MEDICAL POLICY

POLICY TITLE	LOW-LEVEL LASER THERAPY
POLICY NUMBER	MP- 1.097

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I. POLICY

TOP

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 stem 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
- Osteoarthritis knee pain
- Heel pain (i.e., Achilles tendinopathy, plantar fasciitis)
- Rheumatoid arthritis
- Bell palsy
- Fibromyalgia
- Wound healing
- Lymphedema.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

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 (HCT), the

course of LLLT began between day -7 and day 0 and continued as long as day 14 to 15. In studies that began LLLT at day -7 to day -5 before HCT, the course of laser therapy ended at day -1 to day 0.

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 herein.

Cross-reference:

MP-1.094 Skin Contact Monochromatic Infrared Energy for the Treatment of Cutaneous Ulcers, Diabetic Neuropathy, and Other Miscellaneous Musculoskeletal Conditions

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO-Refer to FEP Medical Policy Manual MP-2.01.56, Low-Level Laser Therapy. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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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.

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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 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.

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

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 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 GRT LITE™ 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 United States, 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.

IV. RATIONALE

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SUMMARY OF EVIDENCE

Oral Mucositis

For individuals who have increased risk of oral mucositis due to some cancer treatments (eg, 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.

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, quality of life, 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, 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 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, 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 (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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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, quality of life, 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). 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 (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 osteoarthritic knee 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 2015 systematic review, which pooled study findings, did not find that LLLT significantly reduced pain or improved function 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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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, 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 two RCTs. 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 (>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 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 (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. 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 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 treatment of lymphedema. The evidence is insufficient to determine the effects of the technology on health outcomes.

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V. DEFINITIONS

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CARPAL TUNNEL SYNDROME is a condition of pain or numbness that affects some part of the median nerve distribution of the hand (the palmar side of the thumb, the index finger, the radial half of the ring finger, and the radial half of the palm) and may radiate into the arm.

EPICONDYLITIS is the inflammation of the epicondyle of the humerus and surrounding tissues.

FIBROMYALGIA is chronic and frequently difficult to manage pain in muscles and soft tissues surrounding joints.

RHEUMATOID ARTHRITIS is a chronic systemic disease marked by inflammation of multiple synovial joints.

TENDINITIS is an inflammation of a tendon.

TMJ SYNDROME is severe pain in and about the temporomandibular joint, made worse by chewing.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary, low-level laser therapy for prevention of oral mucositis in patients undergoing cancer treatment:

CPT Codes ®							
97026							

HCPCS Code	Description
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

ICD-10 CM Diagnosis Codes	Description
K12.31	Oral mucositis (ulcerative) due to antineoplastic therapy
K12.33	Oral mucositis (ulcerative) due to radiation
K12.39	Other oral mucositis (ulcerative)

IX. REFERENCE

TOP

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X. POLICY HISTORY

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MP-1.097	**CAC 10/28/03**
	CAC 5/31/05
	CAC 2/28/06
	CAC 2/27/07

POLICY TITLE	LOW-LEVEL LASER THERAPY
POLICY NUMBER	MP- 1.097

	CAC 1/29/08
	CAC 1/27/09
	CAC 1/26/10 Consensus review.
	CAC 4/26/11 Consensus review.
	CAC 6/26/12 Consensus review. BCBSA Background/Description adopted for low-level laser therapy. No change to policy statements, references updated.
	7/26/13 Admin coding review complete
	CAC 9/24/13 Consensus review. No change to policy statements. References updated.
	CAC 9/30/14 Consensus review. No change to policy statements. Rationale added for low level laser therapy. References updated.
	CAC 9/29/15 Consensus review. No change to the policy statements. Reference and rationale update. Coding Review
	CAC 5/31/16 Minor revision. BCBSA adopted for this review. Policy title revised to "Low Level Laser Therapy". Statement added that low-level laser therapy may be considered medically necessary for prevention of oral mucositis in selected patients. Additional bullet points to the investigational statement and the statement was changed to investigational for "all other indications". High power Class IV therapeutic laser light lasers removed from policy. Background, rationale, and references updated. FEP variation revised. Coding reviewed.
	Administrative Update 11/22/16 Variation section reformatted.
	CAC 7/25/17 Consensus. Policy statements unchanged. Medicare variation to NCD 270.6 added. Policy Guidelines, Description/Background, Rationale and Reference sections updated. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies. 2/28/18 Admin coding review. No changes.
	6/13/18 Consensus review. No changes to the policy statements. Background and references updated. Rationale revised**.**

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