Low-level Laser and High-Power Laser Therapy

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DESCRIPTION

Low-level laser therapy (LLLT) also known as cold laser or photobiomodulation therapy, refers to a wide variety of procedures involving several laser types and treatment methods. LLLT uses red beam or near infrared nonthermal lasers with wavelengths between 600 and 1000 nanometers and from five to 500 milliwatts. In contrast, lasers used for surgery typically use 300 watts.6 When applied, the lasers penetrate the surface of the skin without a heating (burning) effect, produce no sensation and do not damage the skin. Purportedly due to the low skin absorption and no side effects, the laser light can penetrate deeply into tissues and reach the site of damage or injury.

LLLT may be administered by a physician, physical therapist, occupational therapist or Doctor of Chiropractic (DC) in a provider's office or other outpatient setting and requires no sedation or anesthesia. It is theorized that LLLT may cause a biostimulatory healing effect for the treatment of a range of conditions, including alopecia, arthritis, carpal

tunnel syndrome, chronic pain, prevention of oral mucositis, temporomandibular joint disorders, tissue injuries (e.g., tendinopathy, tendinitis) and wound healing.

Examples of LLLT devices include, but may not be limited to the following:

- GRT LITE, Model 8-A
- Lightstream Low-Level Laser
- Luminex Laser Therapy System
- MicroLight ML830 Laser System
- RianCorp LTU-904
- Super Pulsed Laser Technology
- TerraQuant
- Thor Laser System

High-power laser therapy devices, also referred to as high dose laser therapy (HDLT), (class IV therapeutic lasers) are purported to stimulate accelerated healing energy from superficial to deep levels (six to nine inches) over a larger surface treatment area. It is proposed for treating conditions such as arthritis, carpal tunnel syndrome, chronic pain, epicondylitis, sprains/strains, trigger points and various other musculoskeletal disorders. These devices are not the same as (or equivalent to) class IV surgical lasers.

Examples of high- power laser therapy devices include, but may not be limited to the following:

- AVI HP-7.5
- AVI HPLL-12
- Diowave Laser System
- OptonPro

Despite little scientific support, high-power laser therapy has been employed for various indications including musculoskeletal disorders, pain relief, and wound healing. The current evidence is insufficient to support high-power laser therapy compared with standard of care. Additional RCTs are needed to establish the efficacy of high-power laser therapy for musculoskeletal disorders, pain relief, and wound healing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Context and Therapy Purpose

The purpose of low-level laser therapy (LLLT) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is those who have increased risk of oral mucositis due to come cancer treatments and/or hematopoietic stem cell transplant, carpal tunnel syndrome, neck pain, low back pain, temporomandibular joint pain (TMJ), adhesive capsulitis, subacromial impingement syndrome, osteoarthritic knee pain, Achilles

tendinopathy, plantar fasciitis, rheumatoid arthritis, Bell Palsy, Fibromyalgia, chronic nonhealing wounds, and lymphedema.

Interventions
The therapy being considered is low-level laser therapy (LLLT).

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Comparators
Oral mucositis usually heals 2 to 4 weeks after the cessation of cytotoxic chemotherapy when no infection is present. Comparators of interest include general oral care protocols and medications, including topical anesthetics, antiseptics, and analgesics.

The following practice is currently being used to treat carpal tunnel syndrome (CTS): conservative therapy (e.g., physical therapy, wrist splints) and medication for pain and inflammation. Surgery may also be performed, during which the transverse carpal ligament is cut often under local anesthetic.

The following practice is currently being used to treat neck pain: conservative therapy (e.g., physical therapy), medication, and surgery.

The following practice is currently being used to treat subacromial impingement syndrome: conservative therapy (e.g., physical therapy, rest, cessation of painful activity), medication (such as corticosteroids and local anesthetics), and surgery. Surgery can be done arthroscopically or as open surgery.

The following practice is currently being used to treat adhesive capsulitis: conservative therapy (e.g., physical therapy), medication, and surgery.

The following practice is currently being used to treat TMJ pain: conservative therapy (e.g., physical therapy), medication, and surgery.

The following practices are currently being used to treat low back pain: conservative therapy (e.g., physical therapy), medication, and surgery. These medications can include muscle relaxants and nonsteroidal anti-inflammatory drugs.

The following practices are currently being used to treat osteoarthritic knee pain: conservative therapy (e.g., physical therapy), medication, and surgery.

The following practice is currently being used to treat heel pain: conservative therapy (e.g., physical therapy), medication, and surgery.

The following practices are currently being used to treat RA: conservative therapy (e.g., exercise) and medication, including nonsteroidal anti-inflammatory drugs, steroids, disease-modifying antirheumatic drugs, and biologic agents.

The following practices are currently being used to treat Bell palsy: conservative therapy (e.g., exercise) and medications, including corticosteroids and antiviral drugs.

The following practice is currently being used to treat fibromyalgia: conservative therapy (e.g., exercise) and medications, including pain relievers, antidepressants, and anti-seizure drugs.

The following practice is currently being used to treat chronic nonhealing wounds: standard wound care, including wound debridement, compression therapy, and antibacterial treatment.

The following practice is currently being used to treat lymphedema: conservative care (e.g., exercise), pneumatic compression, and complete decongestive therapy.

Outcomes
General outcomes of interest are any of the following:

- Improvements in functional outcomes
- Quality of life (QOL0
- A reduction in symptoms and treatment-related morbidity
- Complete healing or healing to a degree that permits a procedure that results in complete healing

The effects of low-level laser therapy (LLLT)to promote healing are expected to occur from weeks to months.

Prevention of Oral Mucositis
In 2020, Peng et. al. conducted a systematic review with meta-analysis comparing low-level laser therapy (LLLT) to placebo, usual care, or no therapy in patients receiving chemotherapy or radiotherapy for hematologic malignancies with or without hematopoietic stem cell transplant (HCT) or head and neck squamous cell cancer (HNSCC). The systematic review included 30 studies including 1 with a stratified analysis. For the purposes of the meta-analysis, this was treated as an additional trial; 14 were conducted in Brazil and 10 were published between 2014 and 2018. Patients underwent HCT or chemotherapy in 19 studies: radiotherapy in 5 studies, and chemoradiotherapy in 6 studies. The application of LLLT was prophylactic in 26 studies and 6 studies reported on therapeutic LLLT use. Using the Jadad scale to assess for quality, 19 were considered high-quality (score of ≥3 out of 5 considered high quality). Ten trials were considered to be at low risk for bias. For use of prophylactic LLLT, a

total of 22 studies (n=1190 patients) evaluated the incidence of the primary outcome of severe oral mucositis during the treatment of hematologic disorders or head and neck cancer. Severe oral mucositis occurred significantly less in patients receiving LLLT compared to control (relative risk, 0.40; 95% CI, 0.25 to 0.57; p <.01). This significant reduction in severe oral mucositis incidence with LLLT therapy was sustained in multiple subgroup analyses including by underlying condition/treatment regimen: HCT (relative risk, 0.46; 95% CI, 0.23 to 0.94; p =.03), chemotherapy (relative risk, 0.2; 95% CI 0.05 to 0.92; p =.04), and radiotherapy (relative risk, 0.36; 95% CI, 0.27 to 0.50; p <.01). An analysis of 15 trials (n=900) found that prophylactic LLLT numerically, but not significantly reduced, the incidence of oral mucositis of any grade (relative risk, 0.90; 95% CI, 0.98 to 1.00; p =.06). A subgroup analysis of patients receiving chemotherapy showed a significant reduction in any grade of mucositis with LLLT (relative risk, 0.73; 95% CI, 0.55 to 0.96; p =.03); this difference was not significant in patients receiving radiotherapy and chemoradiotherapy (relative risk, 1.00; 95% CI, 0.92 to 1.09; and relative risk, 1.00; 95% CI, 0.98 to 1.01, respectively).

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 low-level laser therapy (LLLT) for the prevention of oral mucositis in patients receiving HCT conditioned with high-dose chemotherapy and for patients undergoing head and neck radiotherapy, 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 the well-designed, placebo-controlled, randomized trial by Schubert et al (2007), together with "weaker evidence" from 3 observational studies that showed positive results. This phase 3 trial was double-blind and sham-controlled evaluating 70 patients.[2,] Trial limitations included lack of statistically significant findings for the primary outcome measure and 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.

Section Summary

The literature on low-level laser therapy (LLLT) for the prevention of oral mucositis includes several systematic reviews, including a review by MASCC/ISOO (2012), with a resulting recommendation for LLLT for adults receiving HCT conditioned with high-dose chemotherapy. 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. Several systematic reviews have found benefit of LLLT, including a 2014 systematic review of LLLT for prevention of oral mucositis in patients undergoing HCT that 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. A 2020 systematic review not limited to patients undergoing HCT showed benefit with using prophylactic LLLT compared to control in

reducing the incidence of severe oral mucositis in patients undergoing chemotherapy or radiotherapy.

Carpal Tunnel Syndrome
A 2016 Cochrane report assessed the benefits and harms of low-level laser therapy (LLLT) compared with placebo and compared with other non-surgical interventions in the management of carpal tunnel syndrome (CTS). Twenty-two randomized controlled trials (RCTs) with 1153 participants were included. The authors concluded the quality of evidence was very low and found no data to support a clinical effect of LLLT in treating CTS.

Li et. al. (2016) published a meta-analysis of randomized controlled trials (RCTs) on low-level laser therapy (LLLT) for carpal tunnel syndrome (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 no 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 driven 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
A number of randomized controlled trials (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 lower-level laser therapy (LLLT) compared with a control condition for most of the outcome measures (6 of 8). More recent RCTs have not found that LLLT significantly improves outcomes.

Neck Pain
In a systematic review and meta-regression, Gross et. al. (2013) evaluated 17 trials on lower-level laser therapy (LLLT) for neck pain. Ten trials demonstrated a high-risk of bias. Two trials (N=109 subjects) were considered 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.

Summary Section
A number of RCTs and several systematic reviews have been published. A 2013 systematic review identified 17 trials. Only 2 trials considered of moderate quality found

that LLLT led to better outcomes than placebo for chronic neck pain. Other trials were considered low-quality. 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
In 2020, Alfredo et. al. randomized 122 patients to low-lelve laser therapy (LLLT) plus exercise (n=44; 42 included in analysis), LLLT alone (n=42), or exercise alone (n=42) for 8 weeks. Therapy was given 3 times a week for 8 weeks. Between-group comparison showed that patients in the LLLT plus exercise group had a significantly greater improvement in SPADI compared to other groups; however, no between-group comparison was performed exclusively for patients receiving LLLT alone and exercise alone.

Section Summary
Several randomized controlled trials (RCTs) evaluating low-level laser therapy (LLLT) for the treatment of subacromial impingement syndrome have been published. Most trials failed to show a significant benefit of LLLT compared with sham treatments or alternative interventions (e.g., exercise).

Adhesive Capsulitis
A Cochrane review by Page et. al. (2014) evaluated low-level laser therapy (LLLT) and other electrotherapy modalities for adhesive capsulitis (i.e., frozen shoulder). Reviewers found limited evidence on which to conclude whether electrotherapy modalities are effective 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 improvements on a global assessment of treatment success compared with patients receiving a placebo. However, this trial was considered 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 moderate quality. In that RCT, Stergioulas et. al. (2008) randomized 63 patients with frozen shoulder to an 8-week program of LLLT (n=31) or placebo (n=32). Both groups also participated in exercise therapy. Compared with the sham group, the active laser group had a significant decrease in overall, night, and activity pain scores after 4 and 8 weeks of treatment and at the end of 8 more weeks of follow-up. At the same assessment intervals, significant decreases in Shoulder Pain and Disability Index 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 16 weeks post-randomization; significant decreases in Health Assessment Questionnaire scores were observed at 4 weeks and 8 weeks of treatment.

Section Summary
A Cochrane review evaluating 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 conclude whether LLLT is effective for adhesive capsulitis.

Temporomandibular Joint Pain

Del Vecchio et. al. (2021) randomized 90 patients between the ages of 18 and 73 years old with temporomandibular joint (TMJ) disorders to home low-level laser therapy (LLLT) (808 nm, 5 J/min, 250 mW, 15 KHz for 8 minutes twice daily), sham control, or standard conventional drugs (nimesulide 100 mg dialy with 5-days of cyclobenzaprine 10 mg daily) for 1 week.[40,] Pain was measured using a 100-mm VAS, and the examiner was blinded. At the end of treatment, the reduction in VAS was greater in the LLLT group (MD, 13.030; p =.036) and the drug group (MD, 14.409; p =.17) compared to the sham group. However, no significant difference in pain reduction was observed between the LLLT group and the drug group (MD, 1.379; p = 1). This study evaluated a specific at-home LLLT protocol and cannot be generalized to other LLLT regimens.

Several randomized controlled trials (RCTs) have been published since the meta-analyses, showing inconsistent results. In a double-blind, placebo-controlled randomized trial, Shobha et al (2017) investigated the effectiveness of low-level laser therapy (LLLT) in patients with temporomandibular joint (TMJ) pain. Forty TMJ patients were evenly randomized to an active or a placebo group. Treatment included 2 to 3 weekly sessions of LLLT for a total of 8 sessions. Patients were evaluated at baseline, after treatment, and at a 30-day follow-up. Both groups experienced pain reduction at all evaluation points. The most significant pain reduction was reported at the 30-day follow-up (p =.001). There were no significant differences between groups at baseline (p =.214), final session (p =.806), or the 30-day follow-up (p =.230). For a secondary outcome (the ability to open one's mouth), while both groups showed improvement, the difference between groups was not significant (p =.330). Therefore, LLLT was determined to have no greater impact on healing or pain reduction over placebo. A study limitation is that magnetic resonance imaging was not used, which is the traditional method for diagnosing TMJs.

Several meta-analyses of RCTs on low-level laser therapy (LLLT) for temporomandibular joint (TMJ) pain have been published. A meta-analysis by Chen et al (2015) 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 =.08). However, meta-analyses did find significantly better functional outcomes (i.e., maximum active mouth opening, maximum passive mouth opening) favoring LLLT. For example, the mean difference (MD) in maximum active mouth opening for active treatment versus placebo was 4.18 (95% CI, 0.73 to 7.63).

Chang et al (2014) published a meta-analysis of 7 RCTs on LLLT for TMJ pain. Single- or double-blind RCTs included in the review compared LLLT with no treatment or placebo. The primary outcome of interest was pain measured by a VAS. Six studies (N=223 patients) were eligible for 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, -0.6, 0.6; 95% CI, -0.47 to -0.73).

Section Summary
A number of RCTs and several systematic reviews have evaluated LLLT for TMJ pain. 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 functional outcomes (e.g., mouth opening). Randomized controlled trials have not compared the impact of LLLT with physical therapy on health outcomes.

Low Back Pain
In a double-blind RCT, Koldas Dogan et al (2017) compared the effectiveness of 2 laser therapy regimens on pain, lumbar ROM, and functional capacity in patients with chronic low back pain. This trial assessed 49 patients with chronic low back pain who were randomized to a hot pack and the 2 different laser therapies for a total of 15 sessions. A series of assessments were conducted before and after treatment, including a modified Schober test, right and left lateral flexion measurements, VAS , and a modified ODI. After treatment, both groups saw a significant improvement in VAS, ODI, and lumbar ROM ($p < .05$). However, group 2 saw significantly better results in lateral flexion measurements and ODI scores ($p < .05$). Trial limitations included: (1) the short duration of follow-up; and (2) use of hot packs, which might have biased the pain measurements. No superiority was found for 1 laser treatment over the other regarding pain relief; however, regarding functionality, patients might find the Helium-Neon laser to be superior.

A number of randomized controlled trials (RCTs) and several systematic reviews of RCTs have assessed low-level laser therapy (LLLT) for low back pain. For example, Glazov et al (2016) published a meta-analysis of blinded sham-controlled trials evaluating LLLT for treatment of chronic low back pain. Fifteen RCTs (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 to 12 weeks) follow-up. Longer-term outcomes (ie, at 6 and 12 months) were secondary measures. For the pain outcomes, a meta-analysis of 10 trials found a 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 a 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 to 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 and

12 months, and neither found statistically significant differences between the LLLT and sham groups.

Huang et al (2015) published a systematic review of randomized controlled trials (RCTs) on low-level laser therapy (LLLT) for treating nonspecific chronic low back pain. Reviewers included trials comparing LLLT with placebo that reported pain and/or functional outcomes and a PEDro quality score. Seven trials (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 ³7; 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. Change in pain and ROM scores were secondary outcomes. In pooled analyses, 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
The literature on low-level laser therapy (LLLT) for low back pain consists of RCTs and several systematic reviews of RCTs. Meta-analyses found that LLLT resulted in significantly greater reductions in pain scores and global assessment scores than a placebo control in the immediate posttreatment setting. Meta-analyses also found that other outcomes (e.g., disability index, ROM) were significantly better immediately after treatment with active versus placebo LLLT, though not at longer-term follow-up.

Osteoarthritic Knee Pain
Several randomized controlled trials (RCTs) and systematic reviews of RCTs have evaluated low-level laser therapy (LLLT) for treatment of knee osteoarthritis (OA), coming to inconsistent conclusions. The most inclusive and up to date of these was published by Stausholm et. al. (2019) and compared LLLT with placebo for knee OA patients. To be eligible for inclusion, trials had to report pain, disability, or QOL. A total of 22 trials (N=1063) met the eligibility criteria. Interventions included between 5 to 16 sessions of LLLT or sham LLLT. A total of 9 included studies used a non-recommended dose of LLLT, which had a mean treatment duration of 3.7 weeks. The mean treatment duration was 3.53 weeks in studies using appropriate dosing. The primary outcome was posttreatment pain measured by a 0 to 100 mm VAS score at end of treatment and follow-up (1 to 12 weeks). The mean difference in VAS score was statistically significant favoring LLLT over placebo at end of treatment (14.23 mm; 95% CI, 7.31-21.14; I^2=93%) and at follow up (15.92 mm; 95% CI, 6.47 to 25.37; I^2=93%). There was high heterogeneity for the primary outcome, possibly due to differences in the follow-up time period. Risk of bias appeared low. Only 1 study included QOL data, and therefore no QOL meta-analysis was performed.

Section Summary
The literature on low-level laser therapy (LLLT) for osteoarthritis (OA) includes RCTs and multiple systematic reviews of RCTs. One of the more recent systematic reviews, which pooled study findings, did find that LLLT significantly reduced pain and improved disability compared with a sham intervention; however, there was high heterogeneity between studies, and individual studies are limited by small sample size and inconsistent timing of follow-up.

Heel Pain

Achilles Tendinopathy
Tumilty et. al. (2012) reported on a randomized, double-blinded, sham-controlled trial of low-level laser therapy (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 daily for 12 weeks. The primary outcome was the Victorian Institute of Sport Assessment-Achilles Questionnaire at 12 weeks. The only significant difference between groups using intention-to-treat analysis was at 4 weeks for the Victorian Institute of Sport Assessment-Achilles Questionnaire scores, and that difference favored the sham control group. The Victorian Institute of Sport Assessment-Achilles Questionnaire 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
In 2019, Wang et. al. published a systematic review and meta-analysis of 6 randomized controlled trials (RCTs) comparing low-level laser therapy (LLLT) (alone or combined with other interventions) and controls (placebo or other interventions). A total of 315 adults with plantar heel pain or plantar fasciitis were included in the analysis. Compared with controls, VAS was significantly reduced after treatment (SMD=-0.95; 95% CI -1.20 to -0.70; p <.001), as well as remaining significantly better at 3 months (SMD= -1.13; 95% CI -1.53 to -0.72; p <.001). The meta-analysis was limited by the small number of studies included, small sample size, and insufficient data for longer-term outcomes.

Cinar et. al. (2018) conducted a prospective single-blinded randomized controlled trial (RCT) investigating combination therapy consisting of low-level laser therapy (LLLT) plus exercise and orthotic care versus orthotic care alone in persons with plantar fasciitis.[90,] Forty-nine individuals were randomized to LLLT (n=27) or a control therapy (n=22). Each person performed a home exercise routine and received orthotic care; persons in the LLLT group received treatment 3 times a week for a total of 10 sessions. The function subscale of the American Orthopedic Foot and Ankle Society Score, a VAS, and the 12-minute walk test were used to measure progress. Scores were recorded at baseline, 3 weeks, and 3 months after treatment. At week 3, both groups saw a significant improvement in American Orthopedic Foot and Ankle Society total score (LLLT, p <.001; control, p =.002). However, at the 3-month follow-up, only the LLLT group progressed as assessed on the American Orthopedic Foot and Ankle Society total score (p =.04). At all check-ins, the group scores for the 12-minute walk test were comparable.

Both groups showed significant pain reductions at the 3-month follow-up (LLLT, p <.001; control, p =.01); however, the LLLT group had a more significant reduction in pain at month 3 (p =.03). Thus, reviewers concluded that combination therapy plus LLLT was more effective in reducing pain and improving function for patients with plantar fasciitis than orthotic care alone. Limitations included a lack of a control group, which would have accounted for the natural progression of recovery in patients with plantar fasciitis.

Section Summary
Multiple sham-controlled randomized trials have evaluated low-level laser therapy (LLLT) for heel pain (Achilles tendinopathy, plantar fasciitis) but findings were inconsistent. One RCT compared LLLT plus therapy with orthotic care alone, and while a significant advantage was observed in LLLT treatment, LLLT treatment was used as a combination therapy. A meta-analysis of Achilles tendinopathy trials found no benefit in pain reduction with LLLT with the exception of at 2 months of follow-up reported in a single trial. None of the studies presented long-term follow-up data. Given all factors, further studies are needed to validate the technology.

Rheumatoid Arthritis
A randomized, double-blind, placebo-controlled trial assessing outcomes for pain reduction and improvement in hand function in 82 patients with rheumatoid arthritis (RA) treated with low-level laser therapy (LLLT) or placebo laser was reported by Meireles et. al. (2010). 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 trial was ineffective for treating RA.

Section Summary
A 2010 RCT did not find that LLLT was significantly better than a placebo treatment for most outcomes.

Bell Palsy (Facial Nerve Palsy)
Ordahan et. al. (2017) investigated the efficacy of low-level laser therapy (LLLT) when used in combination with traditional facial exercises to treat facial paralysis. Forty-six patients with Bell palsy were randomized to 2 groups: 1 group underwent LLLT plus facial exercise therapy (n=23); the other group underwent facial exercise therapy alone (n=23). Laser therapy was administered 3 times a week for 6 weeks. Patients were evaluated during the treatment and at 3- and 6-weeks posttreatment. The Facial Disability Index was used to evaluate progress. No significant improvement was observed at week 3 in the facial exercise therapy-alone treatment group (p <.05), but significant improvement was noted at week 6 (p <.001). In the LLLT plus facial exercise therapy group, significant improvement was noted at 3 and 6 weeks (p <.001); moreover, improvements in the Facial Disability Index scores in the LLLT plus facial exercise therapy group were significantly greater than those of the facial exercise therapy-alone treatment group at week 3 and week 6 (p <.05). Study limitations included lack of long-term follow-up and the use of combination therapy, which obscures the contribution of LLLT.

Section Summary
A randomized controlled trial (RCT) found significant short-term benefit with facial exercise therapy plus low-level laser therapy (LLLT) over facial exercise therapy alone, but no long-term data were 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. Also, no sham-controlled trials are available.

Fibromyalgia
In 2018, Honda et al published a systematic review and meta-analysis of randomized controlled trials (RCTs) evaluating pain relief modalities for fibromyalgia. Eleven studies with a total of 498 patients (range, 20 to 80) were included; 5 studies evaluated low-level laser therapy (LLLT) and the remainder covered other treatment modalities. Compared with control, LLLT was not associated with a reduction of VAS-measured pain (MD -4.0; 95% CI -23.4 to 15.4; p =.69). LLLT showed a significant reduction in tender points compared with control (MD, -2.21; 95% CI, -3.51 to -0.92; I^2=42%; p =.0008) and in the FIQ score (MD, -4.35; 95% CI, -6.69 to -2.01; I^2= 62%; p =.03). The analysis was limited by its inclusion criteria limited to a pure control group or placebo group for a specific intervention and exclusion of those that used another intervention as a comparator. Several treatment modalities were evaluated and individual pooled results for each intervention had a high degree of heterogeneity.

Section Summary
Few RCTs evaluating LLLT for fibromyalgia are available, which have been included in a systematic review and meta-analysis; the existing trials are small (i.e., <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
Li et al (2018) published a systematic review and meta-analysis of 7 randomized controlled trials (RCTs) (N=194) evaluating low-level laser therapy (LLLT) as a treatment for a diabetic foot ulcer. Ulcer area was significantly reduced with LLLT compared with control (WMD 34.18; 95% CI 19.38 to 48.99; p <.001), and the complete healing rate significantly improved with LLLT (OR 6.72; 95% CI 1.99 to 22.64; p =.002). The analysis was limited by the number of studies included and small sample size, and by each study having different parameters, demographic information, ulcer characteristics, follow-up time, and treatment period.

Machado et. al. (2017) also published a systematic review evaluating the treatment of pressure ulcers with low-level laser therapy (LLLT). Reviewers identified 4 studies meeting eligibility requirements (N=210 patients). Outcomes were the ulcer area, healing rate, and overall healing rate. Two of the 4 studies used LLLT with a single wavelength; and the other 2 used LLLT with probe cluster, which employs the simultaneous

assimilation of different types of diodes and wavelengths. In the study that employed the 658 nm wavelength, reviewers found that particular frequency reduced pressure ulcers by 71%. The other wavelengths did not produce any significant findings related to the study outcome; moreover, the studies using the probe cluster technique were also not successful in producing significant findings. While studies should be conducted to investigate further the success found in single wavelength at 658 nm, at this time there is insufficient evidence to suggest LLLT can significantly benefit patients with pressure ulcers.

Section Summary
Multiple 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 randomized controlled trials (RCTs) and observational studies have been published. For example, Smoot et al (2015) published a systematic review of studies on the effect of low-level laser therapy (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 with an alternative intervention (e.g., intermittent compression). Only 3 studies had blinded outcomes assessments, and in 3 studies, participants were blinded. A pooled analysis of 4 studies found significantly greater reductions in upper-extremity volume with LLLT than with the control condition (pooled effect size, -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 levels between LLLT and control (pooled effect size, -1.21; 95% CI, -4.51 to 2.10).

One of the larger double-blind randomized controlled trials (RCTs) was published by Omar et al (2011); it reported on 50 patients with postmastectomy lymphedema. The average length of time that patients had swelling was 14 months (range, 12 to 36 months). They were treated with active or sham laser 3 times a week for 12 weeks over the axillary and arm areas. Also, 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 reductions 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
Several systematic reviews of RCTs and observational studies found methodologic flaws in the available studies and collectively these studies did not consistently report better outcomes in patients receiving LLLT versus a control condition for treatment of lymphedema.

Summary of Evidence

Oral Mucositis

For individuals who have an increased risk of oral mucositis due to some cancer treatments (e.g., chemotherapy, radiotherapy) and/or hematopoietic stem cell transplantation (HSCT) who receive low-level laser therapy (LLLT), the evidence includes systematic reviews. Several systematic reviews of RCTs have found better outcomes with LLLT used to prevent oral mucositis than with control treatments. Results have consistently supported a reduction in severe oral mucositis in patients undergoing chemotherapy, HSCT, radiotherapy, and chemoradiotherapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Musculoskeletal and Neurologic Disorders

For individuals who have carpal tunnel syndrome who receive low-level laser therapy (LLLT), the evidence includes RCTs and systematic reviews. A systematic review and a TEC Assessment did not find sufficient evidence from RCTs that LLLT improves outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have neck pain who receive low-level laser therapy (LLLT), the evidence includes RCTs and systematic reviews. A 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 TEC Assessment found conflicting evidence. Additionally, laser types, application dosages, and treatment schedules vary in the available evidence and require further study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have subacromial impingement syndrome who receive low-level laser therapy (LLLT), the evidence includes RCTs. Most trials did not show a significant benefit of LLLT compared with sham treatment or with an alternative intervention (e.g., exercise). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have adhesive capsulitis who receive low-level laser therapy (LLLT), the evidence includes RCTs and a systematic review. A Cochrane review evaluating 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 that the technology results in an improvement in the net health outcome.

For individuals who have temporomandibular joint (TMJ) pain who receive low-level laser therapy (LLLT), the evidence includes RCTs and several systematic reviews. Meta-analyses of RCTs had mixed findings. A 2015 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 functional outcomes (e.g., mouth opening). Furthermore, RCTs have not compared the impact of LLLT with physical therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have low back pain who receive low-level laser therapy (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 (e.g., disability index, range of motion) were significantly better immediately after treatment with active rather than placebo LLLT but not at longer-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteoarthritis (OA) knee pain who receive low-level laser therapy (LLLT), the evidence includes RCTs and systematic reviews. A 2020 systematic review, which pooled study findings, did find that LLLT significantly reduced pain or improved functional outcomes compared with a sham intervention; however, the study was limited by high heterogeneity and inconsistency between regimens and follow-up duration. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heel pain (i.e., Achilles tendinopathy, plantar fasciitis) who receive low-level laser therapy (LLLT), the evidence includes RCTs and a systematic review. Findings of sham-controlled randomized trials were inconsistent, and RCTs lacked long term follow up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have rheumatoid arthritis (RA) who receive low-level laser therapy (LLLT), the evidence includes RCTs and a systematic review. A systematic review of RCTs found an inconsistent benefit of LLLT for a range of outcomes. A RCT published after the systematic review, did not find that LLLT was significantly better than a placebo treatment on most outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have Bell palsy who receive low-level laser therapy (LLLT), the evidence includes a systematic review of 4 RCTs. One RCT found a 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. Also, no sham-controlled trials are available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fibromyalgia who receive low-level laser therapy (LLLT), the evidence includes RCTs and SR. The RCTs evaluating LLLT for treatment of fibromyalgia are small (i.e., <25 patients each). One RCT (N=20 patients) found significantly better outcomes with LLLT than with sham, while another (N=20 patients) did not find statistically significant between-group differences for similar outcomes. Additional RCTs with sufficient numbers of patients are needed to establish the efficacy of LLLT for fibromyalgia. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Lymphedema and Wound Care
For individuals who have lymphedema who receive low-level laser therapy (LLLT), the evidence includes RCTs and systematic reviews. Multiple systematic reviews detected methodologic flaws in the available studies and did not consistently find better outcomes for patients receiving LLLT than those receiving a control condition for the treatment of lymphedema. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic nonhealing wounds who receive low-level laser therapy (LLLT), the evidence includes RCTs and systematic reviews. The few existing RCTs tend to have small sample sizes and potential risk of bias. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American College of Physicians
In 2020, the American College of Physicians published a joint guideline on management of acute pain from non-low back musculoskeletal injuries with the American Academy of Family Physicians. No recommendations are made specific to LLLT, but the guideline notes that laser therapy did not significantly reduce pain in 1 to 7 days compared to placebo.

In 2017, the American College of Physicians released guidelines relating to noninvasive treatments for chronic low back pain. The guidelines strongly recommended that patients with chronic low back pain should first seek nonpharmacologic treatment such as exercise, multidisciplinary rehabilitation, acupuncture, and mindfulness-based stress reduction-all based on moderate quality evidence. The recommendation also stated that patients with chronic low back pain should seek treatments such as tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, LLLT, operant therapy, cognitive behavioral therapy, or spinal manipulation-all based on low-quality evidence. While the College stated that LLLT has a small effect on pain and function, it found the evidence insufficient for the use of LLLT.

American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation
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 (2011). The guideline notes LLLT is probably not effective for the treatment of this condition and is not recommended.

The American Academy of Orthopedic Surgeons
In 2016, the American Academy of Orthopedic Surgeons (AAOS) published clinical practice guidelines on the treatment of carpal tunnel syndrome which indicated the following: “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 against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.)

American Physical Therapy Association
In 2018, the American Physical Therapy Association published an updated guideline on the diagnosis and treatment of Achilles tendinitis.[9] The use of LLLT was given a level D recommendation, meaning that no recommendation could be made due to contradictory evidence. This is a change from the previous version of the guideline published in 2010, which gave LLLT a level B recommendation.

Multinational Association of Supportive Cancer Care (MASCC)
In 2020, the Multinational Association of Supportive Cancer Care (MASCC) updated their guidelines the management of mucositis secondary to cancer therapy which includes the following:

A recommendation for the prevention of OM with intraoral photobiomodulation (PBM) therapy in patients who undergo HSCT.

A recommendation for the prevention of OM with intraoral PBM therapy in patients with cancer who receive H&N RT (without CT).

A recommendation for the prevention of OM with intraoral PBM therapy in patients with cancer who receive H&N RT with CT. This new guideline is based on recent evidence.

TABLE 1. Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology Clinical Practice Guidelines for Oral Mucositis

Section	LoE	Guideline Statement
BOC	III	• The panel suggests that implementation of *multiagent combination* oral care protocols is beneficial for the prevention of OM during CT.
	III	• The panel suggests that implementation of *multiagent combination* oral care protocols is beneficial for the prevention of OM during H&N RT.
	III	• The panel suggests that implementation of *multiagent combination* oral care protocols is beneficial for the prevention of OM during HSCT.
	III	• No guideline was possible regarding the use of *professional oral care* for the prevention of OM in patients with hematologic, solid, or H&N cancers because of limited and inconsistent data. An expert opinion complements this guideline: Although there was insufficient evidence to support the use of professional oral care for OM prevention, the panel is of the opinion that dental evaluation and treatment as indicated before cancer therapy are desirable to reduce risk for local and systemic infections from odontogenic sources.
	III	• No guideline was possible regarding the use of *patient education* for the prevention of OM in patients with hematologic cancer during HSCT or CT because of limited and inconsistent data. An expert opinion complements this guideline: The panel is of the opinion that educating patients about the benefits of BOC strategies is still appropriate because this may improve self-management and adherence to the recommended oral care protocol during cancer treatment.
	III	• No guideline was possible regarding the *use of saline or sodium bicarbonate* rinses in the prevention or treatment of OM in patients undergoing cancer therapy because of limited data. An expert opinion complements this guideline: Despite the limited data available for both saline and sodium bicarbonate, the panel recognizes that these are inert, bland rinses that increase oral clearance, which may be helpful for maintaining oral hygiene and improving patient comfort.
	III	• The panel suggests that *CHX* not be used in the prevention of OM in patients undergoing H&N RT.
Anti-inflammatory agents	I	• The panel recommends *benzydamine* mouthwash for the prevention of OM in patients with H&N cancer receiving a moderate dose RT (<50 Gy).
	II	• The panel suggests the use of *benzydamine* mouthwash for the prevention of OM in patients with H&N cancer who receive RT-CT.
PBM	I	• The panel recommends the use of intraoral *PBM* therapy using low-level laser therapy for the prevention of OM in adult patients receiving HSCT conditioned with high-dose CT, with or without TBI, using one of the selected protocols listed in Table 2.
	II	• The panel recommends the use of intraoral *PBM* therapy using low-level laser therapy for prevention of OM in adults receiving RT to the H&N (without CT) (Table 2); safety considerations unique to patients with oral cancer should be considered.
	I	• The panel recommends the use of intraoral *PBM* therapy using low-level laser therapy for the prevention of OM in adults receiving RT-CT for H&N cancer (Table 2); safety considerations unique to patients with oral cancer should be considered. • For all PBM guidelines, it is recommended that the specific PTPs of the selected protocol will be followed for optimal therapy.
Cryotherapy	II	• The panel recommends using oral *cryotherapy* to prevent OM in patients undergoing autologous HSCT when the conditioning includes high-dose melphalan.
	II	• The panel recommends using 30 min of oral *cryotherapy* to prevent OM in patients receiving bolus 5-FU CT during the infusion of the CT.
Antimicrobials, coating agents, anesthetics, and analgesics	III	• Topical *morphine* 0.2% mouthwash is suggested for the treatment of OM-associated pain in patients with H&N cancer who receive RT-CT.
	II	• *Sucralfate* (combined topical and systemic) is not recommended for the prevention of OM-associated pain in patients with H&N cancer who receive RT.
	II	• *Sucralfate* (combined topical and systemic) is not recommended for the treatment of OM-associated pain in patients with H&N cancer who receive RT.
	II	• *Sucralfate* (combined topical and systemic) is not recommended for the treatment of OM-associated pain in patients with solid cancer who receive CT.
Growth factors and cytokines	I	• The use of *KGF-1* intravenously is recommended for the prevention of OM in patients with hematologic cancer undergoing autologous HSCT with a conditioning regimen that includes high-dose CT and TBI.
	II	• The evidence suggests that topical *GM-CSF* should not be used for the prevention of OM in patients undergoing HSCT.
Natural and miscellaneous	I	• The panel recommends against the use of *glutamine* (parenteral) for the prevention of OM in patients undergoing HSCT.
	II	• The panel suggests oral *glutamine* for the prevention of OM in patients with H&N cancer who receive receiving RT-CT. The suggestion is with caution because of the higher mortality rate seen in patients undergoing HSCT who receive parenteral glutamine.
	II	• *Honey* is suggested for the prevention of OM in patients with H&N cancer who receive treatment with either RT or RT-CT.
	III	• *Chewing gum* is not suggested for the prevention of OM in pediatric patients with hematological or solid cancer who receive CT.

Mucositis Prevention Guideline Development Group

In 2017, the Mucositis Prevention Guideline Development Group guideline for the prevention of oral and oropharyngeal mucositis in children receiving treatment for cancer or undergoing hematopoietic stem cell transplantation included the following recommendation:

Recommendation 1.2: We suggest that low-level laser therapy may be offered to cooperative children receiving chemotherapy or HSCT conditioning regimens associated with a high rate of mucositis.

Remarks: This recommendation places high value on the possible reduction in mucositis with an intervention with a low risk of harm. It is a weak recommendation because this strategy requires specialized equipment and expertise and it is unknown whether it is feasible to deliver this therapy modality in routine clinical practice, particularly in a pediatric population. The ideal treatment parameters and cost-effectiveness of this approach are unknown.

North American Spine Society
In 2020, the North American Spine Society published a guideline on the diagnosis and treatment of low back pain. The guideline was based on a systematic review of the literature to address key clinical questions regarding the diagnosis and treatment of adults with nonspecific low back pain. This guideline included the following recommendations:

Guideline Recommendation	Grade of Recommendation
"It is suggested that the combination of laser therapy (low-level or high-level) with exercise provides better short-term relief of pain than either exercise or laser therapy alone."	B
"There is conflicting evidence that the combination of laser therapy with exercise provides better short-term improvement in function compared to exercise or laser therapy alone."	I
"It is suggested that there is no short-term benefit of laser therapy (low-level or high-level) when compared with exercise alone."	B

Grade of Recommendation (levels of evidence range from Level I [high quality randomized controlled trial] to Level V [expert consensus]): A=Good evidence (Level I studies with consistent findings) for or against recommending intervention; B=Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention; C=Poor quality evidence (Level IV or V studies) for or against recommending intervention; I=Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Regulatory Status

Low-Level Laser Therapy (LLLT) Devices

Device	Manufacturer	FDA Approved Date
GRT LITE, Model 8-A: Pulsed therapeutic light therapy and is clinically indicated for adjuctive use in providing temporary pain relief for minor chronic neck and shoulder pain and chronic pain associated with carpal tunnel syndrome (CTS).	GRT Solutions, Inc.	February 2006
Lightstream Low-Level Laser: Handheld non-invasive low energy non-thermal infrared therapeutic medical laser indicated for adjunctive use in the temporary relief of pain associated with knee disorders.	Solica Corporation	April 2009
Luminex Laser Therapy System: The Luminex LL System is a non-thermal, non-invasive, low energy infrared laser, therapeutic medical device that is intended for use as an adjunctive treatment for the temporary relief of hand and wrist pain associated with carpal tunnel syndrome.	Medical Laser System, Inc.	January 2007
MicroLight ML830 Laser System: Contains infrared lamps that are indicated for use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature: for the temporary relief of minor	MicroLight Corporation of America	December 2004

muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.		
RianCorp LTU-904: Is indicated for use as tool as part of a therapy regimen for the treatment of post mastectomy lymphedema	Rian Corp	October 2006
TerraQuant MQ2000 Laser Therapy Device: Uses a combination of a super pulsed laser, pulsed infrared, red light and static magnetic field, which is purported to accelerate pain relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue and to temporarily increase local blood circulation where heat is indicated.	Escada International, Inc.	July 2005
Thor Laser System: The TH0R DDII 83OCL3 Laser System is a non-heating infrared lamp and is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with carpal tunnel syndrome (CTS)	Thor International LTD.	February 2003

High-Power Laser Therapy Devices

Device	Manufacturer	FDA Approved Date
AVI HP-7.5		
AVI HPLL-12		
Diowave Laser System: The Diowave Laser System is intended to emit energy in the infrared spectrum 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.	Technological Medical Advancements, Incorporated	November 2012
OptonPro: Is a topical heat lamp with laser light. It emits energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature. The indications for use of the proposed device are: • temporary relief of minor muscle and joint aches, pains, and stiffness • temporary relief of muscle spasm • temporary relief of minor pain and stiffness associated with arthritis • promoting relaxation of the muscle tissue • temporary increase of local blood circulation.	Zimmer MedizinSysteme GmbH	October 2014

PRIOR APPROVAL

Not applicable.

POLICY

Low-level laser therapy (cold laser therapy, photobiomodulation) may be considered **medically necessary** for the prevention of oral mucositis (OM) in individual's undergoing cancer treatment associated with increased risk of oral mucositis (OM) including one of the following:

- Individuals receiving head and neck radiation therapy (RT) with chemotherapy; **or**
- Individuals receiving head and neck radiation therapy (RT without chemotherapy; **or**
- Individuals who undergo hematopoietic stem cell transplantation (HSCT).

Low-level laser treatment (cold laser treatment, photobiomodulation) not meeting the above criteria is considered **investigational.**

Low-level laser therapy (cold laser treatment, photobiomodulation) or high-power laser therapy (nonsurgical) is considered **investigational,** including but not limited to the following indications, because evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Adhesive capsulitis
- Bell palsy
- Carpal tunnel syndrome
- Chronic neck pain
- Chronic back pain
- Fibromyalgia
- Heel pain (i.e., Achilles tendinopathy, plantar fasciitis)
- Lymphedema
- Osteoarthritic knee pain
- Rheumatoid arthritis
- Subacromial impingement/Shoulder impingement syndrome
- Temporomandibular joint pain
- Wound healing, including diabetic ulcers

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 17999 Unlisted procedure, skin, mucous membrane and subcutaneous tissue

- 97039 Unlisted modality (specify type and time if constant attendance)
- 97139 Unlisted therapeutic procedure (specify)
- 99199 Unlisted special service, procedure or report
- S8948 Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes.
- 0552T Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional

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POLICY HISTORY		
Date	**Reason**	**Action**
February 2022	Annual Review	Policy Revised
February 2021	Annual Review	Policy Revised
February 2020	Annual Review	Policy Revised
February 2019	Annual Review	Policy Revised
February 2018	Annual Review	Policy Revised
February 2017	Annual Review	Policy Revised
February 2016	Annual Review	Policy Renewed
December 2015	Interim Review	Policy Revised
March 2015	Annual Review	Policy Revised
April 2014	Annual Review	Policy Renewed
June 2013	Annual Review	Policy Renewed
July 2012	Annual Review	Policy Renewed
August 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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