Low-Level Laser Therapy

Policy # 00194
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider low-level laser therapy for prevention of oral mucositis in patients undergoing cancer treatment associated with increased risk or oral mucositis, including chemotherapy and/or radiotherapy, and/or hematopoietic stem cell transplantation to be eligible for coverage.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers low-level laser therapy (LLLT) to be investigational* for all indications including but not limited to treatment of the following:

- Carpal tunnel syndrome
- Neck pain
- Subacromial impingement
- Adhesive capsulitis
- Temporomandibular joint pain
- Low back pain
- Osteoarthritis knee pain
- Heel pain (ie, Achilles tendinopathy, plantar fasciitis)
- Rheumatoid arthritis
- Bell’s palsy
- Fibromyalgia
- Wound healing
- Lymphedema

Background/Overview
Low-level laser therapy also called photobiomodulation, is being evaluated to treat a variety of conditions including joint pain, myofascial pain, oral mucositis, lymphedema and chronic wounds.

Low-level laser therapy refers to the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and power from 5 to 500 MW. (In contrast, lasers used in surgery typically use 300 W.) When applied to the skin, these lasers produce no sensation and do 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
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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. Low-level laser therapy is being evaluated to treat a wide variety of conditions, including soft tissue injuries, myofascial pain, tendinopathies, nerve injuries, and joint pain. Low-level laser therapy has also been evaluated for lymphedema.

One of the primary disorders that LLLT has been evaluated for is the treatment of carpal tunnel syndrome. Carpal tunnel syndrome 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 9 flexor tendons and the median nerve. Therefore, any space-occupying lesion can compress the median nerve and produce the typical symptoms of carpal tunnel syndrome—pain, numbness, and tingling in the distribution of the median nerve. Symptoms of more severe cases include hypesthesia, clumsiness, loss of dexterity, and weakness of pinch. In the most severe cases, patients experience marked sensory loss and significant functional impairment with thenar atrophy. Mild to moderate cases of carpal tunnel syndrome are usually first treated conservatively with splinting and cessation of aggravating activities. Other conservative therapies include oral steroids, diuretics, nonsteroidal anti-inflammatory drugs (NSAIDs), and steroid injections into the carpal tunnel itself. Patients who do not respond to conservative therapy or who present with severe carpal tunnel syndrome with thenar atrophy may be considered candidates for surgical release of the carpal ligament, using either an open or endoscopic approach.

Another key disorder LLLT is being evaluated for is cancer therapy-induced oral mucositis in patients treated by radiotherapy and/or chemotherapy and hematopoietic stem-cell transplantation. Oral mucositis describes inflammation of the oral mucosa and typically manifests as erythema or ulcerations that appear 7 to 10 days after initiation of high-dose cancer therapy. Oral mucositis can cause significant pain and increase risk of systemic infection, dependency on total parenteral nutrition, and use of narcotic analgesics. Treatment planning may also need to be modified due to dose-limiting toxicity. There are a number of interventions for oral mucositis that may partially control symptoms, but none are considered a criterion standard treatment. When uncomplicated by infection, oral mucositis is self-limited and usually heals within 2 to 4 weeks after cessation of cytotoxic chemotherapy.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

A number of low-level lasers have received clearance for marketing from FDA through the 501k 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 carpal tunnel syndrome are similar to the predicate devices: “adjunctive use in providing temporary relief of minor chronic pain.” The LightStream™ LLL device received 510(k) marketing clearance in 2009 for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic
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practice. A number of clinical trials of LLLT are underway in the United States, including studies of wound healing.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source
The principal outcomes associated with treatment of musculoskeletal conditions, including carpal tunnel syndrome, are relief of pain and/or functional status. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, blinded and randomized controlled trials (RCTs) are required to control for the placebo effect and determine its magnitude and whether any treatment effect provides a significant advantage over the placebo. The technology must also be evaluated in general groups of patients. In patients with mild to moderate symptoms, LLLT may be compared with other forms of conservative therapy such as splinting, rest, NSAIDs, or steroid injection. Second, in a group of patients who have exhausted conservative therapy.

Oral Mucositis
In 2014, the Multinational Association of Supportive Care in Cancer (MASCC) and the International Society of Oral Oncology (ISOO) issued guidelines that reiterated findings from their 2012 systematic review recommending LLLT for the prevention of oral mucositis in patients receiving hematopoietic stem cell transplantation (HSCT) conditioned with high-dose chemotherapy and for patients undergoing head and neck radiotherapy, without concomitant chemotherapy. The 2012 systematic review included 24 trials on a variety of prophylactic treatments. The recommendation on which LLLT for prevention of oral mucositis in patients receiving HSCT was based on what the authors considered to be 1 well-designed, placebo-controlled, randomized trial (described in more detail next), together with observational studies. The trial was double-blind and sham-controlled with 70 patients. Patients were randomized to 650 nm laser, 780 nm laser, or placebo. Patients in the 650-nm laser group were more likely to have received a total body irradiation (TBI)–containing regimen compared with the other 2 groups; otherwise, the groups were comparable. LLLT began on the first day of conditioning and continued for 3 days posttransplant. Of the 70 patients, 47 (67%) had complete or nearly complete mucositis measurements over time; the average number of visits per patient was similar among the 3 groups. The difference between groups in mean oral mucositis scores was greatest at day 11 (placebo, 24.3; 650 nm, 16.7; 780 nm, 20.6), but this difference between the 650-nm group and placebo group was not statistically significant (p=0.06). Patient-specific oral mucositis scores differed significantly between the 2 groups only when adjusted for TBI exposure. Of the 70 patients in the study, 17 (24%) were assessed for oral pain. With group sizes of 5 and 6, the 650-nm group had significantly lower patient-specific average pain scores (15.6) than the placebo group (47.2). No adverse events from LLLT were noted. This study was flawed because it did not achieve statistical significance for the primary outcome measure and had a very small percentage of patients with pain assessments.

The MASCC/ISOO recommendation for LLLT for the prevention of oral mucositis in patients undergoing radiotherapy, without concomitant chemotherapy, for head and neck cancer was based on "weaker
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Evidence from 3 studies that showed positive results but had major flaws. Evidence was considered encouraging but insufficient to recommend LLLT in other populations. The authors emphasized that due to the range of laser devices and variations in individual protocols, results of each study applied exclusively to the cancer population studied and the specific wavelength and settings used.

Additional systematic reviews have been published since the 2012 MASCC/ISOO systematic review. In 2014, Oberoi et al reported on a systematic review and meta-analysis of 18 RCTs on LLLT versus no treatment or placebo for oral mucositis. Eight RCTs assessed patients undergoing HSCT, 8 evaluated head and neck cancer patients receiving radiotherapy or chemoradiation, and the rest studied patients with other conditions receiving chemotherapy. The investigators used the Cochrane risk of bias tool to evaluate the RCTs. Most studies were considered at low risk of bias on most domains. For example, 68% were at low risk of bias for blinding of patients and personnel, and 89% were at low risk of bias on incomplete outcome data. The primary outcome measure for the review was the incidence of severe mucositis. Ten studies (total N=689 patients) were included in a pooled analysis of this outcome. The overall incidence of severe mucositis (grades 3-4) decreased with prophylactic LLLT, with a risk ratio (RR) of 0.37 (95% confidence interval [CI], 0.20 to 0.67; p=0.001). Moreover, the absolute risk reduction in the incidence of severe mucositis (-0.35) significantly favored LLLT (95% CI, -0.48 to -0.21; p<0.001). Among secondary outcomes, LLLT also significantly reduced the overall mean grade of mucositis (standardized mean difference [SMD], -1.49; 95% CI, -2.02 to -0.95), duration of severe mucositis (weighted mean difference [WMD], -5.32; 95% CI, -9.45 to -1.19), and incidence of severe pain as measured on a visual analog scale (VAS; RR=0.26; 95% CI, 0.18 to 0.37). In a subgroup analysis of the primary outcome (incidence of severe mucositis), the investigators did not find a statistically significant interaction between the type of condition treated and the efficacy of LLLT.

A 2015 qualitative systematic review by Doeuk et al addressed literature on LLLT for patients undergoing maxillofacial surgery. The authors identified 45 studies that included more than 10 patients. Three RCTs on treatment of oral mucositis in patients with head and neck cancer were identified and found significantly better outcomes (eg, pain, symptoms, quality of life) in patients receiving active LLLT versus sham treatment. Overall, the authors concluded that LLLT "seems to be effective" for treating oral mucositis after head and neck cancer therapy, but that LLLT cannot be considered a valid treatment option for patients undergoing other types of maxillofacial surgery. The systematic review did not address prophylactic LLLT.

Two of the larger RCTs evaluating LLLT for prevention of oral mucositis were published by Gautam et al in 2012. One of these studies reported LLLT for the prevention of chemoradiotherapy-induced oral mucositis in 121 oral cancer patients. The second publication reported LLLT for the prevention of chemoradiotherapy-induced oral mucositis in 221 head and neck cancer patients. There is an apparent overlap in patients in these 2 reports, with the head and neck cancer study including the 121 patients with a primary tumor site in the oral cavity. Patients in these studies received LLLT before radiotherapy at 66 Gy delivered daily in 33 fractions, 5 days per week and concurrent with cisplatin. LLLT was delivered at a wavelength of 632.8 nm, power density of 24 mW/cm², and a dosage of 3 to 3.5 J. In the report on oral cancer, LLLT before radiotherapy led to significant reductions in the incidence of severe oral mucositis (29% vs 89%) and its associated pain (18% vs 71%, with a VAS score >7), opioid analgesic use (7% vs 21%), and total parenteral nutrition (30% vs 39%), all respectively, during the last weeks of chemoradiotherapy. LLLT also
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reduced the duration of severe oral mucositis (4.07 days vs 13.96 days), severe pain (5.31 days vs 9.89 days), and total parenteral nutrition (14.05 days vs 17.93 days), all respectively. In the 221 patients treated for head and neck cancer, LLLT was reported to lead to significant reductions in the incidence and duration of severe oral mucositis (8.19 days vs 12.86 days) and its associated pain (VAS score of approximately 4 vs 7), total parenteral nutrition (45.0% vs 65.5%), and opioid analgesic use (9% vs 26% for step III), all respectively. In 2013, Gautam et al assessed patient-reported outcomes from the same study of 221 head and neck cancer patients using the Oral Mucositis Weekly Questionnaire-Head and Neck (OMWQ-HN) and the Functional Assessment of Cancer Treatment- Head and Neck (FACT-HN) questionnaire.8 Patients received LLLT as described earlier in this paragraph. Patients in the LLLT group reported significantly better outcomes than the placebo group with lower scores on both the OMWQ-HN (p<0.001) and FACT-HN (p<0.05).

In 2015 and 2016, 3 relatively small (ie, each <50 patients), double-blind, sham-controlled RCTs on prevention of oral mucositis in patients undergoing cancer treatment were published. Gautam et al reported on 46 patients with head and neck cancer scheduled for radiotherapy and found significant reductions in the incidence and duration of severe oral mucositis (p=0.002) and severe pain (p=0.023) after LLLT versus sham. Oton-Leite reported on 30 head and neck cancer patients undergoing chemoradiation and found that oral mucositis grades were significantly lower in the LLLT group than in the control group at the week 1, 3, and 5 evaluations. For example, at the last clinical evaluation (week 5), the rates of grade 3 oral mucositis were 25% in the LLLT group and 54% in the control group. The third RCT, by Ferreira et al, included 36 patients with hematologic cancer undergoing HSCT. The overall incidence of oral mucositis did not differ significantly between groups (p=0.146). However, the rate of severe oral mucositis (grade 3 or 4) was significantly lower in the laser group (18%) than in the control group (61%; p=0.015).

Section Summary: Oral Mucositis
The literature on LLLT for the prevention of oral mucositis includes several systematic reviews, including a 2012 review by MASCC/ISOO with a resulting recommendation for LLLT for the prevention of oral mucositis in adult patients receiving HSCT conditioned with high-dose chemotherapy. Review of the key study evaluated by the MASCC/ISOO investigators for this recommendation revealed limitations that include a lack of statistical significance for the primary outcome measure. The MASCC/ISOO recommendation for LLLT for preventing oral mucositis in patients undergoing radiotherapy for head and neck cancer was based on lower level evidence. A 2014 systematic review of LLLTs for prevention of oral mucositis included 18 RCTs, generally considered at low risk of bias, and found statistically significantly better outcomes with LLLT than with control conditions on primary and secondary outcomes. In addition, 3 double-blind, RCTs published in 2015 found significantly better outcomes in patients undergoing LLLT compared with sham treatment prior to or during cancer treatment.

Neck Pain
The 2010 TEC Assessment, which included 6 trials of LLLT for chronic neck pain, found inconsistent results. In the largest study by Chow et al, 90 patients were randomized to active LLLT or sham treatment. At 5 weeks after the 7-week treatment period, patients in the active treatment group reported a 2.7-point improvement in VAS pain score versus a 0.3-point worsening for the sham group. A calculated mean improvement of 43.8% was reported by the active LLLT group while the sham-treated group improved by
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2.1%. The Assessment noted that baseline VAS pain scores were significantly higher in the active treatment group, possibly biasing results in favor of LLLT. Overall, the authors concluded that the trials were characterized by small sample sizes, limited statistical power, and limited long-term follow-up, and thus the evidence was insufficient.

In a 2013 systematic review and meta-regression, Gross et al evaluated 17 trials on LLLT for neck pain. Ten trials demonstrated high risk of bias. Two trials (n=109 subjects) were considered to be of moderate quality and found LLLT produced better outcomes than placebo for chronic neck pain treatment. Other evidence showed improved outcomes with LLLT compared with placebo for acute neck pain, acute radiculopathy, and cervical osteoarthritis, but was considered to be low quality. There was conflicting evidence on chronic myofascial neck pain.

Section Summary: Neck Pain
The literature on LLLT for treatment of neck pain is conflicting. While some evidence shows positive benefits with LLLT over placebo, larger studies are needed. Additionally, laser types, dosages, and treatment schedules vary in the available evidence and require further study.

Osteoarthritis Knee Pain
Several RCTs and systematic review of RCTs on LLLT for treatment of knee osteoarthritis have been published. In 2015, Huang et al published a systematic review of RCTs comparing at least 8 treatment sessions of LLLT and sham laser treatment in knee osteoarthritis patients. To be eligible for inclusion in the review, trials had to report pain and/or functional outcomes and a PEDro quality score. A total of 9 trials (total N=518 patients) met eligibility criteria. In these studies, interventions included between 8 and 20 laser or sham sessions over 2 to 6 weeks. All 9 trials were considered high quality, as assessed using the PEDro scale (score of ≥7; maximum score, 11 points). Primary outcomes of interest were posttreatment pain measured by VAS scores and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores (Pain and Function). Meta-analyses did not find that LLLT led to significantly better pain scores than the sham control, either immediately after treatment or at the 3-month follow-up. For example, a meta-analysis of 5 studies that reported 12-week pain scores did not find a statistically significant between-group difference (SMD = -0.06; 95% CI, -0.30 to 0.18). Moreover, there were no statistically significant differences between active and sham laser interventions on WOMAC Stiffness scores or WOMAC Function scores. The secondary outcome (range of motion [ROM] after therapy) also did not significantly favor LLLT over a sham intervention.

Previously, in 2007, Bjordal et al published a systematic review of placebo-controlled RCTs to determine the short-term efficacy of physical interventions for pain associated with knee osteoarthritis. They included a total of 36 RCTs. The largest proportion of trials evaluated transcutaneous electrical nerve stimulation (n=11), followed by 8 trials on LLLT and 7 on pulsed electromagnetic fields. Also included were trials on electroacupuncture, manual acupuncture, static magnets, and ultrasound. The authors did not report findings of pooled analyses on LLLT for knee osteoarthritis. In a qualitative analysis, they stated that all the physical interventions but 2 (manual acupuncture, ultrasound) showed better results with active treatment over placebo.
Section Summary: Osteoarthritis Knee Pain
The literature on LLLT for osteoarthritis includes RCTs and 2 systematic reviews of RCTs. The more recent systematic review, which pooled study findings, did not find that LLLT significantly improved pain and functional outcomes compared with a sham intervention.

Low Back Pain
A number of RCTs and several systematic reviews of RCTs have been published. In 2015, Huang et al published a systematic review of RCTs on LLLT for treatment of nonspecific chronic low back pain. The review included trials comparing LLLT and placebo that reported pain and/or functional outcomes and reported a PEDro quality score. Seven trials (total N=994 patients; 202 assigned to LLLT, 192 assigned to placebo) were included. Six of the 7 trials were considered high quality (ie, a PEDro score ≥7; maximum score, 11 points). Primary outcomes of interest were posttreatment pain measured by VAS score and disability measured by the Oswestry Disability Index (ODI) score. ROM and change in pain scores were secondary outcomes. In pooled analyses of study data, the authors found a statistically significant benefit of LLLT on pain outcomes, but not disability or ROM. For the primary outcome (posttreatment pain scores) in a meta-analysis of all 7 trials, mean VAS scores were significantly lower in the LLLT group than in the placebo group (WMD = -13.57; 95% CI, -17.42 to -9.72). In a meta-analysis of 4 studies reporting the other primary outcome (ODI score), there was no statistically significant differences between the LLLT and the placebo groups (WMD = -2.89; 95% CI, -7.88 to 2.29).

A 2008 Cochrane systematic review by Yousefi-Nooraie et al also evaluated LLLT for treatment of nonspecific low back pain. The review included 7 RCTs comparing LLLT, alone or in combination with another intervention, to a control condition. The authors concluded that, due to heterogeneity among trials, the evidence was insufficient to draw firm conclusions on the efficacy of LLLT for low back pain. The authors identified 7 RCTs, but did not pool study findings due to differences among the populations, interventions, and comparison groups.

A large RCT on LLLT for treatment of acute low back pain was published in 2010 by Konstantinovic et al. The study was double-blind and placebo-controlled, and included 546 patients. Patients were randomly assigned to 1 of 3 treatment groups (each including 182 patients). All patients received nimesulide 200 mg; patients in group A received active LLLT, patients in group B received only nimesulide, and patients in group C received placebo LLLT. Treatments were given 5 times a week for 15 weeks. Statistically significant differences after treatment were found for all outcomes (p<0.001), but were larger in group A than in B (p<0.005) or C (p<0.001). Results in group C were better than in group B (p<0.001). The authors concluded that improvement is better in acute low back pain with LLLT as additional therapy. Durability of these outcomes was not measured.

Section Summary: Low Back Pain
The literature on LLLT for low back pain consists of a number of RCTs and several systematic reviews of RCTs. The systematic reviews did not consistently find that LLLT improved outcomes for patients with nonspecific low back pain.
Carpal Tunnel Syndrome
In November 2010, the BlueCross BlueShield Association Technology Evaluation Center (TEC) published a technology assessment of LLLT for carpal tunnel syndrome and chronic neck pain. For inclusion in the assessment, studies had to: be published in a peer-reviewed journal; be randomized, sham-controlled trials, and, if adjunctive therapies were used, they were applied to both groups; measure outcomes at least 2 weeks beyond the end of the treatment period; and, for neck pain studies, be studies of patients with chronic pain. Four RCTs met the inclusion criteria for the TEC Assessment. The authors concluded that the studies have serious limitations including small sample size and limited follow-up, and no one study is so methodologically sound as to provide definitive results.

Several additional RCTs have been published. In 2012, Tascioglu et al reported a randomized double-blind sham-controlled trial of LLLT. Sixty patients with carpal tunnel syndrome were assigned to 1 of 2 active laser dosages (1.2 J or 0.6 J per painful point) or placebo treatment 5 times per week for 3 weeks. There was no significant difference between groups for any of the outcome measures. In this study, LLLT was no more effective than placebo.

In 2015, Barbosa et al evaluated the efficacy of orthoses and patient education with or without the addition of LLLT in patients with mild and moderate carpal tunnel syndrome. Laser treatment was provided twice a week for 6 weeks. Forty-eight patients were randomized and 30 (63%) completed the study protocol. Compared with baseline, outcomes (eg, scores on the Boston Carpal Tunnel Questionnaire and its domains) did not differ significantly between groups after treatment. The study is limited by the high dropout rate.

Section Summary: Carpal Tunnel Syndrome
The literature on LLLT for carpal tunnel syndrome consists of a number of RCTs. However, a 2010 TEC Assessment concluded that the evidence from sham-controlled RCTs was insufficient and more recent RCTs have not found that LLLT significantly improves outcomes.

Subacromial Impingement
Several RCTs evaluating LLLT for treatment of subacromial impingement have been published. Two sham-controlled studies, by Yeldan et al (2009) and by Dogan et al (2010), did not find statistically significantly better pain or functional outcomes with active treatment that with sham. A third RCT, published by Abrisham et al (2011) compared exercise plus pulsed LLLT or sham laser 5 times per week for 2 weeks in 80 patients with subacromial syndrome (rotator cuff and biceps tendinitis). At the end of the treatment period, although both groups improved in VAS scores for pain and shoulder ROM, the improvement was significantly better for the active LLLT group than for the sham laser group for VAS score (4.4 vs 2.9), and all measures of ROM (active and passive flexion, abduction, external rotation). The durability of this effect was not assessed.

Other RCTs did not show statistically significant benefits of LLLT versus conservative treatment. In a 2009 study designed to assess the effectiveness of LLLT in patients with subacromial impingement syndrome, 44 patients were randomized to receive a 12-week home exercise program with or without LLLT. Outcome measures of night pain, Shoulder Pain and Disability Index (SPADI), and University of California-Los
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Angeles (UCLA) end-result scores were assessed at the second and twelfth weeks of intervention. No distinct advantage was demonstrated by LLLT over exercise alone. Both groups showed significant reductions in night pain and SPADI scores at 2- and 12-week assessments, but the differences between groups were not statistically significant.

In 2011, Calis et al randomized 52 patients with subacromial impingement syndrome to LLLT, US, or exercise. Patients were treated 5 days a week for 3 weeks with hotpack + ultrasound + exercise, hotpack + laser + exercise, or hotpack + exercise. All 3 groups showed improvement from baseline to post treatment in pain at rest, ROM, and function. There were no significant differences between the groups.

Section Summary
The literature on LLLT for subacromial syndrome consists of a number of medium-sized RCTs. Most of these trials do not show a benefit of LLLT compared with sham controls.

Adhesive Capsulitis (Frozen Shoulder)
A 2014 Cochrane review evaluated LLLT and other electrotherapy modalities for frozen shoulder. The review found limited evidence to draw conclusions on the effectiveness of electrotherapy modalities for frozen shoulder. Only 1 RCT of 40 patients compared LLLT with placebo. This trial administered LLLT for 6 days. On the sixth day, LLLT was considered to have some improvement in a global assessment of treatment success when compared with placebo. However, this study was considered to be of low quality and the small size and short follow-up limited interpretation of results. One other RCT on LLLT discussed in the Cochrane review by Stergioulas was considered to be of moderate quality. In this study, 63 patients with frozen shoulder were included in an RCT comparing an 8-week program of LLLT (n=31) or placebo (n=32). Both groups also participated in exercise therapy. Compared with the sham group, the active laser group had a significant decrease in overall, night, and activity pain scores after 4 weeks and 8 weeks of treatment, and at the end of 8 more weeks of follow-up. At the same time intervals, a significant decrease in SPADI scores, and Croft shoulder disability questionnaire scores was observed, while a significant decrease in Disability of Arm, Shoulder, and Hand Questionnaire scores was observed at 8 weeks of treatment and at 16 weeks postrandomization; and a significant decrease in health assessment questionnaire scores was observed at 4 weeks and 8 weeks of treatment.

Section Summary: Adhesive Capsulitis
A Cochrane review found limited evidence on LLLT for treating adhesive capsulitis.

Heel Pain
Achilles Tendinopathy
Stergioulas et al randomized 52 recreational athletes with chronic Achilles tendinopathy symptoms to an 8-week (12-session) program of eccentric exercises with LLLT or with sham LLLT. By intention-to-treat (ITT) analysis, results for the primary outcome of pain during physical activity on a VAS were significantly lower in the exercise group with LLLT group at 4 weeks (p<0.001), 8 weeks (p<0.001), and 12 weeks (p=0.007) after randomization.
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Tumilty et al reported a randomized, double-blinded, sham-controlled trial of LLLT as an adjunct to 3 months of exercise training in 40 patients with Achilles tendinopathy. Active or sham LLLT was administered 3 times a week for 4 weeks, and exercises were performed twice a day for 12 weeks. The primary outcome was the Victorian Institute of Sport Assessment–Achilles Questionnaire (VISA-A) at 12 weeks. Following treatment, the only significant difference between the groups on an ITT basis was at 4 weeks on VISA-A scores and the difference favored the sham-control group. The VISA-A and pain numeric rating scale scores did not differ significantly between the active and the sham groups at 12-week or 1-year follow-ups.

Plantar Fasciitis
A 2015, double-blind RCT by Macias et al assessed 69 patients with unilateral chronic plantar fasciitis and chronic heel pain of 3 months or longer that was unresponsive to conservative treatments (eg, rest, stretching, physical therapy). Patients were randomized to twice weekly treatment for 3 weeks of LLLT or sham treatment. The primary efficacy outcome, reduction of heel pain pre- to posttreatment, differed significantly between groups (p<0.001). Mean VAS scores decreased from 69.1 to 39.5 in the LLLT group and from 67.6 to 62.3 in the sham group. The difference in Foot Function Index scores did not differ significantly between groups.

An RCT on LLLT for plantar fasciitis was reported by Kiritsi et al in 2010. The trial was double-blind and sham-controlled trial and included 30 patients. Twenty-five (83%) patients completed the study, with treatment 3 times a week over 6 weeks. At baseline, plantar fascia thickness, measured by ultrasound was significantly greater in symptomatic compared with asymptomatic feet (5.3 mm vs 3.0 mm). Plantar fascia thickness decreased in both the LLLT and the sham groups during the study. Although plantar fascia thickness after 6 weeks of treatment did not differ significantly between the 2 groups (3.6 mm in LLLT, 4.4 mm in sham), there was a significant difference between groups in the change in thickness (1.7 mm LLLT vs 0.9 mm sham). VAS scores after night rest or daily activities improved significantly more in the LLLT group (59% improvement) than in the sham group (26% improvement). At baseline, pain after daily activities was rated as 67 out of 100 by both groups. At the end of treatment, VAS scores after daily activities were rated as 28 out of 100 for LLLT and 50 out of 100 for sham.

Section Summary: Heel Pain
Several sham-controlled RCTs have evaluated LLLT for heel pain (Achilles tendinopathy, plantar fasciitis). Findings are inconsistent. There were no RCTs comparing LLLT to an alternative treatment for heel pain. Moreover, studies offer limited long-term follow-up data.

Temporomandibular Joint Pain
Several meta-analyses of RCTs on LLLT for temporomandibular joint (TMJ) pain have been published. A 2015 meta-analysis by Chen et al assessed pain and functional outcomes after LLLT for TMJ pain. Fourteen placebo-controlled RCTs were identified. Ten trials provided data on pain, measured by a VAS. A pooled analysis of these studies found no significant differences between active treatment and placebo for VAS scores at final follow-up (WMD = -19.39; 95% CI, -40.80 to 2.03; p=0.08). However, meta-analyses did find significantly better functional outcomes (ie, maximum active mouth opening, maximum passive mouth
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opening). For example, the mean difference in maximum active mouth opening for active treatment versus placebo was 4.18 (95% CI, 0.73 to 7.63).

In 2014 Chang et al published a meta-analysis of 7 RCTs on LLLT for TMJ pain. Included RCTs compared LLLT with no treatment or placebo. Only 6 studies were sufficient to be included in the meta-analysis for a total of 223 patients. The number of treatment sessions ranged from 4 to 20. The pooled effect size of pain relief using the VAS was a mean decrease of 0.6 (95% confidence interval [CI], -0.47 to -0.73).

Another meta-analysis of RCTs on LLLT for treating TMJ disorders was published in 2011. The investigators identified 6 randomized, placebo-controlled trials that met the inclusion criteria. A pooled analysis of data from the 6 trials did not find a statistically significant difference in the primary outcome of interest, change in pain from baseline to end point. The pooled difference in pain, measured on a VAS, was a mean difference of 7.77 mm (95% CI, -2.49 to 18.02; p=0.14). All studies had small sample sizes (range, 14-52 participants), and the confidence interval in the pooled analysis was wide.

Outcomes of individual trials of LLLT for TMJ pain are inconsistent. In a study from Brazil, 40 patients with TMJ were treated with LLLT or placebo. After 4 weeks of weekly treatment, patients were evaluated for pain on VAS and the Craniomandibular Index. Both groups improved on both measures (p<0.05), and there were no significant differences between groups. Emshoff et al evaluated LLLT in the management of TMJ in a double-blinded RCT with 52 patients randomized equally to LLLT or sham treatment. After 8 weeks of 2 to 3 treatments/week, both groups showed improvements in pain during function. Between-group differences were not significant.

Fikackova et al treated 61 patients with TMJ or myofascial pain with LLLT at 1 of 2 densities (10 or 15 J/cm²) and 19 patients with sham LLLT (0.1 J/cm²). Outcomes were measured by self-administered questionnaire. The authors report significantly better outcomes in patients treated with 10 or 15 J/cm² than in patients given sham treatment. There were no differences in outcomes between patients with TMJ and myofascial pain.

Carrasco et al randomly assigned 60 patients with myofascial pain and 1 active trigger point in the anterior masseter and anterior temporal muscles to 6 groups. Three groups received laser treatment twice a week for 4 weeks using different energy levels for each group (25, 60, or 105 J/cm²). The other 3 groups received placebo treatment simulating the same parameters as the treated groups. Pain scores were assessed just before, immediately after the fourth and eighth applications, and at 15 days and 1 month after treatment. An analgesic effect was seen starting from the third evaluation in both the treated and placebo groups, and placebo was as effective as laser (p<0.05). Differences in pain VAS between groups treated at different energy levels were not significant.

Venezian et al randomized 48 patients with myofascial pain to 1 of 2 doses of laser (25 or 60 J/cm²) or placebo twice a week for 4 weeks. Surface electromyography at the conclusion of testing showed no difference between groups. Pain with palpation was measured by VAS before, at the conclusion of, and 30 days after laser therapy. VAS scores declined in all groups and were more consistently decreased (more
regions of the palpated muscles) after active laser therapy. However, there were no significant differences in VAS between the active and sham-controlled groups.

Marini et al compared superpulsed LLLT with NSAIDs for pain caused by TMJs secondary to disc displacement without reduction or osteoarthritis. Ninety-nine patients were randomized to 1 of 3 groups: 39 received LLLT in 10 sessions over 2 weeks, 30 received sham LLLT on the same schedule, and 30 patients received ibuprofen 800 mg twice/day. Pain intensity was measured at baseline and after 2, 5, 10, and 15 days of treatment. Mandibular function (active and passive mouth openings and right and left lateral motions) was evaluated at baseline, 15 days, and 1 month of treatment. Durability of pain relief beyond the end of treatment is not reported. Mandibular function was significantly better at 1 month after treatment in the active laser-treated group.

**Section Summary: Temporomandibular Joint Pain**

There are a number of medium to large, randomized, sham-controlled trials of LLLT for TMJ syndrome. Findings of these trials, as well as of systematic reviews of RCTs, are mixed, and most trials do not show a benefit of LLLT.

**Rheumatoid Arthritis**

A 2005 Cochrane Review included 5 placebo-controlled RCTs and found that relative to a separate control group, LLLT reduced pain by 1.10 points on VAS compared with placebo, reduced morning stiffness duration by 27.5 minutes, and increased tip-to-palm flexibility by 1.3 cm. Other outcomes, such as functional assessment, ROM, and local swelling, did not differ between groups. For RA, relative to a control group using the opposite hand (1 study), there was no difference observed between the control and treatment hand for morning stiffness duration and no significant improvement in pain relief. The authors noted that “despite some positive findings, this meta-analysis lacked data on how LLLT effectiveness is affected by four important factors: wavelength, treatment duration of LLLT, dosage, and site application over nerves instead of joints.”

A 2010 randomized, double-blind, placebo-controlled trial comparing outcomes of pain reduction and improvement in hand function in 82 patients with RA treated with LLLT or placebo laser was reported by Meireles et al. There were no statistically significant differences between groups in most of the outcome measurements including the primary variables, though a few measures significantly favoring either the active or placebo treatment were found. The authors concluded that LLLT at the dosage used in the study was not effective for the treatment of hands among patients with RA.

**Section Summary: Rheumatoid Arthritis**

A Cochrane review and a more recent RCT did not find consistent evidence supporting the efficacy of LLLT for treating rheumatoid arthritis.

**Fibromyalgia**

Several small RCTs evaluating LLLT for treating fibromyalgia have been published. In 2014, Ruaro et al reported on 20 patients randomized to receive LLLT or sham treatment 3 times a week for 4 weeks (12 total treatments). Outcomes included scores in the Fibromyalgia Impact Questionnaire (FIQ), which measures
physical function, ability to work, pain, fatigue, and depression; the McGill Pain Questionnaire (MPQ); and a pain VAS. All 3 outcomes were significantly better in the active than in sham after treatment. Mean overall FIQ scores were 18.6 in the LLLT group and 5.2 in the sham group (p=0.003). Mean change scores also differed significantly between groups for MPQ score (p=0.008) and VAS score (p=0.002).

In 2007, Matsutani et al randomized 20 patients with fibromyalgia to receive laser treatment and stretching exercises or stretching alone. Outcome measures were VAS scores and dolorimetry at tender points, QOL on the FIQ, and the 36-Item Short-Form Health Survey (SF-36) scores. At the end of treatment, both groups demonstrated pain reduction, higher pain threshold at tender points (all p<0.01), lower mean FIQ scores, and higher SF-36 mean scores (all p<0.05). No significant differences were found between groups.

**Section Summary: Fibromyalgia**

Few RCTs evaluating LLLT for treatment of fibromyalgia are available and existing trials are small (ie, <25 patients each). One RCT with 20 patients found significantly better outcomes with LLLT than with sham, and another RCT with 20 patients did not find statistically significant between-group differences for similar outcomes. Additional RCTs with sufficient numbers of patients are needed.

**Bell Palsy**

In 2014, Alayat et al reported on a randomized, double-blind, placebo-controlled trial of laser therapy for the treatment of 48 patients with Bell palsy. Facial exercises and massage were given to all patients. Patients were randomized to 1 of 3 groups: high-intensity laser therapy, LLLT, or exercise only. Laser treatment was given 3 times a week to 8 points of the affected side for 6 weeks. At 3 and 6 weeks posttreatment, outcomes were assessed using the Facial Disability Scale and the House-Brackmann Scale. Significant improvements in recovery were seen in both laser therapy groups over exercise alone, with the most improvement seen with high-intensity laser.

**Section Summary: Bell Palsy**

The limited evidence on laser therapy for Bell palsy is insufficient to draw conclusions. Because Bell palsy often improves within weeks and may completely resolve within months, it is difficult to determine any improvements from laser therapy over the natural resolution of the illness. Therefore, sham-controlled studies are needed in addition to comparisons with corticosteroids, antivirals, or other Bell palsy treatments.

**Lymphedema**

Several systematic reviews of RCTs and observational studies have been published. In 2015, Smoot et al published a systematic review of studies on the effect of LLLT on symptoms in women with breast cancer–related lymphedema. The authors identified 9 studies, 7 RCTs and 2 single-group studies. Three studies had a sham control group, 1 used a waitlist control, and 3 compared LLLT to an alternative intervention (eg, intermittent compression). Only 3 studies had blinded outcome assessment and, in 3 studies, participants were blinded. A pooled analysis of 4 studies found significantly greater reduction in upper-extremity volume with LLLT than with the control condition (effect size [ES], -0.62; 95% CI, -0.97 to -0.28). Only 2 studies were suitable for a pooled analysis of the effect of LLLT on pain. This analysis did not find a significant difference in pain between LLLT and control (ES = -1.21; 95% CI, -4.51 to 2.10).
Omar et al published a qualitative systematic review of LLLT for the management of breast cancer-related lymphedema in 2012. They included 8 studies (total N=230 patients) in the review. Five studies were graded as Sackett evidence level II (small randomized trial with high false-positive or false-negative errors), 2 were graded as level III (nonrandomized comparative study), and 1 study was graded as level V evidence (case series). The authors noted major methodologic flaws and little uniformity in trial designs.

One of the larger double-blind RCTs was published in 2011 by Omar et al; the study reported on 50 patients with postmastectomy lymphedema. The average length of time that patients had swelling was 14 months (range, 12-36 months). Patients were treated with active or sham laser 3 times a week for 12 weeks over the axillary and arm areas. In addition, all participants were instructed to perform daily arm exercises and to wear a pressure garment. Limb circumference, shoulder mobility, and grip strength were measured before treatment and at 4, 8, and 12 weeks. Limb circumference declined over time in both groups, with significantly greater reduction in the active laser group at 8 (20.0 cm vs 16.4 cm), 12 (29 cm vs 21.8 cm), and 16 (31 weeks vs 2 weeks 3) weeks. Shoulder flexion and abduction were significantly better in the active laser group at 8 and 12 weeks. Grip strength was significantly better in the active laser group after 12 weeks (26.2 kg vs 22.4 kg). The durability of these effects was not assessed.

Section Summary: Lymphedema
Two systematic reviews of RCTs and observational studies found methodologic flaws in the available studies and did not consistently find better outcomes in patients receiving LLLT versus a control condition for treatment of lymphedema.

Chronic Wounds
A 2004 evidence report on vacuum-assisted and low-level laser wound therapies for treatment of chronic nonhealing wounds, prepared for the Agency for Healthcare Research and Quality, was based on 11 studies of LLLT. It stated: “The best available trial [of low-level laser wound therapy] did not show a higher probability of complete healing at 6 weeks with the addition of low-level laser compared to sham laser treatment added to standard care. Study weaknesses were unlikely to have concealed existing effects. Future studies may determine whether different dosing parameters or other laser types may lead to different results.”

In 2014, a Cochrane review of RCTs on light therapy, including phototherapy, ultraviolet, and laser, for pressure ulcers was published. The few trials available for analysis were of small size and very low quality. The reviewers found the available evidence overall was insufficient to draw conclusion on the effects light therapy on pressure ulcers.

Section Summary: Chronic Wounds
Two systematic reviews of the literature did not find sufficient evidence from controlled studies demonstrating that LLLT is effective for wound healing.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.
Low-Level Laser Therapy

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Original Effective Date:  05/15/2010
Current Effective Date:  03/15/2017

Table 1. Summary of Key Trials

<table>
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<td>Laser Mucite ORL : Effectiveness of Laser Therapy for Mucositis Induced by a Radio-chemotherapy in Head and Neck Cancer (LaserMucite)</td>
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<td>Laser and Therapeutic Ultrasound in the Management of the Chronic Non-specific Low Back Pain</td>
<td>150</td>
<td>May 2014</td>
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<td>NCT02636764</td>
<td>Influence of Using Physical Therapy Resources for Knee Osteoarthritis (osteoarthritis)</td>
<td>100</td>
<td>Dec 2016</td>
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</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Summary of Evidence

The evidence for LLLT in individuals who have increased risk of oral mucositis due to some cancer treatments (eg, chemotherapy, radiotherapy) and/or hematopoietic stem cell transplantation includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Studies included patients undergoing various cancer chemotherapy regimens or hematopoietic stem cell transplantation. A recent systematic review of RCTs on LLLT for prevention of oral mucositis included 18 RCTs, generally considered at low risk of bias, and found statistically significantly better outcomes with LLLT than control conditions on primary and secondary outcomes. In addition, 3 double-blind, RCTs published in 2015 found significantly better outcomes in patients undergoing LLLT than undergoing sham treatment prior to or during cancer treatment. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for LLLT in individuals who have orthopedic pain (ie, neck pain, osteoarthritis knee pain, low back pain, carpal tunnel syndrome) includes RCTs and, for some indications, systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Findings of the RCTs were mixed and had methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcome.

The evidence for LLLT in individuals who have shoulder conditions, heel pain, or temporomandibular joint pain includes RCTs and, for some indications, systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Findings of the RCTs were mixed and had methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcome.

The evidence for LLLT in individuals who have bone, ligament, and joint conditions (eg, rheumatoid arthritis, fibromyalgia) includes RCTs and, for some indications, systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Findings of the RCTs were mixed and had methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcome.
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The evidence for LLLT in individuals who have Bell palsy includes an RCT. Relevant outcomes are change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Bell palsy may completely resolve within months and, thus, it is difficult to determine improvements from laser therapy over the natural resolution of the illness. The available RCT did not include a sham treatment; LLLT was superior to exercise only in this study. Sham-controlled studies are needed as well as additional studies comparing LLLT with alternative Bell palsy treatments. The evidence is insufficient to determine the effects of the technology on health outcome.

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

The evidence for LLLT in individuals who have chronic wounds includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. The few existing RCTs tend to have small sample sizes and risk of bias. The evidence is insufficient to determine the effects of the technology on health outcome.

References
Low-Level Laser Therapy

Policy # 0194
Original Effective Date: 05/15/2010
Current Effective Date: 03/15/2017

13. Cross Blue and Shield Technology Evaluation Center (TEC). Low-level laser therapy for carpal tunnel syndrome and chronic neck pain. TEC Assessment. Nov 2010;Volume 25, Tab 4. PMID 21638940
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Low-Level Laser Therapy

Policy # 0194
Original Effective Date: 05/15/2010
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Current Effective Date: 03/15/2017

Policy History

Original Effective Date: 05/15/2006
Current Effective Date: 03/15/2017

12/07/2005 Medical Director review
12/20/2005 Medical Policy Committee review
01/17/2006 Medical Policy Committee review
01/26/2006 Quality Care Advisory Council approval with processing changes effective 60 days following notification of providers (5/15/06)
03/14/2007 Medical Director review
03/21/2007 Medical Policy Committee approval. Policy updated with literature review. No change to policy guideline.
03/04/2009 Medical Director review
03/18/2009 Medical Policy Committee approval. No change to coverage.
03/05/2010 Medical Policy Committee approval
03/19/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2011 Medical Policy Committee review
03/16/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2012 Medical Policy Committee review
03/21/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Policy updated.
03/07/2013 Medical Policy Committee review
03/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2014 Medical Policy Committee review
03/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2015 Medical Policy Committee review
03/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/03/2016 Medical Policy Committee review
03/16/2016 Medical Policy Implementation Committee approval. Added eligibility statement for oral mucositis and new INV indications.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
03/02/2017 Medical Policy Committee review
03/15/2017 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 03/2018

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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