing hematopoietic cell transplantation.¹⁰⁸ 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.

In 2020, the Multinational Association of Supportive Care in Cancer and the International Society of Oral Oncology published joint guidelines on the management of mucositis secondary to cancer therapy.¹⁰⁹

For the prevention of oral mucositis, the 2 associations recommended the following treatments, based on level 1 evidence: LLLT in patients undergoing radiotherapy with chemotherapy for head and neck cancer; LLLT in patients receiving hematopoietic cell transplantation conditioned with high-dose chemotherapy with or without total body irradiation; 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, numerous treatments were recommended for the prevention of oral mucositis based on level II evidence, including LLLT in patients undergoing radiotherapy, without concomitant chemotherapy, for head and neck cancer. Several LLLT protocols are outlined by the guideline based on cancer treatment modality, ranging in wavelength from 632.9 to 660 nm.

American Physical Therapy Association

In 2018, the American Physical Therapy Association published an updated guideline on the diagnosis and treatment of Achilles tendinitis.¹¹⁰ The use of LLLT was given a level D recommendation, meaning that no recommendation could be made due to contradictory evidence. This is a change from the previous version of the guideline published in 2010, which gave LLLT a level B recommendation.¹¹¹

National Institute for Health and Care Excellence

In 2009, the National Institute for Health and Care Excellence issued guidance on early management of persistent, nonspecific low back pain and did not recommend laser treatment, citing limited evidence.¹¹² The 2016 updated guidance does not mention laser therapy.¹¹²

North American Spine Society

In 2020, the North American Spine Society published a guideline on the diagnosis and treatment of low back pain.¹¹³ The guideline was based on a systematic review of the literature to address key clinical questions regarding the diagnosis and treatment of adults with nonspecific low back pain.

Table 2. North American Spine Society Guideline Recommendations for Laser Therapy

Guideline Recommendation	Grade of Recommendation
"It is suggested that the combination of laser therapy (low-level or high-level) with exercise provides better short-term relief of pain than either exercise or laser therapy alone."	B
"There is conflicting evidence that the combination of laser therapy with exercise provides better short-term improvement in function compared to exercise or laser therapy alone."	I
"It is suggested that there is no short-term benefit of laser therapy (low-level or high-level) when compared with exercise alone."	B

Grade of Recommendation (levels of evidence range from Level I [high quality randomized controlled trial] to Level V [expert consensus]): A=Good evidence (Level I studies with consistent findings) for or against recommending intervention; B=Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention; C=Poor quality evidence (Level IV or V studies) for or against recommending intervention; I=Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

American College of Physicians

In 2017, the American College of Physicians released guidelines relating to noninvasive treatments for chronic low back pain.¹¹⁴ The guidelines strongly recommended that patients with chronic low back pain should first seek nonpharmacologic treatment such as exercise, multidisciplinary rehabilitation, acupuncture, and 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.

In 2020, the American College of Physicians published a joint guideline on management of acute pain from non-low back musculoskeletal injuries with the American Academy of Family Physicians.¹¹⁵ No recommendations are made specific to LLLT, but the guideline notes that laser therapy did not significantly reduce pain in 1 to 7 days compared to placebo.

American Academy of Orthopaedic Surgeons

In 2016, the American Academy of Orthopaedic Surgeons' guidelines on the management of carpal tunnel syndrome indicated the: "limited evidence supports that laser therapy might be effective compared to placebo."¹¹⁶

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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
March 2013	Replace policy	Policy updated with literature review through September 2012, references added and reordered, policy statement unchanged.
March 2014	Replace policy	Policy updated with literature review. References 14, 37, 46-47, 56, 59- 60 added. Policy statement unchanged.
March 2015	Replace policy	Policy updated with literature review. References 29, 31, 58-59 and 68 added. Policy statement unchanged.
December 2016	Replace policy	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.
September 2018	Replace policy	Policy updated with literature review through April 26, 2018; references 13, 26, 29, 36, 40, 45-49, 53, 55, and 60 added; reference 45 updated. Policy statements unchanged.
September 2019	Replace policy	Policy updated with literature review through April 3, 2019, references added. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through August 20, 2020, references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through April 23, 2021; references added. Policy statements unchanged.

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