CIGNA MEDICAL COVERAGE POLICY

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Subject  Low-Level Laser Therapy

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Coverage Policy

CIGNA does not cover low-level laser therapy (LLLT) for any indication because it is considered experimental, investigational or unproven.

General Background

Low-level laser therapy (LLLT) refers to the use of red-beam or near-infrared lasers with a wave-length between 600 and 1000nm power from 5–500 milliwatts. In contrast, lasers used in surgery typically use 300 watts. These lasers are nonthermal. While the exact mechanism of its effect is unknown, it is theorized that due to the low absorption by human skin the laser light can penetrate deeply into the tissues where it may have a photobiostimulation effect. These types of lasers have been advocated for use in a wide range of medical conditions encompassing: wound healing; smoking cessation; tuberculosis; temporomandibular joint (TMJ) disorders; and a variety of musculoskeletal conditions that includes carpal tunnel syndrome, fibromyalgia, osteoarthritis, and rheumatoid arthritis. 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.
LLLTT is also referred to as cold laser therapy, low-power laser therapy (LPLT), low-intensity laser and low-energy laser therapy. When LLLTT is administered to the acupuncture pressure points, it may be referred to as laser acupuncture. LLLTT includes an extensive variety of procedures involving several laser types and treatment methods. There does not appear to be standards regarding the laser dose, number of treatments or the length of treatment. This results in difficulties with the consistency of the literature. Several randomized controlled trials involving patients with venous ulcers, rheumatoid arthritis, and other musculoskeletal disorders have failed to demonstrate any significant benefits of LLLTT when compared to standard treatment methods or placebos for these conditions.

**Literature Review—Musculoskeletal Conditions**

Blue Cross Blue Shield Technology Assessment Center (TEC) conducted a review of the evidence to determine if low-level laser therapy is effective treatment for carpal tunnel syndrome and chronic neck pain. For the indication of carpal tunnel syndrome, four randomized, sham-controlled clinical trials of low-level laser therapy with 151 patients were included. The studies had serious limitations. Two of the four studies demonstrated statistically significant differences in pain assessed on a visual analog scale (VAS) scale showing benefit of low-level laser therapy. One of the studies that indicated benefit had a small sample size of 19 and enrolled patients with rheumatoid arthritis. The other study had limited follow-up of two weeks beyond the period of treatment. For the indication of chronic neck pain, six trials enrolling with a 285 patients were included. There were variable results. Two studies showed statistically significant findings for the principal outcome of change in VAS pain score. Two studies showed magnitudes of change in VAS pain score consistent with benefit, but were not statistically significant—One of these studies had a small sample size and the other may have had a flawed analysis. Two studies showed similar improvements in pain scores in both laser- and sham-treated control groups which resulted in no difference between the treatments. The review concluded that for both clinical indications of carpal tunnel syndrome and chronic neck pain, the existing randomized clinical trials are insufficient to make conclusions regarding the effect of low-level laser therapy.

Several studies have been published regarding LLLTT 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. A double-blind, randomized, placebo-controlled study to investigate clinical effects of low-level laser therapy (LLTT) in patients with acute neck pain with radiculopathy was conducted by Konstantinovic et al (2010). Sixty subjects received a course of 15 treatments over 3 weeks with active or an inactivated laser as a placebo procedure. Statistically significant differences between groups were found for intensity of arm pain (p<0.003, with high effect size d=0.92) and for neck extension (p=0.003 with high effect size d=0.94). While there was improvement seen in the LLLTT group, there were limitations of the study that included that it considered only short-term effects, and there was potential for selection bias. A randomized, double-blind, placebo-controlled study of 40 patients found no significant differences between four treatment groups with respect to all outcome parameters (p>0.05) and there were no differences between laser and placebo laser treatments on pain severity and functional capacity in patients with acute and chronic low back pain caused by lumbar disk herniation (Ay, et al., 2010). In 2008, Oken et al. reported on a randomized, controlled, single-blind trial of 59 patients that evaluate the efficacy of LLT compare to effects of brace or ultrasound (US) in lateral epicondylitis. No significant difference was noted between the groups in terms of visual analog scale (VAS), grip strength and global assessment at baseline and at follow-up assessments (p>0.05). Limitations of the study included the relatively small study size, lack of long-term follow-up and that activities of daily living were not evaluated. Djavid et al. (2007) conducted a randomized, controlled trial of 61 patients to evaluate LLLTT for chronic low back pain. There was no between-group difference for any outcome measure immediately after the six-week intervention. At 12 weeks, there was no difference in the LLLTT plus exercise group compared with exercise group, while there was improvement noted that in the LLLTT plus exercise group when compared to the placebo laser therapy plus exercise group—pain was reduced by 1.8 cm (95% CI 0.1 to 3.3, p=0.03), lumbar range of movement increased by 0.9 cm (95% CI, 0.2 to 1.8, p<0.01) on the Shober Test and by 15 degrees (95% CIs to 25, p<0.01) of active flexion and disability reduced by 9.4 points (95% CI 2.7 to 16.0, p=0.03) on the Oswestry Disability Index.

There are several systematic and technical reviews published regarding the use of LLLTT for musculoskeletal conditions. Bjordal et al. conducted a systematic review with meta-analysis of LLLTT in lateral elbow tendinopathy, with primary outcome measures of pain relief and/or global improvement and subgroup analyses of methodological quality, wavelengths and treatment procedures. The review included 13 randomized controlled trials (730 patients). The weighted mean difference for pain relief was 10.2 mm (95% CI: 3.0 to 17.5). Trials which targeted acupuncture points reported negative results, as did trials with wavelengths 820, 830 and
In a subgroup of five trials with 904 nm lasers and one trial with 632 nm wavelength where the lateral elbow tendon insertions were directly irradiated, the weighted mean difference for pain relief was 17.2 mm (95% CI: 8.5 to 25.9) and 14.0 mm (95% CI: 7.4 to 20.6) respectively. The LLLT doses in this subgroup ranged between 0.5 and 7.2 Joules. In the secondary outcome measures of pain free grip strength, pain pressure threshold, sick leave, the follow-up data from 3 to 8 weeks after the end of treatment showed consistently significant results in favor of the same LLLT subgroup (p < 0.02). 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.

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)."

**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 an evidence report technology assessment (Samson, 2004) and found that regarding LLLT, it was noted that 11 studies met selection criteria, of which nine were rated poor in quality; one was rated good, and one was rated fair. It was concluded by the reviewers that the "available data suggest that the addition of laser therapy does not improve wound healing, as the vast majority of comparisons in these studies do not report any group differences in the relevant outcomes." A Cochrane systematic review (Flemming, et al., 2004) was performed for the purpose of assessing the effectiveness of LLLT in the treatment of venous leg ulcers. The reviewers concluded that "there is insufficient evidence in this review to give a clear direction for practice. There is no evidence of a benefit of lasers on leg ulcer healing." It was noted that the trials were small and of poor quality. The Alberta Heritage Foundation for Medical Research (AHFMR) (Simon, 2004) published a technology assessment regarding LLLT in treatment of chronic wounds, specifically leg ulcers and pressure sores. It was noted in this review that "systematic reviews of the literature indicate that the efficacy of LLLT in this application is not established, although it poses little or no safety risk to patients. There is no good scientific evidence to support its use and mounting evidence to indicate it does not benefit wound healing."

**Literature Review—Oral Mucositis**

Clarkson et al. (2010) reported on a Cochrane 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.
Kuhn et al. (2009) conducted a placebo-controlled randomized trial using LLT or placebo (sham treatment). The study involved 21 children with cancer who developed oral mucositis as a complication of chemotherapy. Nine patients were randomized in the laser group and 12 in the placebo group. Both groups of patients had daily oral mucositis grading assessments before treatment and thereafter until there was healing of the lesions. At day seven after the oral mucositis diagnosis, there were one of nine patients that remained with lesions in the laser group and in the placebo group there was nine of the 12 patients (p=0.029). The mean of oral mucositis duration was 5.8 ± 2 days in the laser group and in placebo group it was 8.9 ± 2.4 days (p=0.004). In 2008, Arora et al. reported on a prospective, controlled study that evaluated the efficacy of LLLT for the prevention and treatment of radiotherapy-induced oral mucositis in oral cancer patients. The study included 24 patients who were assigned to either group treated with laser daily before radiotherapy (n=11) or Group 2, the control group (n=13). Pain increased gradually and was the greatest at the end of seven weeks with the difference between the laser and control groups noted to statistically significant (p = 0.033). The authors noted that additional studies using different laser energies and application schedules are needed to define optimal treatment variables along with cellular and molecular studies to define mechanisms of laser effect.

Literature Review—Various Medical Conditions
Systematic and Technical Reviews:
There are several Cochrane reviews that are not specifically focused on LLLT, but rather examine a range of interventions, including LLLT, for various medical conditions. These reviews include White et al. (2011) who conducted a review of effectiveness of various interventions for smoking cessation including laser treatment. It was found that the evidence on acupressure and laser stimulation was insufficient and could not be combined and the evidence suggest that electrostimulation is not superior to sham electrostimulation. McNeely et al. (2006), who conducted a systematic review that assessed the evidence concerning the effectiveness of physical therapy interventions, including LLLT in the management of TMD. Of the six studies in the review, there was one that compared LLLT to sham laser. No significant difference was found in pain reduction between these two groups. No evidence was found to support the use of any of the electrophysical modalities to reduce pain. The authors concluded that there is a clear need for well-designed, randomized controlled clinical trials to examine physical therapy interventions for TMD. McLauchlan et al. (2003) conducted a Cochrane review to assess the interventions for treating acute and chronic Achilles tendinitis. The review included nine trials, with one study comparing low-energy laser with sham laser in 98 patients. It was noted that no data could be extracted from six charts showing stiffness, mean pain, reddening, swelling, mean soreness and crepitation presented in the trial report.

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.

Professional Societies/Organizations
The evidence-based guidelines published by the American Pain Society /American College of Physicians found that there is insufficient evidence to recommend LLLT for treatment of low back pain (Chou, et al., 2007).

The American Academy of Orthopaedic Surgeons (AAOS) published clinical practice guidelines on the treatment of carpal tunnel syndrome (AAOS, 2008). In the guidelines, laser treatment was included in
treatments that carry no recommendation for or against their use and notes that there is insufficient evidence to recommend the use of the treatment. It was noted that the modality requires further investigation in appropriately designed studies to determine the efficacy in treatment of carpal tunnel syndrome.

Summary
Low-level laser therapy (LLLT) has been proposed for a wide variety of uses, including wound healing, tuberculosis, and musculoskeletal conditions such as osteoarthritis, rheumatoid arthritis, fibromyalgia and carpal tunnel syndrome. There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that LLLT is effective for these conditions or other medical conditions. Large, well-designed clinical trials are needed to demonstrate the effectiveness of LLLT for the proposed conditions.

Coding/Billing Information

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

Experimental/Investigational/Unproven/Not Covered:

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<thead>
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<th>HCPCS Codes</th>
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<td>S8948</td>
<td>Application of a modality (requiring constant provider attendance) to one or more areas, low-level laser, each 15 minutes</td>
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<td>Displacement of lumbar intervertebral disc without myelopathy</td>
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<td>723.4</td>
<td>Brachial neuritis or radiculitis NOS</td>
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<td>739.3</td>
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<td>844.2</td>
<td>Sprains and strains of knee and leg, Cruciate ligament of knee</td>
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References


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Policy History

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<td>7/15/2008</td>
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Low level laser therapy (LLLT), also called photobiomodulation, refers to the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and Watts from 5 to 500 milliwatts. This is in contrast to surgical lasers that typically use 300 Watts. Low-level laser energy that is applied to acupuncture points on the body may be referred to as "laser acupuncture."

When applied to the skin, low level lasers produce no sensation and do not burn the skin. Because of the low absorption by human skin, it is hypothesized that the laser light can penetrate deeply into the tissues where it has a photobiostimulative effect. The exact mechanism of its effect is unknown; hypotheses have included improved cellular repair and stimulation of the immune, lymphatic, and vascular systems.

LLLT has been proposed as a treatment of carpal tunnel syndrome, painful musculoskeletal disorders such as temporomandibular joint disfunction and low back pain, soft tissue injuries, tendinopathies, and osteoarthritis. LLLT has been used outside the US to treat oral mucositis associated with radiation and chemotherapy, stimulate healing of chronic wounds, treat nerve injuries, and as an adjunct to antituberculosis drug treatment.

A number of low level lasers have received US Food and Drug Administration (FDA) 510 (k) approval, including:

- MicroLight ML830®
- GRT LITE™
- LightStream™ Low Level Laser
- TouchOne™ (OTC)

**POLICY/CRITERIA**

Low level laser treatment and laser acupuncture are considered investigational for all
indications, including but not limited to the following:

1. Acute or chronic headache
2. Acute pain (e.g., postoperative pain, strains and sprains, labor pain)
3. Arthritis
4. Back, neck or shoulder pain
5. Carpal tunnel syndrome
6. Chemotherapy-induced mucositis
7. Fibromyalgia
8. Lateral or medial epicondylitis
9. Orthodontic pain
10. Other pain disorders
11. Temporomandibular joint (TMJ) pain
12. Tendinitis
13. Tinnitus
14. Wound healing

SCIENTIFIC BACKGROUND

The principal outcomes associated with treatment of carpal tunnel syndrome and musculoskeletal conditions are relief of pain, return to work, and improved functional level. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect provides a significant advantage over the placebo.

The technology must also be evaluated in general groups of patients against existing treatments. In patients with mild to moderate symptoms, LLLT or laser acupuncture may be compared to other forms of conservative therapy such as splinting, rest, non-steroidal anti-inflammatory medications, or steroid injection. In patients who have exhausted conservative therapy, LLLT or laser acupuncture must be compared to surgical treatment, if any.

Low-level laser treatment

Carpal Tunnel Syndrome (CTS)

The largest body of evidence for LLLT describes its use in the treatment of CTS. This evidence was evaluated in a 2010 BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment, which concluded that the existing randomized clinical trials were insufficient to determine the effect of low-level laser therapy on CTS. [2]

For inclusion in the assessment, studies had to meet the following criteria:

- Published in a peer-reviewed journal
- Randomized
- Sham-controlled
- If adjunctive therapies were used, they had to be applied to both groups of patients
- Outcomes had to be measured at least 2 weeks beyond the end of the treatment period

Only four studies met the above inclusion criteria, and findings from these studies were inconsistent. No one study was so methodologically sound that its results were considered definitive. Overall, the available studies were small and most did not follow patients for sufficient periods of time beyond the treatment period to determine the durability of any treatment effects.

Chemotherapy-induced Mucositis

Treatment of malignant diseases with cytotoxic chemotherapy or radiotherapy is associated with severe ulceration of the oral mucosa. A 2010 Cochrane review concluded
there was weak and unreliable evidence that LLLT reduced the severity of mucositis. [3]

**Chronic Neck Pain**

The 2010 TEC Assessment also determined that the evidence was insufficient to allow conclusions regarding the effect of LLLT on chronic neck pain. [2] The 6 trials that met the assessment inclusion criteria reported variable results, and no single study was methodologically sound. It was not possible to explain the differences in results due to the numerous differences in patient selection, treatment regimens, and trial co-interventions.

**Low Back Pain**

- An update of the Cochrane Database systematic review of LLLT for nonspecific low back pain was conducted in 2008. [4] The authors stated that "based on the heterogeneity of the populations, interventions, and comparison groups, we conclude that there are insufficient data to draw firm conclusions on the clinical effect of LLLT groups for low-back pain."
- A systematic review by Chou and colleagues assessed benefits and harms of nonpharmacological therapies including LLLT for acute and chronic low back pain. [5] The reviewers did not find good evidence of efficacy for LLLT for either indication.
- Since publication of the Cochrane Review, two additional randomized trials, reporting conflicting results were published.
  - In a large double-blind placebo-controlled study, Konstantinovic et al. randomized 546 patients with acute low back pain to 3 groups of 182 patients. [6] All patients received nimesulide 200 mg; patients in group A received active LLLT, patients in group B received only nimesulide, and patients in group C received placebo LLLT. Treatments were given 5 times per week for 15 weeks. Statistically significant differences after treatment were found on all outcomes ($p<0.001$) but were larger in group A than in B ($p<0.005$) and C ($p<0.0005$). Results in group C were better than in group B ($p<0.0005$). The authors conclude that improvement is better in acute low back pain with LLLT as additional therapy. However, duration of these outcomes was not measured.
  - Ay and colleagues randomized 80 patients with acute and chronic low back pain attributed to lumbar disc herniation (LDH) into 4 groups of 20. [7] All patients received hot-packs and group 1 (acute LDH) received laser therapy; group 2 (chronic LDH) received laser therapy, group 3 (acute LDH) received placebo laser therapy; and group 4 (chronic LDH) received placebo laser therapy for 15 sessions over 3 weeks. After treatment all groups had statistically significant improvements in pain severity, patients’ and physician’s global assessment, range of motion, Roland Disability Questionnaire, and Modified Oswestry Disability Questionnaire ($p<0.05$). There were no significant differences between treatment groups on any outcomes ($p<0.05$). Durability of treatment effect was not reported.

**Rheumatoid Arthritis (RA)**

- A 2005 Cochrane Review included 5 placebo-controlled randomized trials and found that relative to a separate control group, LLLT reduced pain and morning stiffness, and increased tip-to-palm flexibility. [8] Other outcomes did not differ between groups, including functional assessment, range of motion, and local swelling. For RA, relative to a control group using the opposite hand (1 study), there was no difference observed between the control and treatment hand for morning stiffness duration and no significant improvement in pain relief. The authors noted that "despite some positive findings, this meta-analysis lacked data on how LLLT effectiveness is affected by four important factors: wavelength, treatment duration of LLLT, dosage and site application over nerves instead of joints."
- A randomized double-blind placebo-controlled trial comparing outcomes of pain reduction and improvement in hand function in 82 patients with RA treated with low-level laser or placebo laser was reported by Meireles et al. [9] There were no statistically significant differences between groups in most of the outcome measurements, including the primary variables, though a few measures significantly favoring either the active or placebo treatment were found. The authors concluded that low-level laser at the dosage used in the study was not effective for the treatment of hands among patients with rheumatoid arthritis.
Shoulder Pain

Three randomized trials report conflicting results:

- In a study designed to assess the effectiveness of LLLT in patients with subacromial impingement syndrome, 44 patients were randomized in equal numbers to receive a 12-week home exercise program with or without LLLT. No distinct advantage was demonstrated by LLLT over exercise alone.
- Another randomized controlled trial compared outcomes of a 3-week program of exercise with either LLLT or sham therapy for treatment of subacromial impingement. Both groups improved significantly, and there were no significant between-group differences on measures of pain, function, disability, and muscle strength.
- Seventy-four patients with frozen shoulder were included in a randomized, controlled, double-blind trial comparing an 8-week program of LLLT (n=31) or placebo (n=32). Compared to the sham group, the active laser group had a significant decrease in overall, night, and activity pain scores after 4 weeks and 8 weeks of treatment, and at the end of 8 more weeks of follow-up. At the same time intervals, a significant decrease in shoulder pain, disability index (SPADI) scores, and Croft shoulder disability questionnaire scores was observed, while a significant decrease in disability of arm, shoulder, and hand questionnaire (DASH) scores was observed at 8 weeks of treatment and at 16 weeks' post-randomization; and a significant decrease in health assessment questionnaire scores was observed at 4 weeks and 8 weeks of treatment. Results from this study are not reliable because 11 patients included in the original randomization were excluded from analysis after leaving the study to seek other treatments. It is not known how this loss might have biased the final outcomes of the study.

Temporomandibular Joint (TMJ) Pain

Two randomized trials of LLLT for TMJ pain are reported no significant differences between sham and active treatment groups.

Wound Healing

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

Laser acupuncture

The randomized clinical trial data related to laser acupuncture is limited to four small, short-term studies, each focused on a different pain condition. The conditions included chronic tension headache, migraine and tension headaches in children, whiplash injury, and osteoarthritis of the knee. The available clinical trial data did not permit scientific conclusions concerning the impact of laser acupuncture on health outcomes for any of these conditions.

- Ebnesiahidi and colleagues in a single-blind, randomized, placebo-controlled trial of 50 patients with chronic tension headache reported that laser acupuncture using a LLLT device may provide benefit over placebo. The study was small and the acupuncturists administering the true or sham treatments as well as the assessors were aware of the allocation and thus could have positively influenced the laser acupuncture group. In addition, the baseline measures were different from the subsequent measurements performed in follow-up. The results from this small study need to be validated in a larger, randomized, double-blind clinical trial.
- A second trial of laser acupuncture on 43 children with both migraine and tension headaches provided highly individualized treatment and additional therapies which do not permit conclusions regarding the independent effects of laser treatment.
- Two studies reported no significant difference between patients treated with active vs. sham laser acupuncture for the treatment of whiplash injury and knee
osteoathritis [19].

Clinical Practice Guidelines

- The American Academy of Orthopaedic Surgeons 2008 clinical practice guideline on the treatment of carpal tunnel syndrome included laser treatment among treatments that carry no recommendation for or against their use because there is insufficient evidence to recommend their use. [20]
- The 2007 American Pain Society guideline states that there is insufficient evidence to recommend LLLT for treatment of low back pain and LLLT is not mentioned in the 2009 guideline. [21]
- The British NHS National Institute for Health and Clinical Excellence (NICE) 2009 guideline on early management of persistent non-specific low back pain does not recommend laser treatment citing limited evidence and a systematic review. [22]

Summary

The available literature has not shown LLLT to be as effective as established treatments for a variety of indications, including carpal tunnel syndrome, various musculoskeletal conditions, chemotherapy-induced mucositis, and wound healing. Outcomes of studies comparing LLLT with sham laser therapy for treatment of pain and other conditions are inconsistent and generally involve small numbers of participants. Most studies found no statistically significant difference in symptom relief or functional status between the active LLLT group and the control group. This was true whether the control group received sham LLLT, surgical treatment, or other conservative treatment modalities. The bulk of the clinical trials included small numbers of patients with short follow-up periods that did not permit assessment of the durability of any benefit received from treatment. Data from adequately powered, blinded RCTs that report longer follow up and consistent dosing parameters are needed to determine efficacy and safety for each indication.

There is no evidence-based clinical practice guideline that recommends LLLT as a treatment for any condition.

REFERENCES

11. Yeldan, I, Cetin, E, Ozdemir, AR. The effectiveness of low-level laser therapy on shoulder function in subacromial impingement syndrome. Disabil Rehabil. 2009;31


Cross References

Regence ConsumerTx: Low Level Laser Therapy

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<td>There is no specific CPT code identifying low level laser therapy. HCPCS code 58948 specifically identifies LLLT. Since the service is used by a variety of practitioners who may be required to bill using specific codes related to their specialty, the following are documented:</td>
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<td></td>
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<td>When LLLT is administered in the office or clinic setting CPT codes 97026, 97039, 97799 for physical medicine modalities, 97810-97814 for acupuncture or 98940-98943 for chiropractic services may be used. These CPT codes are not specific for LLLT and cannot be distinguished by CPT code alone from other types of modalities, acupuncture or chiropractic services.</td>
</tr>
<tr>
<td>CPT</td>
<td>None</td>
<td>Application of a modality (requiring constant provider attendance) to one or more areas; low level laser, each 15 minutes</td>
</tr>
</tbody>
</table>