



CIGNA MEDICAL COVERAGE POLICY

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Subject **Low-Level Laser Therapy**

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- Chiropractic Care
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- Physical Therapy
- Plantar Fasciitis Treatments

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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. Due to the low absorption by human skin, it is hypothesized that 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 a physician's office or other outpatient setting with no anesthesia or sedation needed.

LLLT is also referred to as cold laser therapy, low-power laser therapy (LPLT), low-intensity laser and low-energy laser therapy. When LLLT is administered to the acupuncture pressure points, it may be referred to as laser acupuncture. LLLT includes an extensive variety of procedures involving several laser types and treatment

methods. These various treatment procedures have been proposed for a wide range of medical conditions. There does not appear to be standards regarding the 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 LLLT when compared to standard treatment methods or placebos for these conditions.

The exact mechanism of its effect is unknown; however, hypotheses have included improved cellular repair and stimulation of the immune, lymphatic and vascular systems. The principle outcome associated with treatment of carpal tunnel syndrome and musculoskeletal conditions is generally relief of pain. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, blinded and randomized controlled trials are required to monitor for the placebo effect, determine its magnitude and whether any treatment effect provides a significant advantage over the placebo. Since the condition has a spectrum of severity with different treatments, the technology must be evaluated in different groups of patients that represent the spectrum of the disease to allow for candidate selection. No such evaluations are available in the peer-reviewed, evidence-based literature.

Literature Review

Studies: Gur et al. (2002) conducted a randomized, single-blind, placebo-controlled study to evaluate the efficacy of low-energy laser therapy in 40 female patients with fibromyalgia. Patients with fibromyalgia were randomly allocated to active laser or placebo laser treatment daily for two weeks. Both the laser and placebo laser group were evaluated for improvement in pain, number of tender points, skinfold tenderness, morning stiffness, sleep disturbance, muscular spasm and fatigue. An ordinal Likert scale scoring system was used for grading outcome parameters. It is also noted that there are unanswered questions regarding the mechanism of the treatment, differences in technology, devices, laser beam and divergence of beam. Even though the conclusions revealed that low-level laser therapy appeared to be effective in treating fibromyalgia pain and muscle spasm, the sample size of the study was small, there was potential for provider bias, and the study was short-term with no indication of follow-up.

Lucas et al. (2003) conducted a prospective, observer-blinded multicenter, randomized clinical trial to assess the effect of LLLT as adjunct to standard decubitus care. The study involved 86 patients, who received the prevailing consensus decubitus treatment. Forty-seven of these patients received only this treatment. Thirty-nine patients received in addition to the prevailing consensus decubitus treatment, LLLT, five times a week over six weeks. The primary outcome measure was the wound size reduction at six weeks compared to baseline. Secondary outcome was the number of patients who developed stage IV ulcers during the six weeks. The study indicated that no significant difference between groups could be demonstrated. In addition, it was noted that during the treatment period, 11% of the patients in the control group and 8% of the patients in LLLT group developed a stage IV decubitus. The authors concluded that they found no evidence that justifies using LLLT as an adjuvant to standard ulcer treatment.

Gur et al. (2004) conducted a prospective, double-blind, randomized controlled study to assess the effects of LLLT on patients with myofascial pain syndrome in the neck. Sixty patients were randomly assigned to either receive actual laser or placebo laser. The LLLT was administered daily for two weeks, except for weekends. The patients were evaluated at baseline, and at two, three and 12 weeks. Patients were evaluated with regard to pain at rest, pain at movement, number of trigger points and the Neck Pain and Disability Visual Analog Scale, Beck Depression Inventory and the Nottingham Health Profile. The study noted that in the active laser group, improvement was detected in all outcome measures compared to baseline. In the placebo group, significant improvements were detected in the pain score. The authors note that there was difficulty in finding readings in the literature related to the use of laser therapy with this condition. In addition, it was noted that there do not appear to be standard therapy programs regarding the dose and duration of the laser, and current publications have revealed various results. The authors concluded that the study revealed that short-period application of LLLT is more effective for pain relief and in the improvement of functional ability and quality of life than that of placebo laser in patients with myofascial pain syndrome.

Brosseau et al. (2004) conducted a randomized study to examine the efficacy of active LLLT versus sham LLLT on finger joints and three superficial nerves in patients with osteoarthritis (OA). Patients were randomly assigned to receive three treatments of LLLT (n=42) or sham LLLT (n=46) per week for six weeks. The results indicated that pain relief, morning stiffness and functional status did not significantly improve for LLLT versus placebo.

The authors concluded that “for patients with OA of the hand, treatment with LLLT “is not significantly better than a placebo treatment at reducing intensity of pain and morning stiffness, or at improving range of motion, strength and functional status. Further studies need to be conducted to refine the therapeutic application (dosage, treatment, duration, etc.) of LLLT.”

Bingol et al. (2005) conducted a study to investigate the effect of low-power gallium-arsenide laser treatment on patients with shoulder pain. The study included 40 patients who were randomly assigned into group I (n=20) and received 10 sessions of laser treatment and an exercise program for two weeks or group II (n=20), the control group, who received placebo laser and the same exercise protocol for the same period. Evaluations included the parameters of pain, palpation sensitivity, algometric sensitivity, and shoulder joint range of motion before and after treatment. Analysis of measurement results within each group showed a significant post-treatment improvement for some active and passive movements in both groups, and also for algometric sensitivity in group I ($p<0.05-0.01$). Post-treatment palpation sensitivity values indicated improvement in 17 patients (85%) for group I and six patients (30%) for group II. A comparison of the two groups showed superior results ($p<0.01$ and $p<0.001$) in group I for the parameters of passive extension and palpation sensitivity but no significant difference for other parameters. The authors concluded that, “The results of our study have shown better results in palpation sensitivity and passive extension, but no significant improvement in pain, active range, and algometric sensitivity in laser treatment group compared to the control group in the patients with shoulder pain.” The authors also noted that, “The need to standardize study designs in LLLT applications, with particular emphasis on the laser type/duration and patient selection criteria, is obvious for further delineation of the role of this promising treatment modality in painful musculoskeletal conditions.”

Bjordal et al. (2006) conducted a study to investigate if LLLT has an anti-inflammatory effect on activated tendinitis of the Achilles tendon. The study involved seven patients with bilateral Achilles tendinitis (14 tendons). LLLT was applied to both Achilles tendons in random blinded order. Results included: prostaglandin E₂ concentrations were significantly reduced at 75, 90, and 105 minutes after active LLLT treatment compared with before treatment and after placebo; pressure pain threshold had increased significantly after LLLT compared to placebo. The authors concluded that LLLT can reduce inflammation and pain in activated Achilles tendinitis and may have potential in management of disease with an inflammatory component. More trials are needed to determine optimal dose ranges and intervals between applications, and then the results should be confirmed in larger clinical trials of longer duration.

Djavid et al. (2007) conducted a randomized, controlled trial to evaluate LLLT for chronic low back pain. The trial included 61 patients who had low back pain for at least 12 weeks. The patients were assigned to either laser therapy alone (n=16), laser therapy and exercise (n=38) and a third group that received placebo laser therapy and exercise (n=18). The laser therapy was provided twice a week for six weeks. Outcome measures included pain, lumbar range of motion and disability. Eight patients withdrew from the study during the intervention or during follow-up. 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 LLLT plus exercise compared with exercise group, while there was improvement noted that in the LLLT 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% CI 5 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. The authors note that the small study size was unable to detect differences between groups for some outcomes and that LLLT should be investigated in trials with larger sample sizes and longer follow-up time periods.

Mazzetto et al. (2007) conducted a randomized, double blind study to evaluate the effectiveness of LLLT for the control of pain from temporomandibular joint disorders (TMD). Forty-eight patients were divided into an experimental group or a placebo group. Treatment with infrared laser was applied in continuous mode on the affected region at on point inside the external auditive duct toward the retrodiskal region, twice a week, for four weeks. The control group received treatment with two identical probes (one activated and one not emitting radiation) that was unknown to the practitioner and patient. The intensity of pain was evaluated after palpation of the condylar lateral pole, pre-auricular region and external auditive duct, according to the visual analog scale (VAS). There were four evaluations performed: before laser application (Ev1); after 4th application (Ev2), after 8th application (Ev3) and 30 days after the last application (Ev4). Results indicated a decrease in the pain level mainly for the active probe. The Ev3 exhibited lower sensitivity to palpation.

Emshoff et al. (2007) conducted a randomized, double-blind study to assess the effectiveness of LLLT in the management of TMJ pain. The study included 52 consecutive patients with unilateral TMJ pain. They were randomly assigned to either treatment with active LLLT (n=26) or sham laser (n=26). Measures of TMJ pain during function were evaluated at baseline and 2, 4, and 8 weeks after the first laser therapy. The treatments were two to three per week for eight weeks. There were no significant differences seen in the listed parameters ($p>.05$). The results indicated that, with time both study groups had a significant improvement in TMJ pain during function ($p=.000$) and there were no significant group differences ($p>.05$).

Oken et al. (2008) reported on a randomized, controlled, single-blind trial to evaluate the efficacy of LLT and to compare these with effects of brace or ultrasound (US) treatment in lateral epicondylitis. The study included 59 patients who were divided into three groups: brace group—brace plus exercise (n=20); ultrasound group—US plus exercise (n=19); laser group—LLLTT plus exercise (n=20). In the brace group, a lateral counterforce brace was used for three weeks; US plus hot pack was used in the ultrasound group; and in the LLLT group laser plus hot pack was used. All patients were provided with progressive stretching and strengthening exercise programs. The grip strength and pain severity were evaluated with VAS at baseline, at the second week of treatment, and at the sixth week of treatment. VAS was noted to be improved in all groups after the treatment and in the ultrasound and laser groups at the sixth week ($p<0.05$). The grip strength of the affected hand increased only in the laser group after treatment, but was not changed at the sixth week. No significant difference was noted between the groups in terms of VAS, grip strength and global assessment at baseline and at follow-up assessments ($p>.05$). 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.

Arora et al. (2008) 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 with oral cancer that were scheduled to receive radiotherapy. The patients were assigned to either Group 1, where they were treated with Helium-Neon laser daily before radiotherapy (n=11) or Group 2, the control group (n=13). All patients received oral prophylaxis before radiation and the same kind of oral care during the treatment. The patients were evaluated on each day of treatment for pain severity, functional impairment and oral mucositis and then were followed until the end of cancer treatment. Pain increased gradually and was the greatest at the end of seven weeks with the difference between the laser and control groups noted to be statistically significant ($p=.033$). The laser patients experienced maximum functional impairment of grade 1 (54.5%). The control group progressed to grade II and grade III. In addition one patient of the control group developed grade IV and required nasogastric feeding. Regarding mucositis, it was noted that in five, six, and seven weeks that the laser group patients continued to experience grade II and III mucositis, and most of the control group progressed to grade III and IV (p values: .004 in second week; .000 in third week; .019 in sixth week; .045 in seventh week). 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.

Systematic and Technical Reviews: A systematic review (Cullum, et al., 2001) was performed to assess the clinical effectiveness and cost-effectiveness of therapies for treatment of chronic wounds. There were four randomized controlled trials that utilized laser for venous leg ulcers, with the studies noted to be small and of poor methodological quality. Regarding LLLT, it was noted that there is generally insufficient reliable evidence to draw a conclusion regarding this treatment.

Crossley et al. (2001) conducted a systematic review of physical interventions for patellofemoral pain syndrome. The criteria for inclusion in the study were: that the trial was a controlled trial; and that the treatment was a nonpharmacological, nonsurgical physical intervention. One study was identified that involved LLLT. No difference in outcome was noted when compared to sham laser. Among the findings, it was noted that there is no evidence to support the use of LLLT for this condition.

Bjordal et al. (2003) conducted a systematic review of the low-level laser therapy with location-specific doses for pain from chronic joint disorders. Eleven trials were included that involved 565 patients. In these trials, LLLT within the suggested dosage range was administered to the knee, temporomandibular or zygapophyseal joints. The results indicated a mean weighted difference in change of pain in the VAS in favor of the LLLT group. The authors note that the heterogeneity in patient samples, treatment procedures and trial design calls for cautious interpretation of the results. The authors note that the results of the review may have been affected by several factors including: a lack of hard data on biological effects that laser causes at certain depths and tissues in the

human body; heterogeneity in treatment procedures and within the patient sample; only some trials prohibited co-intervention by anti-inflammatory drugs; differences in numbers and frequencies of treatment sessions. It is indicated in the conclusion that more and larger trials are needed to precisely determine optimal treatment procedures for LLLT and possible interaction with other therapies for chronic joint disorders.

A Cochrane systematic review (Brosseau, et al., 2004) was performed for the purpose of reviewing the literature regarding LLLT as treatment for osteoarthritis. The review included seven controlled clinical trials, with 184 patients randomized to laser and 161 to an inactive laser probe. It was noted that the “main limitation of this systematic meta-analysis is the heterogeneity of clinical application, including different dosages, wavelengths, and types of LLLT.” The authors summarized the implications for its practice as “there is insufficient evidence to draw any firm conclusions regarding the use of LLLT for treatment of osteoarthritis.” It was concluded that there is a need for further large-scale studies of laser therapy for osteoarthritis.

The Agency for Healthcare Research and Quality (AHRQ) published an evidence report technology assessment (Samson, 2004). The purpose of the evidence report is to systematically review and synthesize the available evidence on the effectiveness of LLLT and vacuum-assisted closure for wound healing. With regard to 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.”

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. It was noted that the main limitation of this systematic meta-analysis is the heterogeneity of clinical application, including different dosages, wavelengths, and types of LLLT. In addition, the results are subject to publication bias, if negative trials have not been published. It was also noted that the treated joints in all but one of the RA studies involved hand joints and therefore it may not be possible to generalize the results to other treatment sites. 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).”

A Cochrane systematic review (Vlassov, et al., 2006) was performed for the purpose of assessing the use of LLLT for tuberculosis. The review notes that LLLT has been used as an adjunct to anti-tuberculosis drugs, mainly in the former Soviet Union and India. In 2006, an update to this review noted that there was one randomized controlled trial with 130 participants conducted in India who met the inclusion criteria. The trial was poorly reported, with no information on the generation of allocation sequence or allocation concealment. In addition, there were no details reported regarding the group that each of the participants were randomized into or which group those participants who left the trial were from. These deficiencies precluded the use of its data on time to sputum conversion and other outcome measures for analysis. The authors concluded that, “the use of low level laser therapy for treating tuberculosis is still not supported by reliable evidence. Researchers need to focus on conducting well-designed randomized controlled trials to justify the continued participation of volunteers for studies of this experimental intervention.”

In addition to the above Cochrane systematic 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 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.

White et al. (2006) conducted a Cochrane review to determine the effectiveness of acupuncture and related interventions of acupressure, laser therapy and electrostimulation, in smoking cessation in comparison with no intervention, sham treatment or other interventions. Twenty-four studies were included in the review, with one study involving laser therapy compared to placebo laser. The authors concluded that, "There is no consistent evidence that acupuncture, acupressure, laser therapy or electrostimulation are effective for smoking cessation, but methodological problems mean that no firm conclusions can be drawn. Further research using frequent or continuous stimulation is justified."

Bjordal et al. (2007) conducted a systematic review and meta-analysis of randomized, placebo-controlled trials that examined the short-term efficacy of physical interventions in osteoarthritic knee pain. The treatments that were included in the review included transcutaneous electrical nerve stimulation (TENS), (including interferential currents), electro-acupuncture (EA) and LLLT. Thirty-six randomized controlled trials were included—with eight trials involving LLLT (n=343). The review noted that the treatments offered clinically relevant pain relieving effects of 18.8 mm (95% confidence interval [CI]: 9.6 to 28.1), 21.9 mm [95% CI: 17.3 to 26.5] (n = 73) and 17.7 mm [95% CI: 8.1 to 27.3] (n = 343) on VAS respectively versus placebo control. The follow-up data for the time period of up to 12 weeks were sparse, but it appeared that positive effects seemed to persist for at least four weeks after the course of treatment was stopped. The limitations of this analysis include the small sample size of some trials. The authors note that they "remain cautious in their conclusion until larger scale clinical trials are available to verify the results."

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. The review included only systematic reviews and randomized trials for acute or chronic low back pain that reported pain outcomes, back-specific function, general health status, work disability, or patient satisfaction. In regards to LLLT, there were seven trials that met inclusion criteria. The studies were noted to be generally small, with 20 to 120 patients. The studies evaluated heterogeneous outcome measures and different types of lasers at varying doses. In regards to chronic low back pain or back pain of unspecified duration there were four trials that 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. 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).

Yousefi-Nooraie et al. (2008) conducted a Cochrane review that examined LLLT for nonspecific low-back pain. Seven heterogeneous randomized controlled trials were included in the review. The types of laser, dose, duration and frequency of treatments varied among the studies. The study size was small, varying from 20 to 80 patients. It was noted that three small studies separately demonstrated significant but clinically unimportant pain relief for LLLT as compared to sham therapy for sub-acute and chronic low-back pain at short- and intermediate-term follow-up. One study indicated that LLLT was more effective than sham at receding disability in short term. Three studies showed that LLLT plus exercise was not more superior to exercise, with or without the sham therapy, in the short-term in reducing pain or disability. There were two studies that indicated that LLLT was not more effective than exercise, with or without sham in reducing pain or disability in the short term. 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.

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.”

A large number of devices that provide LLLT have been approved under the 501(k) approval process with various indications. These devices include but are not limited to:

- MicroLight 830™ (MicroLight Corporation of America, Missouri City, TX) received approval in 2002 for the indication of “adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.”
- Axiom BioLaser LLLT Series-3 (Axiom Worldwide, Tampa, FL) received approval in 2003 for the indication of “adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.”
- Acculaser™ Pro4 (PhotoThera, Carlsbad, CA) received approval in 2004 for the indication of “adjunctive use in providing temporary relief of pain associated with iliotibial band syndrome.”
- Thor DDII IR Lamp System (Thor International Ltd, Amersham, UK) received approval in 2004 for the indication of “elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.”
- Thor DDII 830 CL3 Laser System (Thor International Ltd, Amersham, UK) received approval in 2003 for the indication of “adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.”
- Luminex LL Laser System® (Medical Laser Systems, Inc, Branford CT) received approval in 2007 for the indication of adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

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.

Summary

Low-level laser therapy (LLL) 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:

| CPT* Codes | Description |
|------------|-------------------|
| | No specific codes |

| HCPCS Codes | Description |
|-------------|-------------|
| | |

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

| ICD-9-CM Diagnosis Codes | Description |
|--------------------------|-------------|
| | All codes |

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Policy History

| <u>Pre-Merger Organizations</u> | <u>Last Review Date</u> | <u>Policy Number</u> | <u>Title</u> |
|-------------------------------------|-----------------------------|--------------------------|-------------------------|
| CIGNA HealthCare | 7/15/2008 | 0115 | Low-Level Laser Therapy |

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA’s subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.