Protocol

Low-Level Laser Therapy

(20156)

Medical Benefit		**Effective Date**: 04/01/17	**Next Review Date**: 01/19
Preauthorization	No	**Review Dates**: 04/07, 05/08, 05/09, 01/10, 01/11, 07/11, 07/12, 07/13, 07/14, 07/15, 01/16, 01/17, 01/18	

Preauthorization is recommended if the criteria in this protocol are not met.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With increased risk of oral mucositis due to some cancer treatments and/or hematopoietic cell transplantation	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., oral hygiene, hydration) • Medication	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With carpal tunnel syndrome	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy) • Medication • Surgery	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With neck pain	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy) • Medication • Surgery	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With subacromial impingement syndrome	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy) • Medication • Surgery	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With adhesive capsulitis	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy) • Medication • Surgery	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With temporomandibular joint pain	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy) • Medication • Surgery	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With low back pain	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy) • Medication • Surgery	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With osteoarthritic knee pain	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy) • Medication • Surgery	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With heel pain (i.e., Achilles tendinopathy, plantar fasciitis)	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy) • Medication • Surgery	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With rheumatoid arthritis	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative care (e.g., exercise) • Medication	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With Bell palsy	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative care (e.g., exercise) • Medication	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With fibromyalgia	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative care (e.g., exercise) • Medication	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With chronic nonhealing wounds	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Treatment-related morbidity
Individuals: • With lymphedema	Interventions of interest are: • Low-level laser therapy	Comparators of interest are: • Conservative care (e.g., exercise) • Pneumatic compression • Complete decongestive therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

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.

Summary of Evidence

For individuals who have increased risk of oral mucositis due to some cancer treatments (e.g., chemotherapy, radiotherapy) and/or hematopoietic cell transplantation who receive LLLT, the evidence includes randomized

controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, 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.

For individuals who have carpal tunnel syndrome who receive LLLT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Both a 2016 systematic review and a 2010 TEC Assessment 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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 2010 TEC Assessment 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 subacromial impingement syndrome who receive LLLT, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Most trials did not show a significant benefit of LLLT compared with sham treatment or with an alternative intervention (e.g., 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A Cochrane review on 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 temporomandibular joint pain who receive LLLT, the evidence includes RCTs and several systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Meta-analyses of RCTs had mixed findings. A 2015 meta-analysis, which included 14 placebo-controlled RCTs, did not find a statistically significant impact of LLLT on pain, but did find that LLLT significantly improved functional outcomes (e.g., 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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 (e.g., 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 osteoarthritic knee pain who receive low LLLT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A 2015 systematic review, which pooled study findings, did not find that LLLT significantly improved

pain or 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 (i.e., Achilles tendinopathy, plantar fasciitis) who receive LLLT, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Findings of sham-controlled RCTs were inconsistent and there were no RCTs comparing LLLT to an alternative treatment for heel pain. Moreover, studies offered limited long-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have rheumatoid arthritis who receive low LLLT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A systematic review of RCTs found 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 one RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT found significant short-term benefit of LLLT over exercise. Longer term outcomes (> six 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. In addition, 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCTs evaluating LLLT for treatment of fibromyalgia are small (i.e., < 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Policy

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 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 (i.e., Achilles tendinopathy, plantar fasciitis)
- Rheumatoid arthritis
- Bell Palsy
- Fibromyalgia
- Wound healing
- Lymphedema.

Policy Guidelines

In the meta-analysis of 18 trials comparing LLLT to chemotherapy or chemoradiation for prevention of oral mucositis (Oberoi et al 2014), the course of LLLT was generally from day zero through treatment. In studies of hematopoietic cell transplant (HCT), the course of LLLT began between day-seven and day zero and continued as long as day 14 to 15. In studies that began LLLT at day-seven to day-five before HCT, the course of laser therapy ended at day-one to day zero.

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

Medicare Advantage

For Medicare Advantage the use of low-level laser therapy is considered **not medically necessary** for all indications.

Background

LLLT is the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and power between five 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 photo-biostimulative 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.

LLLT is being evaluated to treat a wide variety of conditions, including soft tissue injuries, myofascial pain, tendinopathies, nerve injuries, joint pain, and lymphedema.

One of the primary disorders for which LLLT has been used is cancer therapy–induced oral mucositis in patients treated by radiotherapy and/or chemotherapy and hematopoietic cell transplantation. Oral mucositis describes inflammation of the oral mucosa and typically manifests as erythema or ulcerations that appear seven to 10 days after initiation of high-dose cancer therapy. Oral mucositis can cause significant pain and increased risk of systemic infection, dependency on total parenteral nutrition, and use of narcotic analgesics. Treatment planning may also need to be modified due to dose-limiting toxicity. There are a number of interventions for oral mucositis that may partially control symptoms, but none is considered a criterion standard treatment. When uncomplicated by infection, oral mucositis is self-limited and usually heals within two to four weeks after cessation of cytotoxic chemotherapy.

Another key disorder for which LLLT has been used is carpal tunnel syndrome (CTS). CTS is the most common entrapment neuropathy and the most commonly performed surgery of the hand. The syndrome is related to the bony anatomy of the wrist. The carpal tunnel is bound dorsally and laterally by the carpal bones and ventrally by the transverse carpal ligament. Through this contained space run the nine flexor tendons and the median nerve. Therefore, any space-occupying lesion can compress the median nerve and produce the typical symptoms of

CTS—pain, numbness, and tingling in the distribution of the median nerve. Symptoms of more severe cases include hypesthesia, clumsiness, loss of dexterity, and weakness of pinch. In the most severe cases, patients experience marked sensory loss and significant functional impairment with thenar atrophy. Mild-to-moderate cases of CTS are usually first treated conservatively with splinting and cessation of aggravating activities. Other conservative therapies include oral steroids, diuretics, nonsteroidal anti-inflammatory drugs, and steroid injections into the carpal tunnel itself. Patients who do not respond to conservative therapy or who present with severe CTS with thenar atrophy may be considered candidates for surgical release of the carpal ligament, using either an open or endoscopic approach.

Regulatory Status

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 application of the laser over the carpal tunnel three times a week for five 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 GRT LITE™ for carpal tunnel syndrome 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 FDA through the 510(k) process for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice. A number of clinical trials of LLLT are underway in the United States, including studies of wound healing.

Related Protocols

Temporomandibular Joint Dysfunction

Treatment of Tinnitus

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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