Low-Level Laser Therapy

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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 (i.e., Achilles tendinopathy, plantar fasciitis)
• Rheumatoid arthritis
• Bell’s palsy
• Fibromyalgia
• Wound healing
• Lymphedema

Background/Overview
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

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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.

One of the primary disorders for which LLLT has been used is cancer therapy–induced oral mucositis in patients treated by radiotherapy and/or chemotherapy and hematopoietic 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 increased 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 is 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.

Another key disorder for which LLLT has been used is carpal tunnel syndrome (CTS). 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 9 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. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of low-level lasers have been cleared for marketing by the U.S. FDA through the 510(k) process for the treatment of pain. Data submitted for the MicroLight 830 Laser consisted of application of the laser over the carpal tunnel 3 times a week for 5 weeks. The labeling states that the "MicroLight 830 Laser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome." In 2006, GRT LITE was cleared for marketing, listing the TUCO Erchonia PL3000, the Excalibur System, the MicroLight 830 Laser, and the Acculaser Pro as predicate devices. Indications of the GRT LITE for carpal tunnel syndrome 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...
FDA through the 510(k) process for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice. A number of clinical trials of low-level laser therapy 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 CTS, are relief of pain and/or functional status. Relief of pain is a subjective outcome 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: (1) in patients with mild-to-moderate symptoms, LLLT may be compared with other forms of conservative therapy such as splinting, rest, nonsteroidal anti-inflammatory drugs, or steroid injection; and (2) in patients who have exhausted conservative therapy. The following is a summary of the key findings to date.

**PREVENTION OF 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 cell transplantation (HCT) conditioned with high-dose chemotherapy and for patients undergoing head and neck radiotherapy, without concomitant chemotheray, without concomitant chemotherapy. The 2014 systematic review included 24 trials on a variety of prophylactic treatments. Recommendations for the use of LLLT for prevention of oral mucositis in patients receiving HCT were based on what reviewers considered to be 1 well-designed, placebo-controlled, randomized trial by Schubert et al (described in more detail next), together with “weaker evidence” from 3 observational studies that showed positive results. This 2007 phase 3 trial was double-blind and sham-controlled with 70 patients. 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 (650 nm, 16.7; 780 nm, 20.6; placebo, 24.3), 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 trial, 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. Trial limitations included lack of statistically significant findings for the primary outcome measure and had a very small percentage of patients with pain assessments. Overall, as relates to the 3
observational studies, reviewers noted 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 comparing LLLT to no treatment or placebo for oral mucositis. Eight RCTs assessed patients undergoing HCT, 8 evaluated head and neck cancer patients receiving radiotherapy or chemoradiation, and the rest studied patients with other conditions receiving chemotherapy. Reviewers used the Cochrane risk of bias tool to evaluate the RCTs. Most 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 (n=689 patients) were included in a pooled analysis for this outcome. The overall incidence of severe mucositis (grades 3-4) decreased with prophylactic LLLT, with a relative risk (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.

Two of the larger RCTs evaluating LLLT for prevention of oral mucositis were published by Gautam et al in 2012. One reported LLLT for the prevention of chemoradiotherapy-induced oral mucositis in 121 oral cancer patients. The other 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 gray (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 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 led 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, 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. Patients received LLLT as described above. Patients in the LLLT
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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, randomized trials on prevention of oral mucositis in patients undergoing cancer treatment were published. Gautam et al (2015) 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 (2015) 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. Ferreira et al (2016) included 36 patients with hematologic cancer undergoing HCT. 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: Prevention of 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 adults receiving HCT conditioned with high-dose chemotherapy. Review of the key study evaluated by the MASCC/ISOO investigators for this recommendation revealed limitations that included statistically nonsignificant findings 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 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 with control conditions on primary and secondary outcomes. In addition, 3 double-blind RCTs published in 2015 and 2016 found significantly better outcomes in patients undergoing LLLT compared with sham treatment prior to or during cancer treatment.

CARPAL TUNNEL SYNDROME
In 2010, a TEC Assessment evaluated LLLT for CTS and chronic neck pain. For inclusion in the Assessment, studies had to: be published in a peer-reviewed journal; be a randomized, sham-controlled trial, and, if adjunctive therapies were used, they had to have been applied to both groups; and measure outcomes at least 2 weeks beyond the end of the treatment period. Four RCTs met the inclusion criteria. Reviewers concluded that the studies had serious limitations, including small sample sizes and limited follow-up, and no study was so methodologically sound as to provide definitive results.

In 2016, Li et al published a meta-analysis of RCTs on LLLT for CTS. Reviewers identified 7 RCTs. Meta-analyses evaluated outcomes for hand grip strength, pain measured by a VAS, symptom severity scores, and functional status scores. Short-term follow-up was defined as less than 6 weeks after treatment and long-term follow-up as at least 12 weeks after treatment. For 6 of the 8 meta-analyses, there were not statistically significant between-group differences in outcomes. They included short-term assessment of...
hand grip, short-term assessment of pain (VAS), and short- and long-term assessment of symptom severity and functional status scores. Meta-analyses found stronger hand grip (3 studies) and greater improvement in VAS scores (2 studies) at the long-term follow-up in the LLLT group than in the control. Most data for these 2 positive analyses were provided by a single RCT (Fusakul et al [2014]). Reviewers concluded that additional high-quality trials with similar LLLT protocols would be needed to confirm that the intervention significantly improves health outcomes.

**Section Summary: Carpal Tunnel Syndrome**

A number of RCTs and several systematic reviews have been published. The most recent systematic review (2016) identified 7 RCTs. Meta-analyses did not find a significant benefit of LLLT compared with a control condition for most of the outcome measures (6 of 8). Previously in 2010, a TEC Assessment concluded that the evidence from sham-controlled RCTs was insufficient. More recent RCTs have not found that LLLT significantly improves outcomes.

**NECK PAIN**

The 2010 TEC Assessment, which included 6 trials of LLLT for chronic neck pain, found inconsistent results. In the largest study (Chow et al, 2006), 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 for the active LLLT group while the sham-treated group improved by 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, reviewers 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 trials showed improved outcomes with LLLT compared with placebo for acute neck pain, acute radiculopathy, and cervical osteoarthritis, but they were considered to be low quality. There was conflicting evidence on chronic myofascial neck pain.

**Section Summary: Neck Pain**

A number of RCTs and several systematic reviews have been published. A 2013 systematic review identified 17 trials. Only 2 trials considered moderate quality found that LLLT led to better outcomes than placebo for chronic neck pain. Other trials were considered low quality. A 2010 TEC Assessment found conflicting evidence. While some studies showed positive benefits with LLLT over placebo, others did not. Additionally, laser types, dosages, and treatment schedules varied in the available evidence.
SUBACROMIAL IMPINGEMENT SYNDROME
Several RCTs evaluating LLLT for treatment of subacromial impingement syndrome 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 than with sham. A third RCT, by Abrisham et al (2011), compared exercise plus pulsed LLLT or sham laser 5 times a week for 2 weeks in 80 patients with subacromial syndrome (rotator cuff and biceps tendinitis). At the end of treatment, although both groups had improved VAS scores for pain and shoulder range of motion (ROM), the improvements were significantly better for the active LLLT group than for the sham laser group for pain (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 have not shown 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 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 Angeles shoulder pain 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, ultrasound, or exercise. Patients were treated 5 days a week for 3 weeks with hotpack plus ultrasound plus exercise, hotpack plus LLLT plus exercise, or hotpack plus exercise. All 3 groups showed improvement from baseline to posttreatment in pain at rest, ROM, and function, but between-group improvements with LLLT were not statistically significant.

Section Summary: Subacromial Impingement Syndrome
The literature on LLLT for subacromial impingement syndrome consists of several RCTs. Most trials failed to show a significant benefit of LLLT compared with sham treatments or alternative interventions (eg, exercise).

ADHESIVE CAPSULITIS (FROZEN SHOULDER)
A 2014 Cochrane review evaluated LLLT and other electrotherapy modalities for adhesive capsulitis, also known as frozen shoulder. Reviewers found limited evidence on which to draw conclusions about the effectiveness of electrotherapy modalities for frozen shoulder. Only 1 RCT (N=40 patients) compared LLLT with placebo. That trial administered LLLT for 6 days. On day 6, patients receiving LLLT showed some improvement on a global assessment of treatment success compared with patients receiving placebo. However, this trial was considered of low quality, and its small sample size and short follow-up limited interpretation of results. Another RCT on LLLT discussed in the 2014 Cochrane review was assessed as of moderate quality. In that RCT by Stergioulas (2008), 63 patients with frozen shoulder were randomized to an 8-week program of LLLT (n=31) or to 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 and 8 weeks of treatment, and at the end of 8 more weeks of follow-up. At the same assessment intervals, significant decreases in SPADI scores and Croft Shoulder Disability Questionnaire scores were observed, while significant decreases in Disability of Arm, Shoulder, and Hand Questionnaire scores were observed at 8 weeks of treatment and at 16 weeks post-randomization; significant decreases in Health Assessment Questionnaire scores were observed at 4 weeks and 8 weeks of treatment.

Section Summary: Adhesive Capsulitis
A Cochrane review on treatments for adhesive capsulitis identified 2 RCTs on LLLT for adhesive capsulitis and, due to the small number of trials and study limitations, concluded that the evidence was insufficient to draw conclusions on the effectiveness of LLLT for adhesive capsulitis.

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 randomized trials were identified. Ten provided data on pain, as measured by a VAS. 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 opening) favoring LLLT. 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. RCTs included in the review compared LLLT with no treatment or placebo and were single- or double-blind. The primary outcome of interest was pain measured by a VAS. Six studies (total N=223 patients) were eligible inclusion in the meta-analysis. In a meta-analysis, reduction in VAS scores after treatment was significantly greater in the LLLT group than in the control group (pooled effect size [ES], -0.6, 0.6; 95% CI, -0.47 to -0.73).

Section Summary: Temporomandibular Joint Pain
There are a number of RCTs on LLLT for TMJ pain and several systematic reviews. Meta-analyses of these trials had mixed findings. The most recent meta-analysis, which included 14 placebo-controlled randomized trials, did not find a statistically significant impact of LLLT on pain, but did find that LLLT significantly improved function outcomes (eg, mouth opening). RCTs have not compared the impact of LLLT with physical therapy on health outcomes.

LOW BACK PAIN
A number of RCTs and several systematic reviews of RCTs have been published. Most recently, Glazov et al (2016) published a meta-analysis of blinded sham-controlled trials evaluating LLLT for treatment of chronic low back pain. Fifteen RCTs (total n=1039 patients) met reviewers’ eligibility criteria. Reviewers found that 3 of the 15 trials were at higher risk of bias (using a modified Cochrane risk of bias tool), mainly
due to lack of blinding. The primary outcomes of interest to reviewers were pain measured by a VAS or a numeric rating scale, and a global assessment measure evaluating overall improvement and/or satisfaction with the intervention. Outcomes were reported immediately posttreatment (<1 week) and at short-term (1-12 weeks) follow-up. Longer term outcomes (ie, at 6 and 12 months) were secondary measures. For the pain outcome, meta-analysis of 10 trials found significantly greater reduction in pain scores in the LLLT group at immediate follow-up (WMD = -0.79 cm; 95% CI, -1.22 to 0.36 cm). In a meta-analysis of 6 trials, there was no significant difference in pain reduction at short-term follow-up. However, in subgroup analyses, there was significantly greater reduction in pain with LLLT in trials that used a higher dose (>3 J/point), but not a lower dose, and in trials that included patients with a short duration of back pain (5-27 months) but not long duration (49 months to 13 years). Decisions on the cutoff to use for laser dose and duration of back pain were made post hoc and considered review findings. Findings were similar for the global assessment outcome. Meta-analyses found significantly higher global assessment scores at immediate follow-up (5 trials) but not at short-term follow-up (3 trials). Only 2 trials reported pain or global assessment at 6 months and 12 months and neither found statistically significant differences between the LLLT and sham groups.

In 2015, Huang et al published a systematic review of RCTs on LLLT for treatment of nonspecific chronic low back pain. Reviewers included trials comparing LLLT and placebo that reported pain and/or functional outcomes and reported a PEDro quality score. Seven trials (total N=394 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, reviewers 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 difference between the LLLT and the placebo groups (WMD = -2.89; 95% CI, -7.88 to 2.29). Outcomes were only reported immediately after treatment.

Section Summary: Low Back Pain
The literature on LLLT for low back pain consists of RCTs and several systematic reviews of RCTs. Meta-analyses 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. However, meta-analyses also found that other outcomes (eg, disability index, ROM) were significantly better immediately after treatment with active versus placebo LLLT and did not find significant benefit of LLLT at longer term follow-up.

OSTEOARTHRITIC KNEE PAIN
Several RCTs and systematic review of RCTs have evaluated LLLT for treatment of knee osteoarthritis. In 2015, Huang et al published a systematic review 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. Nine 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 $\geq 7$; maximum score, 11 points). Primary outcomes were posttreatment pain measured by VAS scores and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores (pain, 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 function scores. The secondary outcome (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 selected 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. Reviewers did not report findings of pooled analyses on LLLT for knee osteoarthritis. In a general qualitative analysis, they found that all the physical interventions but 2 (manual acupuncture, ultrasound) showed better results with active treatment over placebo.

**Section Summary: Osteoarthritic 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.

**HEEL PAIN**
**Achilles Tendinopathy**
Stergioulas et al (2008) 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 assessed on a VAS were significantly lower in the exercise with LLLT group at 4 ($p<0.001$), 8 ($p<0.001$), and 12 weeks ($p=0.007$) after randomization.

Tumilty et al (2012) reported on 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 performed twice a day for 12 weeks. The primary outcome was the Victorian Institute of Sport Assessment–Achilles Questionnaire (VISA-A) at 12 weeks. The only significant difference between groups using ITT analysis was at 4 weeks for VISA-A scores, and that 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 and it 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 feet (5.3 mm) compared with asymptomatic feet (3.0 mm). Plantar fascia thickness decreased in both the LLLT and the sham groups during the trial. Although plantar fascia thickness after 6 weeks of treatment did not differ significantly between groups (3.6 mm in LLLT vs 4.4 mm in sham), there was a significant between-groups difference in the reduction 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 for 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 randomized trials 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.

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 a 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 rheumatoid arthritis, relative to a control group using the opposite hand (1 study), no difference was observed between the control and treatment hand for morning stiffness duration and no significant improvement in pain relief. Reviewers 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 for pain reduction and improvement in hand function in 82 patients with rheumatoid arthritis treated with LLLT or placebo laser was reported by Meireles et al. There were no statistically significant differences between groups for most outcome measurements, including the primary variables, though a few measures significantly favored either...
the active or placebo treatment. Reviewers concluded that LLLT at the dosage used in the study was not effective for the treatment of hands among patients with rheumatoid arthritis.

Section Summary: Rheumatoid Arthritis
A Cochrane review of 5 placebo-controlled RCTs found a significant benefit of LLLT on some outcomes (eg, VAS) but not others (eg, functional assessment). A 2010 RCT, published after the Cochrane review, did not find that LLLT was significantly better than a placebo treatment for most outcomes.

BELLS 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 greatest improvement seen with high-intensity laser.

Section Summary: Bell Palsy
One RCT was identified and it found significant short-term benefit of LLLT over exercise but long-term outcomes were not available. The limited evidence on laser therapy for Bell palsy is insufficient to draw conclusions. Because Bell palsy often improves within weeks and may resolve completely 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 were available.

FIBROMYALGIA
Several small RCTs evaluating LLLT for 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 with active than with sham LLLT posttreatment. 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 plus stretching exercises or stretching alone. Outcome measures were VAS scores and dolorimetry at tender points, quality of life 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.
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Section Summary: Fibromyalgia
Few RCTs evaluating LLLT for fibromyalgia are available; the existing trials are small (ie, <25 patients each). One RCT (N=20 patients) found significantly better outcomes with LLLT than with sham, and another RCT (N=20 patients) did not find statistically significant between-group differences for similar outcomes. Additional RCTs with sufficient numbers of patients are needed.

CHRONIC NONHEALING 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 of very low quality. The reviewers found the available evidence overall insufficient to draw conclusion on the effects light therapy on pressure ulcers.

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

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. Reviewers 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 (2012) published a qualitative systematic review of LLLT for the management of breast cancer-related lymphedema. They included 8 studies (total N=230 patients) in their 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). Reviewers noted major methodologic flaws and little uniformity in trial designs.

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One of the larger double-blind RCTs was published in 2011 by Omar et al; it reported on 50 patients with postmastectomy lymphedema. The average length of time that patients had swelling was 14 months (range, 12-36 months). They 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 cm vs 2 cm) 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.

SUMMARY OF EVIDENCE
For individuals who have increased risk of oral mucositis due to some cancer treatments (eg, chemotherapy, radiotherapy) and/or hematopoietic cell transplantation who receive LLLT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. A 2014 systematic review included 18 RCTs and found better outcomes with LLLT used to prevent oral mucositis than with control treatments. RCTs published after the systematic review had similar findings. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have carpal tunnel syndrome who receive LLLT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Both a 2016 systematic review and a 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A 2013 systematic review identified 17 trials, most of which were considered low quality. Only 2 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related
morbidity. Most trials did not show a significant benefit of LLLT compared with sham treatment or with an alternative intervention (eg, exercise). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have adhesive capsulitis who receive LLLT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A Cochrane review on treatments for adhesive capsulitis identified 2 RCTs assessing LLLT. Due to the small number of trials and study limitations, reviewers concluded that the evidence was insufficient to permit conclusions about the effectiveness of LLLT for adhesive capsulitis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have temporomandibular joint pain who receive LLLT, the evidence includes RCTs and several systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. 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 (eg, mouth opening). RCTs have not compared the impact of LLLT with physical therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have low back pain who receive LLLT, the evidence includes RCTs and systematic reviews. Meta-analyses of RCTs found that LLLT resulted in a significantly greater reduction in pain scores and global assessment scores than a placebo control in the immediate posttreatment setting. Meta-analyses also found that other outcomes (eg, disability index, range of motion) were significantly better immediately after treatment with active rather than placebo LLLT, but not at longer term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteoarthritic knee pain who receive low LLLT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A 2015 systematic review, which pooled study findings, did not find that LLLT significantly improved pain or functional outcomes compared with a sham intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heel pain (ie, Achilles tendinopathy, plantar fasciitis) who receive LLLT, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Findings of sham-controlled RCTs were inconsistent and there were no RCTs comparing LLLT to an alternative treatment for heel pain. Moreover, studies offered limited long-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have rheumatoid arthritis who receive low LLLT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity.
related morbidity. A systematic review of RCTs found inconsistent benefit of LLLT for a range of outcomes. A 2010 RCT, published after the systematic review, did not find that LLLT was significantly better than a placebo treatment on most outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Bell palsy who receive LLLT, the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT found significant short-term benefit of LLLT over exercise. Longer term outcomes (>6 weeks) were not available. Because Bell palsy often improves within weeks and may completely resolve within months, it is difficult to isolate specific improvements from laser therapy over the natural resolution of the illness. 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCTs evaluating LLLT for treatment of fibromyalgia are small (ie, <25 patients each). One RCT (N=20 patients) found significantly better outcomes with LLLT than with sham, while another (N=20 patients) did not find statistically significant between-group differences for similar outcomes. Additional RCTs with sufficient numbers of patients are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic nonhealing wounds who receive LLLT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The few existing RCTs tend to have small sample sizes and potential risk of bias. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

References

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13. Blue Cross and Blue 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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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

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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.
03/01/2018 Medical Policy Committee review
03/21/2018 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 03/2019

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