BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Low-Level Laser Therapy

Policy #: 270
Latest Review Date: June 2024
Category: Medicine

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **low-level laser therapy** as a **covered benefit** for prevention of oral mucositis in indiduals undergoing cancer treatment associated with increased risk of oral mucositis, including chemotherapy and/or radiotherapy, and/or hematopoietic cell transplantation.

Blue Advantage will treat **low-level laser therapy** as a **non-covered** benefit and as **investigational** for **ALL** other indications including but not limited to:

- Adhesive capsulitis;
- Arthritis conditions;
- Bell palsy;
- Carpal tunnel syndrome;
- Fibromyalgia;
- Headache;
- Heel pain (i.e., Achilles tendinopathy, plantar fasciitis);
- Knee pain;
- Lateral epicondylitis (tennis elbow);
- Low back pain;
- Lymphedema (not related to post-mastectomy lymphedema);
- Musculoskeletal disorders;
- Myofascial Pain ;
- Neck pain;
- Neurological dysfunctions;
- Osteoarthritic knee pain;
- Plantar fasciitis;
- Raynaud's phenomenon;
- Rheumatoid arthritis;
- Shoulder pain;
- Smoking cessation;
- Subacromial impingement;
- Temporomandibular joint dysfunction;
- Trismus;
- Weight loss/Appetite suppression;
- Wound healing.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contracts and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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 opioid 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 individuals 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 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, individuals experience marked sensory loss and significant functional impairment with thenar atrophy.

Treatment

Several modalities of treatment are used in the management of musculoskeletal pain including medications, immobilization, and physical therapy. The use of LLLT has been investigated for use in musculoskeletal pain conditions. In the case of CTS, mild-to-moderate cases 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.

Individuals 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. Low-level laser therapy is also used to treat CTS.

Wound Care and Lymphedema
Chronic wounds are wounds that do not improve after 4 weeks or heal within 8 weeks. These include diabetic foot ulcers, venous-related ulcerations, non-healing surgical wounds, and pressure ulcers. They are often found on the feet, ankles, heels, calves, and on the hips, thighs, and buttocks of those who cannot walk.

Lymphedema is described as swelling in at least 1 leg and/or arm. It is commonly caused by the removal of a lymph node. The resulting blockage of the lymphatic system prevents lymph fluid from draining well, leading to fluid build-up and swelling. Other symptoms can include heaviness or tightness in the affected limb, restricted range of motion, aching or discomfort, recurring infections, and dermal fibrosis. Risk factors for developing lymphedema after cancer from cancer treatment or from other secondary causes can include older age, obesity, and rheumatoid or psoriatic arthritis.

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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.

KEY POINTS:

This evidence review was created and updated regularly with a search of the PubMed database. The most recent literature update was performed through April 18, 2024.

Summary of Evidence:

Oral Mucositis

For individuals who have an increased risk of oral mucositis due to some cancer treatments (e.g., chemotherapy, radiotherapy)and/or hematopoietic cell transplantation (HCT) who receive low-level laser therapy (LLLT), the evidence includes systematic reviews and 1 RCT in leukemic children. Relevant outcomes are symptoms, morbid events, quality of life (QOL), and treatment-related morbidity. Several systematic reviews of 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 (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 2010 TEC Assessment 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. 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 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 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. 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 (e.g., 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. The relevant outcomes are symptoms, functional outcomes, QOL, 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 that the technology results in an improvement in the net health outcome.

For individuals who have temporomandibular joint (TMJ) pain who receive LLLT, the evidence includes RCTs and several systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Meta-analyses of RCTs had mixed findings. A 2021 meta-analysis, which included 33 placebo-controlled RCTs, found a statistically significant impact of LLLT on pain scores and improved functional outcomes (e.g., 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 have found conflicting evidence regarding other outcomes (e.g., disability index, range of motion). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteoarthritis (OA) knee pain who receive low LLLT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A 2020 systematic review, which pooled study findings, did find that LLLT significantly improved pain or 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 (i.e., 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 sham-controlled randomized trials were inconsistent, and RCTs lack 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 (RA) 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 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 2 RCTs and 1 nonrandomized controlled trial. The 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 beyond 6 weeks were not available. Because Bell's 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 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 systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The RCTs evaluating LLLT for treatment of fibromyalgia are small. 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. A larger (N=42) study found improved pain and QOL with LLLT; however, the trial was conducted at a single center with strict inclusion criteria. Additional RCTs with sufficient numbers of patients are needed. 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 non-healing 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 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. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Multiple 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 the treatment of lymphedema. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements:
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."

American College of Physicians
In 2017, the American College of Physicians (ACP) 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 non-pharmacologic 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 ACP 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 the management of acute pain from non-low back musculoskeletal injuries with the American Academy of Family Physicians. 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 Physical Therapy Association
In 2018, the American Physical Therapy Association published an updated guideline on the diagnosis and treatment of Achilles tendinitis. 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.

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. 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.

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.

National Institute for Health and Clinical Excellence
In 2009, NICE issued guidance on early management of persistent nonspecific low back pain and did not recommend laser treatment, citing limited evidence. The 2016 and 2020 updated guidance does not mention laser therapy.

North American Spine Society
In 2020, the North American Spine Society published a guideline on the diagnosis and treatment of low back pain. 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 1. 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

U.S. Preventive Services Task Force Recommendations:
Not applicable.

KEY WORDS:
Low-level laser therapy (LLLT), laser therapy, cold laser, cold laser therapy, class III laser, Micro Light laser, photobiomodulation, high power laser therapy (HPLT), class IV high power laser, MLS laser therapy, Cutting Edge MLS M6 Robotic Laser, Avicenna's laser, GRT LITE, Excalibur IV Laser, Acculaser Pro, Tuco Erchonia PL3000, Light Stream low-level laser, FX-635, Super Pulsed Laser Technology, WHCRA, Women's Health and Cancer Rights Act

APPROVED BY GOVERNING BODIES:

Table 2. Low-Level Laser Therapy Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510 (k)	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 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 U.S., including studies of wound healing. Since 2009, many more similar LLLT devices have received 510(k) clearance from the FDA.

BENEFIT APPLICATION:

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes

97026	Application of a modality to one or more area; infrared
97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non ablative) for post-operative pain reduction (Effective 1/1/24)
97039	Unlisted modality (specify type and time if constant attendance)
97139	Unlisted therapeutic procedure
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional (Effective 07/01/19)

HCPCS Codes

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

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POLICY HISTORY:

Adopted for Blue Advantage, June 2006
Available for comment July 13-August 28, 2006
Medical Policy Group, February 2007
Available for comment February 10-March 26, 2007
Medical Policy Group, March 2009
Available for comment March 19-May 2, 2009
Medical Policy Group, January 2010
Medical Policy Group March 2011
Available for comment April 4 – May 18, 2011
Medical Policy Group, December 2011
Medical Policy Group, December 2013
Available for comment December 12, 2012 through January 26, 2012
Medical Policy Group, January 2014
Medical Policy Group, November 2014
Medical Policy Group, January 2015
Medical Policy Group, February 2016
Medical Policy Group, March 2017
Medical Policy Panel, July 2018
Medical Policy Group, July 2018 **(6)**: Updates to Key Points, Practice Guidelines and References.
Medical Policy Group, July 2019
Medical Policy Group, November 2020

Medical Policy Group, June 2021
Medical Policy Group, June 2022
Medical Policy Group, June 2023
Medical Policy Group, November 2023: 2024 annual CPT coding update: Added 97037.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, June 2024: Comprehensive non-covered indications updated within Policy statement. No change to policy intent. Title updated to "*Low-Level Laser Therapy*".
