

Cigna Medical Coverage Policy- Therapy Services Low-Level Laser and High-Power Laser Therapy

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GUIDELINES

Low-level laser therapy (LLLT) is considered experimental, investigational or unproven for any indication, including but not limited to:

- Wound healing
- Musculoskeletal pain; (e.g. back and neck pain, carpal tunnel syndrome, lateral epicondylitis, shoulder impingement, myofascial pain syndrome, fibromyalgia and others)
- Osteoarthritis and rheumatoid arthritis
- Temporomandibular joint disorders

High-power Class IV therapeutic laser light therapy or similar therapeutic laser light therapy is considered experimental, investigational, or unproven for all indications.

This Coverage Policy addresses low-level laser therapy (LLLT), also referred to as cold laser therapy, low-power laser therapy (LPLT), low-intensity laser and low-energy laser therapy and high power Class IV therapeutic laser light therapy.

This coverage policy does not address surgical lasers, which involve vaporizing tissue with hot lasers.

GENERAL BACKGROUND

Laser or low level laser therapy (LLLT) has been proposed as a modality used to accelerate and optimize the tissue repair process (Rocha et al., 2007). Laser stands for Light Amplification by Stimulated Emission of Radiation. LLLT is theoretically applied to photoactivate cellular mechanisms, leading to healing and normalization of tissue. The proposed result is reduced pain, inflammation, swelling, and accelerated tissue repair. Therapeutic lasers emit low-energy density but high enough to stimulate target cells with energy. Laser radiation is thought to be absorbed through cytochromes in the mitochondria and converted into ATP by the cell which acts to synthesize protein, mRNA and DNA, and accelerate cell proliferation based on the tissue receiving the light energy (Reddy 2004; Enwemeka 2004; Cameron, 2013).

More recently high power Class IV Therapeutic Laser Light Therapy devices have been used therapeutically. U.S. Food and Drug Administration (FDA) approved High Power Class IV therapeutic laser light therapy produces 7,500 milliwatts of continuous power. It is administered with a hand-held device and is thought to provide deeper penetration over a larger surface area. Per the manufacturer, Diowave (formerly Avicenna Laser Technology, Inc): the High Power, Class IV, therapeutic laser technology is used as a stand-alone modality to produce increased circulation, decreased inflammation, relaxation of muscle spasms and trigger points, accelerated tissue repair, and decreased pain at tissue sites previously unreachable by low-level stimulation. They are purported to stimulate accelerated healing energy from superficial to deep levels and a larger surface treatment area. Its proposed use includes conditions such as arthritis, carpal tunnel syndrome, epicondylitis, sprains/strains, trigger points and various other musculoskeletal disorders.

LLLT may be administered by several different types of providers, including physicians, chiropractors, physical therapists, or occupational therapists. It is generally provided in an office or other outpatient setting with no anesthesia or sedation needed.

Evidence and Research

There are numerous randomized trials on various applications of LLLT and some show positive results. The difficulty in interpreting these results is that they represent a wide range of conditions, methods of application, and characteristics of the laser instruments themselves. As such, it is difficult to come to any general conclusions regarding the effectiveness of LLLT. In 2006, the World Association of Laser Therapy (WALT) established effective parameters and methods of application as a guideline for investigators to follow. These guidelines state that power densities below 100 mW/cm² should be used for superficial tendons with an energy dose range of 1-8 Joules. For deeper tendons of the rotator cuff, power densities can go as high as 600 mW/cm², with an energy dose of 3-9 Joules. Wavelengths should be in the range of 780-904 nm. These guidelines allow researchers to selectively analyze studies that fall into these parameters to evaluate effectiveness (WALT, 2006).

Literature Review – Joint Pain and Osteoarthritis (OA)

Several systematic reviews have been published regarding LLLT for treatment of joint pain and osteoarthritis. In general they are inconsistent in the findings and do not substantiate the effectiveness of this treatment for these conditions.

Bjorndal et al. (2003) performed a systematic review that included 7 randomized, placebo controlled trials where an adequate dose of laser therapy was applied to a chronic joint disorder. These authors found a weighted mean difference of 29.84 mm on the pain visual analog scale (VAS) following laser treatment for knee pain, temporomandibular pain, or zygapophyseal joints. They concluded that LLLT significantly reduces pain and improves health status in chronic joint disorders when parameters are within the suggested dose range. However, the review also notes that the results should be cautiously interpreted due to the heterogeneity in patient samples, treatment procedures, and trial design.

A systematic review of rehabilitative interventions was conducted to assess various rehabilitative interventions on pain, function and physical impairments in hand osteoarthritis (Ye, et al., 2011). There were two studies included in the review that addressed LLLT. It was found that there was no effect on pain with LLLT, but it may be useful for improving range of motion.

A systematic review of conservative interventions for osteoarthritis of the hand concluded that there is moderate evidence that low-level laser therapy is no better than placebo in improving hand function or decreasing hand pain or stiffness (Valdes and Marik, 2010). An overview of systematic reviews for physical therapy interventions for knee osteoarthritis (OA) did confirm moderate evidence to support the effectiveness of low level laser therapy for knee OA (Ottawa Panel Evidence-Based Clinical Practice Guidelines, 2004; Jamtvedt et al., 2008). In a systematic review, Jang and Lee (2012) investigated the clinical effectiveness of LLLT on joint pain. Twenty-two trials were included consisting of 1014 patients. Eleven trials were positive and 11 were negative. The change in pain ratings was in favor of the active LLLT groups. In trials where the WALT guidelines were followed, the mean effect sizes were in favor of the true LLLT groups. This review supported the use of laser therapy for reduction of joint pain, especially when restricting the energy doses to the ranges stated in WALT guidelines.

Huang et al. (2015b) investigated the efficacy of low-level laser therapy (LLLT) treatment of knee osteoarthritis (KOA) by a systematic literature search with meta-analyses on selected studies. Nine Studies included were randomized controlled trials (RCTs) written in English that compared LLLT (at least eight treatment sessions) with sham laser in KOA patients dated from January 2000 to November 2014. No significant difference was identified in studies conforming to the World Association of Laser Therapy (WALT) recommendations (four studies) or on the basis of OA severity. There was no significant difference in the delayed response (12 weeks after end of therapy) between LLLT and control in VAS pain (five studies). Similarly, there was no evidence of LLLT effectiveness based on Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain, stiffness or function outcomes (five and three studies had outcome data right after and 12 weeks after therapy respectively). Authors concluded that their findings indicated the effectiveness of LLLT for patients with KOA is not supported based on the best available current evidence.

Dima et al. (2017) presented a summary of the possible pain management benefits of LLLT. LLLT, using the properties of coherent light, has been seen to produce pain relief and fibroblastic regeneration in clinical trials and laboratory experiments. LLLT has also been seen to significantly reduce pain in the acute setting; it is proposed that LLLT is able to reduce pain by lowering the level of biochemical markers and oxidative stress, and the formation of edema and hemorrhage. Many studies have demonstrated analgesic and anti-inflammatory effects provided by photobiomodulation in both experimental and clinical trials. Authors concluded that based on current research, the utilization of LLLT for pain management and osteoarthritic conditions may be a complementary strategy used in clinical practice to provide symptom management for patients suffering from osteoarthritis and chronic pain.

Alfredo et al. (2018) assessed the long-term effects of LLLT, in combination with strengthening exercises in patients with osteoarthritis of the knee. Forty participants of both genders, aged 50-75 years with knee osteoarthritis participated in the study. The LLLT group received 10 LLLT treatments with invisible infrared laser (904 nm, 3 Joules/point) over three weeks followed by an eight-week supervised strengthening exercise program. The placebo LLLT group received identical treatment, but the infrared laser output was disabled. The new data obtained during the follow-up period showed that all outcomes remained stable and there were no significant differences between the groups at three and six months. However, daily consumption of rescue analgesics was significantly lower in the LLLT group throughout the follow-up period, ending at a group difference of 0.45 vs. 3.40 units ($P < 0.001$) at six months follow-up. Authors concluded that within the limitations of this small study, the previously reported immediate post-intervention improvement after LLLT plus exercise was maintained for a period of six months.

Literature Review – Shoulder Pain

Several systematic reviews have been published regarding LLLT for treatment of shoulder pain. In general they are inconsistent in the findings and do not substantiate the effectiveness of this treatment for these conditions.

Haslerud et al. (2015) performed a systematic review with meta-analysis on shoulder tendinopathy and LLLT. The primary outcome measure was pain using the visual analogue scale (VAS) and relative risk for global improvement. Intervention quality assessments were performed of LLLT dosage and treatment procedures according to World Association for Laser Therapy guidelines. Seventeen randomized controlled trials (RCTs) met the inclusion criteria; 13 RCTs were of high and 4 RCTs of moderate methodological quality. Trials performed with inadequate laser doses were ineffective across all outcome measures. Otherwise this review demonstrated that optimal LLLT offers clinically relevant pain relief and improvement alone and in combination with other physical therapy interventions.

A systematic review for treatment of subacromial impingement did find laser therapy effective compared to placebo based on two RCTs, but it added no benefit when added to ROM exercises (Michener et al., 2004). Several randomized studies conducted for shoulder pain did not find significant results from the treatment with LLLT (Bal, et al., 2009; Dogan, et al., 2010; Abrisham, et al., 2011).

Aceituno-Gómez et al. (2019) evaluated the effectiveness of high-intensity laser therapy on shoulder pain and function in subacromial impingement syndrome. A total of 46 participants with subacromial impingement syndrome. A total of 21 patients in high-intensity laser therapy group and 22 patients in sham-laser group concluded the study. No differences were found between groups for pain and disability ($P > 0.05$). Authors concluded the effect of high-intensity laser therapy plus exercise is not higher than exercise alone to reduce pain and improve functionality in patients with subacromial syndrome.

Literature Review – Carpal Tunnel Syndrome

Several systematic reviews have been published regarding LLLT for treatment of carpal tunnel syndrome. In general they are inconsistent in the findings and do not substantiate the effectiveness of this treatment for these conditions.

The American Academy of Orthopaedic Surgeons (AAOS) published clinical practice guidelines on the treatment of carpal tunnel syndrome (AAOS, 2016). In the guidelines, regarding laser treatment, it is noted that, "Limited evidence supports that laser therapy might be effective compared to placebo." (Strength of Recommendation: Limited Evidence. Limited evidence: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study for recommending for or against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.)

Peters et al. (2013) reported on a Cochrane review that examined the effectiveness of rehabilitation following carpal tunnel syndrome (CTS) surgery compared with no treatment, placebo, or another intervention. The review found limited and low quality evidence for the benefit of the reviewed treatments, including laser therapy. The review included one quasi-randomized trial which compared LLLT to a placebo laser. This study found that there was no statistically significant difference in CTS symptoms with low-level laser therapy compared with a placebo. An update to this review (Peters, et al., 2016) included no new studies and similar findings regarding LLLT for rehabilitation following CTS.

Li et al. (2016) reported on a meta-analysis that was conducted to evaluate the effectiveness of low-level laser in the treatment of mild to moderate CTS using a Cochrane systematic review. The review included seven randomized clinical trials with 270 wrists in the laser group and 261 wrists in the control group with high heterogeneity noted when the analysis was conducted. Hand grip (at 12 weeks) was stronger in the LLLT group than in the control group and there was better improvement in the visual analog scale (VAS) (at 12 weeks) in the LLLT group. The sensory nerve action potential (SNAP) (at 12 weeks) was better in the LLLT group. It was noted that one included study was weighted at >95% in the calculation of these three parameters. There were no statistically significant differences in the other parameters between the two groups. The authors concluded that that low-level laser improved hand grip, VAS, and SNAP after three months of follow-up for mild to moderate CTS, however, additional high-quality studies using the same laser intervention protocol are needed to confirm the effects of low-level laser in the treatment of CTS.

Bekhet et al. (2017) performed a meta-analysis to investigate the efficacy of low-level laser therapy (LLLT) with anti-inflammatory and analgesic effects, in the management of mild-to-moderate carpal tunnel syndrome (CTS). Eight RCTs (473 patients/631 wrists) were eligible for the final analysis. The overall effect estimates did not favor LLLT therapy group over placebo in all primary outcomes: visual analogue scale, symptom severity scale score, and functional status scale score. However, LLLT was superior to placebo in terms of grip strength and inferior to placebo in terms of sensory nerve action potential. Authors concluded that laser therapy is superior to placebo in terms of improving the grip strength; however, no significant difference was found between both groups in terms of functional status improvement, pain reduction, or motor electrodiagnostic evaluations. Further high-quality trials with longer follow-up periods are required to establish the efficacy of LLLT for CTS treatment.

Franke et al. (2018) systematically reviewed the literature on the effectiveness of low-level laser therapy for patients with carpal tunnel syndrome. Strong evidence was found for the effectiveness of low-level laser therapy

compared to placebo treatment in the very short term (0≤5 weeks). After five weeks, the positive effects of low-level laser therapy on pain, function, or recovery diminished over time (moderate and conflicting evidence were found at seven and 12-weeks follow-up, respectively). Authors concluded that in the very short term low-level laser therapy is more effective as a single intervention than placebo low-level laser therapy in patients with carpal tunnel syndrome, after which the positive effects of low-level laser therapy tend to subside. Evidence in the mid and long term is sparse.

Literature Review – Myofascial Pain

For myofascial pain, a randomized controlled study comparing laser treatment with placebo for treatment of myofascial pain found no differences in results between the groups, with both groups achieving some analgesic effect (Carrasco et al., 2009). In a randomized controlled trial of 63 participants with myofascial pain syndrome of the shoulder and neck area, Rayegani et al. (2011) compared LLLT, sham LLLT, and ultrasound (US) and measured pain using the VAS, disability using the Neck Disability Index (NDI), and an algometric assessment of improvement. Each group also received exercises. After 10 sessions of daily treatment, results demonstrated that use of laser therapy demonstrated significant improvements when compared with the sham laser group and also between pre- and post-intervention scores in pain and NDI. There were no significant differences related to pain between LLLT and US; however, the NDI showed more improvement with laser treatment. The authors recommended further study with larger patient populations (Rayegani et al., 2011).

Literature Review – Low Back Pain

Several systematic reviews have been published regarding LLLT for treatment of low back pain. In general they are inconsistent in the findings and do not substantiate the effectiveness of this treatment for these conditions.

Yousefi-Nooraie et al. (2008) conducted a Cochrane review that included seven studies and examined LLLT for nonspecific low-back pain. The authors concluded that based on the heterogeneity of the populations, interventions and comparison groups, “that there are insufficient data to draw firm conclusion on the clinical effect of LLLT for low-back pain.” In addition the authors note that there is a need for further methodologically rigorous randomized, controlled trials to evaluate the effects of LLLT compared to other treatments, different lengths of treatment, wavelengths and dosage.

A review of evidence was conducted for the development of an American Pain Society /American College of Physicians clinical practice guideline for diagnosis and treatment of low back pain (Chou and Huffman, 2007). The review examined nonpharmacologic therapies for acute and chronic low back pain and included only systematic reviews and randomized trials, with seven trials that included LLLT. Four trials found laser therapy superior to sham for pain or functional status up to one year after treatment, but another higher-quality trial found no differences between laser and sham in patients receiving exercise. One lower-quality study reported found similar results for laser, exercise and the combination of laser plus exercise for pain and back-specific functional status. It was noted that optimal treatment parameters, wavelength, dosage, dose intensity are uncertain.

Glazov et al. (2016) reported on a systematic review to determine if LLLT (including laser over acupuncture points) has specific benefits in chronic non-specific low back pain (CNLBP). The review included 15 studies with 1039 participants. The results at immediate and short-term follow-up there was significant pain reduction of up to WMD (weighted mean difference) -1.40 cm in favor of laser treatment, occurring in trials using at least 3 Joules (J) per point, with baseline pain <30 months and in non-acupuncture LLLT trials. Global assessment showed a risk ratio of 2.16 (95% CI 1.61 to 2.90) in favor of laser treatment in the same groups only at immediate follow-up. While there appears to be a benefit with LLLT in the short term, further randomized studies with blinding and longer follow-up are needed to determine the appropriate laser dosage.

Huang et al. (2015b) completed a systematic review and meta-analysis on the effectiveness of low-level laser therapy for nonspecific chronic low back pain. Among 221 studies, seven trials met inclusion criteria. Based on five studies, pain outcome scores were significantly lower for the LLLT group compared with placebo. No significant treatment effect was identified for disability scores or spinal range of motion. The authors concluded that findings indicate LLLT is an effective method for relieving pain in non-specific chronic low back pain (NSCLBP) patients, which contradicts other previous findings.

The Agency for Healthcare Research and Quality (AHRQ) published a review of the comparative effectiveness of non-invasive treatments for low back pain (Chou, et al., 2016). The review included randomized, controlled

trials, along with systematic reviews of randomized controlled trials. Regarding LLLT for acute back pain, the strength of evidence (SOE) was found to be insufficient, and for LLLT for chronic back pain, the SOE was found to be low to insufficient. Among the findings of the review for LLLT for back pain:

- For acute low back pain, insufficient evidence from one trial to determine effectiveness of low-level laser therapy versus sham laser, due to serious methodological shortcomings and imprecision (Strength of evidence [SOE]: insufficient).
- For chronic low back pain, three of four trials found low-level laser therapy more effective than sham laser for pain, with the methods for assessing pain and duration of follow-up varied; two trials found low-level laser therapy more effective than sham laser for function, with small magnitude of effects (SOE: low for pain and function).
- For chronic low back pain, there was insufficient evidence from three trials to determine effects of low-level laser therapy plus exercise versus the other sham laser plus exercise alone, due to methodological shortcomings and inconsistency (SOE: insufficient).
- There was insufficient evidence to determine effects of low-level laser therapy versus another intervention, due to methodological shortcomings and imprecision (SOE: insufficient).
- There was insufficient evidence to determine effects of different wavelengths of low-level laser therapy or different doses, due to methodological limitations and imprecision (SOE: insufficient).

Choi et al. (2017) examined the effects of High Intensity Laser Therapy on pain and function of patients with chronic back pain. This study evenly divided a total of 20 patients with chronic back pain into a conservative physical therapy group that received conservative physical therapy, and a high intensity laser therapy group that received High Intensity Laser Therapy after conservative physical therapy. All patients received the therapy three times a week for four weeks. For the high intensity laser therapy group, treatment was applied to the L1-L5 and S1 regions for 10 minutes by using a high intensity laser device while vertically maintaining the separation distance from hand-piece to skin at approximately 1 cm. A visual analog scale was used to measure the pain and Oswestry Disability Index was used for functional evaluation. In a within-group comparison of the conservative physical therapy and high intensity laser therapy groups, both the visual analog scale and Oswestry Disability Index significantly decreased. In a between-group comparison after treatment, the high intensity laser therapy group showed a significantly lower visual analog scale and Oswestry Disability Index than the conservative physical therapy group. Authors concluded that High Intensity Laser Therapy can be an effective nonsurgical intervention method for reducing pain and helping the performance of daily routines of patients who have chronic back pain.

Literature Review – Neck Pain

Several systematic reviews have been published regarding LLLT for treatment of neck pain. In general they are inconsistent in the findings and do not substantiate the effectiveness of this treatment for these conditions. A meta-analysis and systematic review by Chow et al. (2009) concluded that there is moderate evidence that low level laser therapy reduces pain immediately after treatment in subjects with chronic neck pain and up to 22 weeks after treatment. Low level laser therapy compares favorably with pharmacologic interventions, with no adverse reactions or side effects (Chow et al., 2009). However, reviewers of the systematic review have expressed concerns regarding statistical application and the highly heterogeneous nature of the groups in terms of diagnosis and treatments (Verhagen and Schellingerhout, 2010; Shiri and Viikari-Juntura et al., 2010).

In 2013, Kadhim-Saleh et al. attempted to determine the efficacy of LLLT in reducing acute and chronic neck pain. Eight RCTs involving 443 patients were selected. Five trials included patients with cervical myofascial pain syndrome (CMPS), and three trials had a variety of patient conditions. Results of the review provided inconclusive evidence because of heterogeneity and potential risk of bias. Any benefit noted, although significant from a statistical standpoint, did not reach the threshold of a minimally important clinical difference.

Gross et al. (2013) evaluated LLLT for adults with neck pain. Their systematic review noted moderate quality evidence for chronic neck pain supporting LLLT over placebo to improve pain and disability, and quality of life into the intermediate term. Low quality evidence suggested LLLT improved short term pain and function over placebo for acute radiculopathy, cervical osteoarthritis or acute neck pain. For chronic myofascial neck pain (5 trials, 188 participants), evidence was conflicting. Authors conclude that LLLT may be beneficial for chronic neck pain, function and improvement of quality of life but long term trials are needed.

Wong et al. (2016) aimed to update the findings of the Neck Pain Task Force, which examined the effectiveness of manual therapies, passive physical modalities, and acupuncture for the management of whiplash-associated disorders (WAD) or neck pain and associated disorders (NAD). The review found new evidence suggesting that LLLT is not effective for persistent NAD grades I–II. However, when combining the new evidence with Neck Pain Task Force findings from five studies, the preponderance of evidence suggests that clinic-based LLLT is effective for persistent NAD.

In the American Physical Therapy Association Orthopedic Section Clinical Practice Guideline on Neck Pain revised I 2017, it is recommended that for patients with chronic neck pain with mobility deficits, clinicians should provide a multimodal approach of the following: thoracic manipulation and cervical manipulation or mobilization; mixed exercise for cervical/scapulothoracic regions: neuromuscular exercise (e.g., coordination, proprioception, and postural training), stretching, strengthening, endurance training, aerobic conditioning, and cognitive affective elements; dry needling, laser, or intermittent mechanical/manual traction (Grade B) (Blanpied et al., 2017).

In a report published by the Agency for Healthcare Research and Quality on Noninvasive Nonpharmacological Treatment for Chronic Pain, authors state that short-term low-level laser therapy was associated with moderate improvement in function and pain (Skelly et al., 2018).

Literature Review – Achilles Tendinopathy

One study of 52 recreational athletes with Achilles tendinopathy compared eccentric exercise plus either laser or placebo treatments administered twice per week for 4 weeks, followed by once per week for 4 weeks. The laser group had significantly greater improvements in pain VAS, stiffness, ROM, and tenderness at 4, 8, and 12 weeks (Stergioulas et al., 2008). Tumilty et al. (2008) used low level laser therapy applied to points on the tendon 3 times a week for 12 weeks and noted significant improvement in all outcome measures at 4 and 12 weeks. However, the authors determined that conclusions regarding effectiveness could not be made due to the low statistical power of the study.

The Orthopaedic Section of the American Physical Therapy Association (APTA) published clinical practice guidelines for Achilles pain, stiffness, and muscle power deficits (Carcia, et al., 2010). The guidelines note that based on limited works, the future of LLLT is promising for patients suffering from Achilles tendon pain. Given the limited number of studies employing LLLT in this population, additional study is warranted. Clinicians should consider the use of low-level laser therapy to decrease pain and stiffness in patients with Achilles tendinopathy. (Level B).

*Level B: Moderate evidence - A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation

Literature Review – Lateral Epicondylitis

Several systematic reviews have been published regarding LLLT for treatment of lateral epicondylitis. In general they are inconsistent in the findings and do not substantiate the effectiveness of this treatment for these conditions.

Dingemans et al. (2013) performed a systematic review of the effectiveness of electrophysical modalities for the treatment of medial and lateral epicondylitis. A total of 2 reviews and 22 RCTs were included and evaluated, all of which concerned lateral epicondylitis. Ultrasound plus friction massage showed moderate effectiveness over LLLT on short term follow up. Moderate evidence was found in favor of LLLT over plyometric exercises on short term follow up (Dingemans et al., 2013).

Sims et al. (2014) completed a systematic review of treatments for lateral epicondylitis. They noted that LLLT demonstrates superiority over placebo in some studies and not in others. They determined that the evidence is insufficient to draw conclusions that there is one preferred method of non-surgical treatment for this condition. Dion et al. (2017) evaluated the effectiveness of passive physical modalities for the management of soft tissue injuries of the elbow. Twenty-one were eligible for critical appraisal and (reporting on eight randomized controlled trials) had a low risk of bias. Authors found that adding transcutaneous electrical nerve stimulation to primary care does not improve the outcome of patients with lateral epicondylitis. They found inconclusive evidence for the effectiveness of: (1) an elbow brace for managing lateral epicondylitis of variable duration; and (2) shockwave therapy or low-level laser therapy for persistent lateral epicondylitis. Authors conclude that their review found little evidence to inform the use of passive physical modalities for the management of elbow soft tissue injuries.

A systematic review concluded that low-level laser therapy administered directly to the lateral elbow tendon insertions may offer short-term pain relief and decreased disability, both alone and in conjunction with an exercise program (Bjordal et al., 2008). A systematic review of literature on treatments for lateral epicondylitis did not support the use of low level laser therapy (Trudel et al., 2004).

Lian et al. (2018) compared the efficacy and safety of nonsurgical treatment options for eECRB described in randomized placebo-controlled trials at short-term, midterm, and long-term follow-up and (2) evaluate outcomes in patients receiving placebo. Thirty-six randomized placebo-controlled trials, evaluating 11 different treatment modalities, with a total of 2746 patients were included. At midterm follow-up, laser therapy and local botulinum toxin injection improved pain.

Literature Review – Rheumatoid Arthritis

A Cochrane systematic review (Brosseau, et al., 2005) was performed for the purpose of reviewing literature regarding the use of LLLT as treatment for rheumatoid arthritis (RA). Six studies with 220 patients with rheumatoid arthritis were included in the review. The main limitation with the studies is the heterogeneity of clinical application. In addition, the results are subject to publication bias, if negative trials have not been published. It was concluded in this review that “this meta-analysis found that pooled data gave some evidence of a clinical effect, but the outcomes were in conflict, and it must therefore be concluded that firm documentation of the application of LLLT in RA is not possible. Conversely, a possible clinical benefit in certain subgroups cannot be ruled out from the present meta-analysis and further large scaled studies are recommended with special attention to the findings in this meta-analysis (e.g., low versus high dose wavelength, nerve versus joint application, and treatment duration).”

The Ottawa Panel Evidence-Based Clinical Practice Guidelines reviewed the same set of RCTs using the Cochrane method and concluded there was strong evidence in support of a clinically important benefit for low level laser treatment of foot, knee, or hand pain for patients with rheumatoid arthritis (RA) (Ottawa Panel Evidence-Based Clinical Practice Guidelines, 2004). Their findings were based on positive findings in 4 out of 5 placebo-controlled RCTs, with pain reduction ranging from 19 – 28%. A later review of systematic reviews concluded that there is evidence that low-level laser therapy generally reduces pain and improves function (Christie et al., 2007). A randomized controlled study of LLLT concluded that it was not specifically effective for the treatment of hand pain in patients with rheumatoid arthritis (Meireles, et al., 2010).

Literature Review – Temporomandibular Joint Dysfunction (TMJ or TMD)

Several systematic reviews have been published regarding LLLT for treatment of temporomandibular joint dysfunction (TMJ or TMD). In general they are inconsistent in the findings and do not substantiate the effectiveness of this treatment for these conditions.

Chang et al. (2014) completed a systematic review of selected studies of randomized controlled trials and calculated the effect size (ES) of the pain relief to evaluate the effect of LLLT. Seven studies met inclusion criteria. Results indicated a moderate effect of pain relief. Also, the dosages and treatments with wavelengths of 780 and 830 nm created moderate and large pain relief effects. Authors concluded that use of LLLT for TMJ pain had a moderate analgesic effect. They agree that the optimal parameters for LLLT to treat TMJ pain have not been confirmed.

A systematic review and meta-analysis assessed the evidence for LLLT for Temporomandibular Disorders (TMD) (Petrucci, et al., 2011). Six randomized clinical trials were included in the review. The primary outcome was the change in pain from baseline to endpoint. The pooled effect of LLLT on pain, measured through a visual analog scale was not statistically significant from placebo. The authors concluded that there is no evidence to support the effectiveness of LLLT in the treatment of TMD.

Maia et al. (2012) reported on a systematic review of LLLT on pain levels in patients with temporomandibular disorders (TMD). The review included 14 studies, with 12 studies utilizing a placebo group. The number of sessions varied along with the frequency of applications. There was a range in the energy density and power density used. It was found that there was a reduction in pain levels reported in 13 studies, with nine of these occurring only in the experimental group and four studies reporting pain relief for both experimental and placebo group. The authors concluded that while LLLT appeared to be effective in reducing pain, due to the

heterogeneity in standardization of parameters of laser there should be caution in interpretation of the results. Further research is needed regarding appropriate application laser protocol.

Xu et al. (2018) systematically reviewed randomized controlled trials (RCTs) of the effect of low-level laser therapy (LLLT) versus placebo in patients with temporomandibular disorder (TMD). A total of 31 RCTs were included. Combining data from all clinically heterogeneous studies revealed positive effects of LLLT on pain relief, regardless of the visual analogue scale (VAS) score or the change of VAS score between the baseline and the final follow-up time point, while dosage analyses showed discrepant results about the effects of high or low doses for patients with TMD. Follow-up analyses showed that LLLT significantly reduced pain at the short-term follow-up. Temporomandibular joint function outcomes indicated that the overall effect favored LLLT over placebo. Authors suggest that from this review, LLLT effectively relieves pain and improves functional outcomes in patients with TMD.

Literature Review—Wound Healing

There are several systematic technical reviews published regarding the use of low level laser for wound healing. The Agency for Healthcare Research and Quality (AHRQ) published a review of the comparative effectiveness and harms of different therapies and approaches to treating pressure ulcers (Saha, et al., 2013). Regarding low-level laser therapy, the review found low strength of evidence for laser therapy and that wound improvement was similar with laser therapy compared with sham treatment or standard care (four studies). Beckmann et al. (2014) completed a systematic literature review of LLLT for wound healing of diabetic ulcers. They concluded that although the majority of clinical studies show a potential benefit of LLLT in wound healing of diabetic ulcers, there are several aspects in these studies limiting final evidence about the actual outcomes. In summary, all studies give enough evidence to continue research on laser therapy for diabetic ulcers, but clinical trials using human models do not provide sufficient evidence to establish the usefulness of LLLT as an effective tool in wound care regimes at present. Further well designed research trials are required to determine the true value of LLLT in routine wound care.

Literature Review—Oral Mucositis

A systematic review and meta-analysis was conducted to examine the effect of LLLT in cancer therapy-induced oral mucositis (OM). The review included 11 randomized, placebo-controlled trials with 415 patients (Bjordal, et al., 2011). The study found consistent evidence from small high-quality studies that red and infrared LLLT can partially prevent development of cancer therapy-induced OM. LLLT also significantly reduced pain, severity and duration of symptoms in patients with cancer therapy-induced OM. The limitation of the study included the small sample size of the included trials and the heterogeneity of the treatment procedures and dosing.

Clarkson et al. (2010) reported on a Cochrane review to assess the effectiveness of interventions for treating oral mucositis or its associated pain in patients with cancer receiving chemotherapy or radiotherapy or both. The review found that there is limited evidence from two small trials that low level laser treatment reduces the severity of the mucositis. The authors concluded that there is weak and unreliable evidence that low level laser treatment reduces the severity of the mucositis with a need for further, well designed, placebo or no treatment controlled trials assessing the effectiveness of interventions for mucositis.

He et al. (2018) aimed to synthesize the available clinical evidences on the effects of low-level laser therapy (LLLT) in the prevention and treatment of chemotherapy-induced oral mucositis (OM). Authors found 8 qualified clinical trials with a total of 373 pediatric patients; Authors concluded that prophylactic LLLT reduces mucositis and severe mucositis and decreases the average severity of oral mucositis in pediatric and young patients with cancer. Therapeutic LLLT also reduces the average severity of oral mucositis and oral pain.

Literature Review – Musculoskeletal Conditions

Several studies have been published regarding LLLT for musculoskeletal conditions. Limitations of the studies included small study size, short follow-up time periods, and heterogeneity in terms of laser, dose, duration and frequency of treatments (Dakowicz, et al., 2011; Tascioglu, et al., 2012; Konstantinovic, et al., 2010; Ay, et al., 2010; Oken, et al., 2008; and Djavid, et al., 2007).

Clijisen et al. (2017) completed a systematic review and meta-analysis on the effects of low level laser therapy on pain in patients with musculoskeletal disorders. A random-effects model was used for this meta-analysis. Subgroup meta-analyses were conducted to evaluate the influence of the adherence of the applied LLLT to the World Association of Laser Therapy (WALT) guidelines, the anatomical site under investigation and the study design on the overall weighted mean effect size. Meta regression was used to assess the possible influence of

the study quality on the individual study effect sizes. Eighteen studies allowing for 21 head-to-head comparisons (totaling n=1462 participants) were included. The pooled raw mean difference (D) in pain between LLLT and the control groups was -0.85. There was high and significant between study heterogeneity. The subgroup meta-analysis of the comparisons not following the WALT guidelines revealed a D = -0.68. In this group, heterogeneity decreased. In the WALT subgroup D equaled -1.52. This between groups difference was clinically relevant although statistically not significant. Authors conclude that this meta-analysis presents evidence that LLLT is an effective treatment modality to reduce pain in adult patients with musculoskeletal disorders. Adherence to WALT dosage recommendations seems to enhance treatment effectiveness.

The Royal Dutch Society for Physical Therapy (KNGF) issued a clinical practice guideline for physical therapists that addresses the assessment and treatment of patients with nonspecific neck pain, including cervical radiculopathy, in Dutch primary care. Recommendations were based on a review of published systematic reviews. The physical therapist is advised not to use dry needling, low-level laser, electrotherapy, ultrasound, traction, and/or a cervical collar (Bier et al., 2018).

Song et al. (2018) investigated the effectiveness of high intensity laser therapy (HILT) for musculoskeletal disorders using a systematic review and meta-analysis. Twelve studies were selected for this systematic review. In 11 studies, comprising 736 patients, pain was significantly improved by HILT compared with a control group. From the analysis of 688 patients from 10 studies, HILT showed a significant improvement in disability scores compared with those in the control group. The results of this study show that HILT treatment for back and neck pain significantly improved pain and disability scores compared with controls.

Other

An evidence-based guideline for the treatment of painful diabetic neuropathy published by American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation (Bril, et al., 2011) notes LLLT is probably not effective for the treatment of this condition and is not recommended.

U.S. Food and Drug Administration (FDA)

Since 2002, the U.S. Food and Drug Administration (FDA) granted 510(k) approval to several companies to market lasers that provide LLLT. The LLLT lasers are classified as class II devices under the physical medicine devices section as "Lamp, Non-heating, for Adjunctive Use in Pain Therapy."

Several devices that provide LLLT have been approved under the 501(k) approval process for various indications. These devices include but are not limited to:

- MicroLight 830™ (MicroLight Corporation of America, Missouri City, TX)
- Thor Laser System (Thor International Ltd, Amersham, UK)
- Luminex LL Laser System® (Medical Laser Systems, Inc, Branford CT)
- Vectra Genisys Laser System® (Chattanooga Group, Hixson, TN)

In the data submitted to the FDA as part of the FDA 510(k) approval process in 2002, the manufacturer of the MicroLight device conducted a double-blind, placebo-controlled study of 135 patients with moderate to severe symptoms of carpal tunnel syndrome who had failed conservative therapy for at least a month. However, the results of this study have not been published in the peer-reviewed literature, and only a short summary is available in the FDA Summary of Safety and Effectiveness, which does not permit scientific conclusions.

High power therapeutic laser systems granted FDA 510(k) approval as "Infrared lamp", for therapeutic heating and to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation. These devices include but are not limited to:

- Diawave Lasers (formerly Avicenna Laser Technology Inc.) (Riviera Beach, FL): Diowave Laser System, AVI HP-7.5, AVI HPLL-12
- Zimmer MedizinSystems (Irvine, CA): OptonPro

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven when used to report low-level laser therapy (LLLT) or high-power Class IV therapeutic laser light therapy:

CPT®*	Description
97039	Unlisted modality (specify type and time if constant attendance)

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

*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.

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