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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

ORAL MUCOSITIS

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 (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.

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 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, 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 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 (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, 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 temporomandibular joint 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 (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, 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 (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 LLLT, the evidence includes RCTs and systematic reviews. 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 (i.e., Achilles tendinopathy, plantar fasciitis) who receive LLLT, the evidence includes RCTs. 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 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 the effects of the technology on health outcomes.

For individuals who have Bell palsy who receive LLLT, the evidence includes two RCTs. 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 (more than 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. 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. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The RCTs evaluating LLLT for treatment of fibromyalgia are small (i.e., less than 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. 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. 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.

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 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 (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 or day-five before HCT, the course of laser therapy ended at day negative one or day zero.

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.

MEDICARE ADVANTAGE

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

BACKGROUND

ORAL MUCOSITIS

Oral mucositis describes inflammation of the oral mucosa and typically manifests as erythema or ulcerations that appear seven to ten 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

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. Low-level laser therapy (LLLT) has been used in cancer therapy-induced oral mucositis in patients treated with radiotherapy and/or chemotherapy and hematopoietic cell transplantation.

MUSCULOSKELETAL AND NEUROLOGIC DISORDERS

Carpal tunnel syndrome (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.

Treatment

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. LLLT is also used to treat CTS.

LOW-LEVEL LASER THERAPY

LLLT is the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and power between 5 MW 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.

REGULATORY STATUS

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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
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 (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 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 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 LLT 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.

RELATED PROTOCOLS

Temporomandibular Joint Dysfunction

Treatment of Tinnitus

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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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60. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Outpatient Physical and Occupational Therapy Services (L33631), Revision Effective Date for services performed on or after 10/01/2019.