



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Low-Level Laser and High-Power Laser Therapies

Policy #: 270
Category: Therapy

Latest Review Date: November 2020
Policy Grade: B

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:

For dates of service October 20, 2020 and after:

Blue Advantage will treat **low-level laser therapy** as a **covered benefit** 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.

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:

- Carpal tunnel syndrome
- Chronic headache
- Temporomandibular joint dysfunction
- Low back pain
- Fibromyalgia
- Other painful musculoskeletal disorders
- Chronic non-healing wounds
- Neurological dysfunctions
- Smoking cessation
- Weight loss/Appetite suppression
- Trismus
- Raynaud's phenomenon
- Chronic neck pain
- Lateral epicondylitis (tennis elbow)
- Arthritis conditions
- Plantar fasciitis
- Shoulder pain
- Knee pain
- Rheumatoid arthritis
- Lymphedema
- Myofascial Pain

Effective for dates of service on or after August 29, 2006 and prior to October 20, 2020:

Blue Advantage will treat **low level laser therapy (LLLT)** , also known as **cold laser therapy or class III laser, high-power laser therapy (HPLT), also known as class IV therapeutic laser, and laser acupuncture** as a **non-covered** benefit and as **investigational** for **all** indications, including, but not limited to:

- Carpal tunnel syndrome
- Chronic headache
- Temporomandibular joint dysfunction
- Low back pain
- Fibromyalgia
- Other painful musculoskeletal disorders
- Chronic non-healing wounds
- Neurological dysfunctions
- Smoking cessation

- Weight loss/Appetite suppression
- Trismus
- Raynaud's phenomenon
- Chronic neck pain
- Lateral epicondylitis (tennis elbow)
- Arthritis conditions
- Planter fasciitis
- Shoulder pain **(Effective February 28, 2012)**
- Knee pain **(Effective February 28, 2012)**
- Rheumatoid arthritis **(Effective February 28, 2012)**
- Lymphedema **(Effective February 28, 2012)**
- Myofascial Pain **(Effective December 12, 2012)**
- Oral Mucositis **(Effective December 12, 2012)**

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' contract 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 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 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:

The most recent literature search was performed through August 20, 2020. The following is a summary of the key findings to date.

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 low-level laser therapy (LLLT), the evidence includes randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are symptoms, morbid events, 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. Recent 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. 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 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. 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 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. The 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 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). Furthermore, 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. The 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 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 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. 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 the effects of the technology on health outcomes.

For individuals who have 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 the effects of the technology on health outcomes.

For individuals who have Bell palsy who receive LLLT, the evidence includes two RCTs. 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 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 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 (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.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

Practice Guidelines and Position Statements **Mucositis Prevention Guideline Development Group**

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.

Multinational Association of Supportive Care in Cancer et al

In 2020, the Mucositis Guidelines leadership Group of the Multinational Association of Supportive Care in Cancer (MASCC) and the International Society of Oral Oncology (ISOO) published a guideline on the management of mucositis secondary to cancer therapy.

For the prevention of oral mucositis, the MASCC/ISOO recommended the following treatments, based on level I evidence: LLLT in patients receiving HSCT 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 stem cell transplantation for a hematological malignancy; 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. 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.

National Institute for Health and Clinical Excellence

The U.K.'s National Institute for Health and Clinical Excellence 2009 Guideline on early management of persistent nonspecific low back pain did not recommend laser treatment, citing limited evidence. The 2016 updated guidance does not mention laser therapy.

American College of Physicians

In 2017, the American College of Physicians 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 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. 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 management of carpal tunnel syndrome rated laser therapy state: "limited evidence". The guidelines state "limited evidence supports that laser therapy might be effective compared to placebo."

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

APPROVED BY GOVERNING BODIES:

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

Device	Manufacturer	Date Cleared	510 (k)	Indication
FX-635	Erchonia Corporaion	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 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 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
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

HCPCS

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

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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

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.