**Name of Policy:**
Low Level Laser and High Power Laser Therapies

Policy #: 270       Latest Review Date: January 2014
Category: Therapy       Policy Grade: B

**Background/Definitions:**
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Low-level laser therapy (LLLT) is a light source treatment that generates light of a single wavelength. It is also known as photobiomodulation. Low-level lasers are also known as “cold lasers” and non-thermal lasers. They emit no heat, sound or vibration. They refer to the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and watts from 5 – 500 milliwatts. In contrast, lasers used in surgery typically use 300 watts. When applied to the skin, these 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 photo-bio-stimulative effect. The exact mechanism of its effect on carpal tunnel syndrome is unknown; hypotheses have included improved cellular repair and stimulation of the immune, lymphatic, and vascular systems.

Low-level laser therapy has been proposed as a treatment for a variety of disorders, including carpal tunnel syndrome, temporomandibular joint dysfunction, low back pain, joint disorders and tendinopathies, lateral and medial epicondylitis, osteoarthritis, venous ulcers, and decubitus ulcers, myofascial pain, lymphedema, and oral mucositis.

The most studied application of LLLT is for the treatment of pain associated with carpal tunnel syndrome. Carpal tunnel syndrome is the most common entrapment neuropathy and the most commonly performed surgery of the hand. The syndrome is related to the bony anatomy of the wrist. The carpal tunnel is bound dorsally and laterally by the carpal bones and ventrally by the transverse carpal ligament. Through this contained space run the nine flexor tendons and the median nerve. Therefore any space-occupying lesions can compress the median nerve and produce the typical symptoms of carpal tunnel syndrome: pain, numbness, nocturnal awakening and tingling in the distribution of the median nerve. Symptoms of more severe cases include hypesthesia, clumsiness, loss of dexterity, and weakness of pinch. In the most severe cases, patients experience marked sensory loss and significant functional impairment with thenar atrophy.

A variety of etiologies have been associated with the carpal tunnel syndrome. Nonspecific flexor tenosynovitis is the most common cause and is in turn typically associated with occupationally associated repetitive motion. A variety of space-occupying lesions can compress the median nerve, including benign tumors, or anatomic anomalies. Pregnancy has been associated with carpal tunnel syndrome, presumably as a result of hormone-mediated edema. Carpal tunnel syndrome can also be one of the clinical manifestations of the following medical conditions: rheumatoid arthritis, diabetes, post-traumatic wrist deformities, polymyalgia rheumatica, mucopolysaccharidoses, amyloidosis, myxedema, or acromegaly.

Mild to moderate cases of carpal tunnel syndrome are usually first treated conservatively with splinting and cessation of aggravating activities. Other conservative therapies include oral steroids, diuretics, nonsteroidal anti-inflammatory drugs (NSAIDS), and steroid injections into the carpal tunnel itself. Those patients who do not respond to conservative therapy or who present with severe carpal tunnel syndrome with thenar atrophy may be considered candidates for surgical release of the carpal ligament, using either an open or endoscopic approach.
LLLT is also being evaluated for cancer therapy-induced oral mucositis in patients treated by radiotherapy and/or chemotherapy and hematopoietic stem-cell transplantation (HCST). Oral mucositis describes inflammation of the oral mucosa and typically manifests as erythema or ulcerations that appear 7 to 10 days after initiation of high-dose cancer therapy. Oral mucositis can cause significant pain and increase risk of systemic infection, dependency on total parenteral nutrition, and use of narcotic analgesics. Treatment planning may also need to be modified due to dose-limiting toxicity. There are a number of interventions for oral mucositis that may partially control symptoms, but none are considered a gold standard treatment. When uncomplicated by infection, oral mucositis is self-limited and usually heals within 2 to 4 weeks after cessation of cytotoxic chemotherapy.

High-power laser therapy (HPLT), known as class IV laser therapy, has a power output from 500 to 7500 milliwatts. These devices provide more power than low-level lasers and theoretically provide deeper penetration in less time over a larger surface treatment area. Deep tissue laser therapy has been proposed for use in the office setting to provide topical heating for the purpose of elevating tissue temperature for relief of pain in certain conditions. Despite little scientific support, high-power lasers have been used for various indications including pain relief, wound healing, and musculoskeletal disorders such as carpal tunnel syndrome, low back pain, lateral epicondylitis (tennis elbow), arthritis conditions, headaches, and plantar fasciitis. This type of class IV therapeutic laser should not be confused with class IV surgical laser.

In February 2002 one low-level laser device, the Micro Light 830 Laser, received clearance for marketing from the U. S. Food and Drug Administration (FDA) specifically for the treatment of carpal tunnel syndrome. In the data submitted to the FDA as part of the FDA 510 (k) approval process, the treatment consisted of application of the laser over the carpal tunnel three times a week for five weeks. The labeling states that the “Micro Light 830 Laser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with carpal tunnel syndrome.” In 2006, the FDA provided marketing clearance for the GRT LITE, which listed the Tuco Erchonia PL3000, the Excalibur system, the Microlight 830 Laser, and the AccuLaser Pro as predicate devices. Indications for the GRT LITE for carpal tunnel syndrome are similar to the predicate devices; “Adjunctive use in providing temporary relief of minor chronic pain”. Other protocols have used low-level laser energy applied to acupuncture points on the body. This technique may be referred to as “laser acupuncture”.

The LightStream™ Low Level Laser device received 510(k) marketing clearance in 2009 for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice. As of October 2009, no devices have received FDA clearance for applications other than treatment of pain. A number of clinical trials of LLLLT are underway in the U.S. including studies of wound healing.

The first commercial class IV high-power laser therapy device was invented in 2003 by Avicenna Laser Technology, Inc., and received Food and Drug Administration (FDA) clearance by the end of 2003. It is a therapeutic medical laser and was designed to bio-stimulate tissue healing.
The ALT Laser, model VTR75, is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle tissue.

In November 2007 the U.S. FDA sent a warning letter to the Avicenna Laser Technology Company concerning violations by the company, such as failure to establish and implement written procedures, to control the design process, to properly train personnel, to maintain quality requirements, and others.

**Policy:**

Low level laser therapy (LLLT), also known as cold laser therapy or class III laser; high-power laser therapy (HPLT), also known as class IV therapeutic laser; and laser acupuncture do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered **investigational** for all indications, including, but not limited to:

- Carpal tunnel syndrome
- Chronic headache
- Temporomandibular joint dysfunction
- Low back pain
- Fibromyalgia
- Other painful musculoskeletal disorders
- Chronic non-healing wounds
- Neurological dysfunctions
- Smoking cessation
- Weight loss/Appetite suppression
- Trismus
- Raynaud’s phenomenon
- Chronic neck pain
- Lateral epicondylitis (tennis elbow)
- Arthritis conditions
- Plantar fasciitis
- Shoulder pain
- Knee pain
- Rheumatoid arthritis
- Lymphedema
- Myofascial Pain *(Effective December 12, 2012)*
- Oral Mucositis *(Effective December 12, 2012)*

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members’ contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*
Key Points:
The most recent literature search was performed through September 2013. The following is a summary of the key findings to date.

The principal outcomes associated with treatment of musculoskeletal conditions, including carpal tunnel syndrome, are relief of pain and/or return to work and/or functional status. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, blinded and randomized controlled trials (RCTs) are required to control for the placebo effect and determine its magnitude and whether any treatment effect provides a significant advantage over the placebo. The technology must also be evaluated in general groups of patients. In patients with mild to moderate symptoms, low-level laser therapy (LLLT) may be compared to other forms of conservative therapy such as splinting, rest, nonsteroidal anti-inflammatory drugs (NSAIDs), or steroid injection. Second, in a group of patients who have exhausted conservative therapy, LLLT must be compared to surgical intervention. Another relevant outcome measure for treatment is return to work. It is difficult to analyze this outcome because the criteria for returning to work are often variable and job-specific, and it is not known whether this decision is driven by the patient, physician, or employer. Finally, the extra-clinical issue of workmen's compensation frequently influences the decision to return to work. Outcomes associated with wound healing include incidence of complete wound closure and time to various stages of wound closure.

Multiple Etiologies of Pain
For the most part, studies of LLLT for treatment of pain compare laser treatment with a sham treatment only, rather than comparison with treatments known to be effective. With very few exceptions, the studies are from centers outside the United States. A 2009 systematic review included controlled trials of LLLT as primary intervention for any tendinopathy. Twenty-five trials were included, with conflicting findings for each indication studied. Twelve studies showed positive effects, and 13 were inconclusive or showed no effect. Thirteen studies investigated LLLT for epicondylitis, six of them showing positive results. The largest of these trials had only 58 subjects. Two of the positive studies were of poor quality. Four studies examined LLLT for tendinopathy in the shoulder; four of them were of high quality. The largest of these trials had just 30 subjects. Three of these trials found a positive effect of LLLT. Two of the positive studies had placebo controls, and the third compared LLLT with ultrasound (US) or placebo. Of the five trials of LLLT for Achilles tendinitis included in the review, two demonstrated a benefit of LLLT. One of the positive and one of the negative studies of LLLT for Achilles tendinitis received the highest quality rating. One of the negative studies was the largest study (n=89) included in the review but scored only five of ten possible points for study quality. Three studies included subjects with a variety of indications; all reported inconclusive or no effect of LLLT. The authors reported that dosages used in the positive trials suggested that there is an effective dosage window; however the only parameter reported for all studies was wavelength. Power density and dose were not provided, or there was too little information provided in the studies to calculate the dose.
Jang and Lee conducted a meta-analysis of 22 randomized sham-controlled trials of LLLT for the treatment of joint pain including temporomandibular joints, glenohumeral joints, knee joints, and cervical and lumbar spinal regions. Only trials that had a Physiotherapy Evidence Database (PEDro) quality rating of five or more were included; the average PEDro score of the included trials was 7.96. There were a total of 668 subjects who received laser therapy and 565 subjects who were treated with sham laser. Although half of the trials had negative results, the mean weighted improvement in VAS for pain was 13.96 mm (out of 100 mm). When only trials that were within the range of recommended energy doses for each joint region were included, the mean improvement in VAS for pain increased to 19.88 or 21.05 mm, depending on the specific recommendations. Typically, a 20 to 30% improvement in pain is considered clinically significant. This meta-analysis did not assess the percentage of subjects in each condition who had a clinically significant improvement in pain.

In 2010, Fulop et al published a meta-analysis of 22 studies of LLLT for treatment of pain of a variety of etiologies. Inclusion criteria did not specify the timing of measuring outcomes. Some included studies measured outcomes only at the end of treatment and, for others; the timing of measurement was not reported in the analysis. Given these questions, this analysis was not reviewed further. Key studies of LLLT for specific joints are summarized below.

**Carpal Tunnel Syndrome**

**Sham Controlled Trials**

The largest body of evidence for LLLT describes its use in treatment of carpal tunnel syndrome. As part of the U.S. Food and Drug Administration (FDA) approval process, 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 one 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.

In November 2010, the BlueCross BlueShield Association Technology Evaluation Center (TEC) published a technology assessment of LLLT for carpal tunnel syndrome and chronic neck pain. For inclusion in the assessment, studies had to: be published in a peer-reviewed journal; be randomized, sham-controlled trials, and, if adjunctive therapies were used, they were applied to both groups; measure outcomes at least two weeks beyond the end of the treatment period; and, for neck pain studies, be studies of patients with chronic pain. Four of the studies of carpal tunnel syndrome discussed below met the inclusion criteria for the TEC Assessment. TEC concluded that the studies have serious limitations including small sample size and limited follow-up, and no one study is so methodologically sound as to provide definitive results.

Tascioglu et al reported a randomized double-blind sham-controlled trial of LLLT in 2011. Sixty patients with carpal tunnel syndrome were assigned to one of two active laser dosages (1.2 J or 0.6 J per painful point) or placebo treatment five times per week for three weeks. VAS scores, grip strength, and functional status scores improved significantly in all groups. The only nerve conduction measure to improve was sensorial nerve velocity in the active laser groups. There was no significant difference between groups for any of the outcome measures. In this study, LLLT was no more effective than placebo.
A 2007 double-blinded randomized sham-controlled trial with 81 patients (141 hands) found slight pre- to posttreatment improvements in sensory (0.2 msn) and distal (0.3 msn) latencies for the laser group, while sensory nerve velocity improved (by 2.7 and 2.1 msn, respectively) in both groups (a wrist splint was used at night in both groups). Other measures of nerve conduction were not affected by treatment. There were no differences between the groups in visual analogue scales (VAS) for pain or in symptom severity scores. Irvine et al. reported on the results of a small double-blinded study of 15 patients with carpal tunnel syndrome who were randomized to receive either LLLT or sham laser therapy. There was a significant improvement in both groups, but there was no significant difference between the groups.

Another small, double-blinded RCT (19 patients with rheumatoid arthritis and carpal tunnel syndrome) found slight improvement in subjective scales of pain and function (e.g., 27-point improvement vs 13-point improvement on VAS compared with sham laser therapy), but no differences between groups in objective functional measures (e.g., grip strength, 0.3 vs 0.3, respectively), or in measures of nerve conduction (e.g., motor nerve conduction velocity, 55 vs 55, respectively). Chang et al. report on an RCT with short follow-up comparing LLLT with sham treatment in 36 patients. After two weeks of treatment and two weeks after the end of treatment, VAS scores for pain were lower in the treatment group than in the sham group (p<0.05). After 2 weeks of treatment, differences in grip strength, symptoms, and functional assessment were not significant but were significant at the two week follow-up (p<0.05). There were no significant between-group differences on nerve conduction studies at either time point. Another RCT with sham control, a study with 80 patients, was reported by Shooshtari et al. Outcomes were measured at the end of 15 treatment sessions (five times a week for three weeks). In this study, the treatment group showed significant improvement in clinical symptoms, hand grip, and nerve conduction studies.

**Active Control Trials**

Bakhtiary and Rashidy-Pour reported on the outcomes of 50 consecutive patients with carpal tunnel syndrome who were randomized to receive either US therapy or LLLT. Improvement was significantly better in those randomized to US. Dincer et al compared splinting with US, splinting with LLLT, and splinting alone in an RCT. Sixty women were randomized; ten did not complete the study. One hundred hands (50 women), 30 in the splint with US group, 36 in the splint with LLLT group, and 34 with splint only, were followed for three months after treatment and included in the analysis. Outcome measures were the Boston Questionnaire Symptom Severity Scale (BQ-SSS) score, the Boston Questionnaire Functional Status Scale (BQ-FSS) score, visual analog scale (VAS) score, second digit-wrist median nerve sensory velocity (SV), and median nerve motor distal latency (MDL). Splinting with US or LLLT was more effective than splinting alone on all measures three months after treatment. LLLT was significantly more effective than US on measures of pain on VAS, BQ-SSS (p=0.03), and SV. Patient satisfaction was higher in the US and LLLT groups than the splint-only group (p=0.05).

**Neck Pain**

In a 2013 systematic review and meta-regression, Gross et al. evaluated 17 trials on LLLT for neck pain. Ten of these trials were found to demonstrate high risk of bias. Two trials consisting of 109 subjects were considered to be of moderate quality and found LLLT produced better...
outcomes than placebo for chronic neck pain treatment. Other evidence showed improved outcomes with LLLT compared to placebo for acute neck pain, acute radiculopathy and cervical osteoarthritis but was considered to be low quality. There was conflicting evidence on chronic myofascial neck pain.

The 2010 TEC Assessment included six trials of LLLT for chronic neck pain and found inconsistent results. In the largest study by Chow et al, 90 patients were randomized to active LLLT or sham treatment. At five weeks after the seven-week treatment period, patients in the active treatment group reported a 2.7 point improvement in VAS pain versus a 0.3 point worsening for the sham group. A calculated mean improvement of 43.8% was reported by the active LLLT group while the sham-treated group improved by 2.1%. TEC noted that baseline VAS pain scores were significantly higher in the active treatment group possibly biasing results in favor of LLLT. In a 2004 RCT, possibly a pilot study for the larger trial reported by Chow, 20 patients were randomized to LLLT or sham laser. The VAS pain scores improved 2.1 points in the laser-treated group and 0.7 in the sham-treated group, which was not significant; however the percent change was statistically significant, and the change in the neck pain questionnaire scores, McGill pain questionnaire, and a global measure of self-reported improvement were significantly greater in the laser-treated group.

Gur et al randomized 30 patients to active or sham laser treatment and reported significant improvement in the active—but not in the sham-treated groups—on numerous measures; however, analysis of the presented results was problematic. In a study by Ceccherelli et al, 27 women were randomized to active (n=13) or sham (n=14) laser treatment and, at three months after treatment, the VAS pain score was significantly more improved in the active treatment group. An imbalance in patient characteristics may have impacted results. In a study by Altan et al, 48 patients with myofascial pain syndrome were randomized to active or sham treatment, and all were instructed to perform daily isometric and stretching exercises. At 12 weeks, both groups had improved pain VAS, and there were no significant between-group differences. Ilbuldu et al randomized 40 women with myofascial pain syndrome to active or sham laser. All patients were instructed to do stretching exercises. There were no significant differences between groups for any outcomes measure. (A third group received dry needling; those results were not included in the TEC Assessment.) The TEC Assessment did comment on a systematic review and meta-analysis of randomized placebo or active-treatment controlled trials by Chow et al and noted “some studies evaluated acute neck pain, some had insufficient follow-up beyond the period of treatment, one had no sham control, …” Overall, TEC concluded that “the studies are characterized by small sample sizes, limited statistical power, and limited long-term follow-up.”

An RCT of LLLT for acute neck pain with radiculopathy by Konstantinovic et al published in 2010 did not report outcomes at least two weeks beyond the end of the treatment period.

**Myofascial Neck/Shoulder Pain**

Rayegani et al evaluated LLLT in a randomized trial of 49 patients with myofascial pain of the upper trapezius muscle. Following baseline assessments, the patients were randomized to active or sham laser or to ultrasound (five times a week for two weeks). All of the patients received stretching exercises, transcutaneous electrical nerve stimulation (TENS), and hot packs. The patients, assessors, and statisticians were blinded to treatment condition. Compared to sham
controls, the LLLT group showed significantly greater improvements in VAS during activity, VAS at rest, VAS at night, the neck disability index (NDI), and pain-provoking threshold. Laser was also found to be more effective than ultrasound for the NDI and pain provoking threshold, but not in the VAS for pain.

Subacromial Impingement

In a 2009 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. Outcome measures of night pain, shoulder pain, and disability index (SPADI), and University of California-Los Angeles (UCLA) end-result scores were assessed at the second and twelfth week of intervention. Both groups showed significant reductions in night pain and SPADI at two- and 12-week assessments. UCLA scores improved significantly in both groups at 12 weeks. No distinct advantage was demonstrated by LLLT over exercise alone.

Another RCT 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.

In a 2010 report, Dogan et al randomized 52 patients with subacromial impingement syndrome to active or sham LLLT 5 times per week for 14 sessions. All patients were also given an exercise program. Both groups showed improvements in pain, some measures of range of motion (ROM), and on the SPADI. There were no significant differences between the two groups.

In 2011, Calis et al randomized 52 patients with subacromial impingement syndrome to LLLT, US, or exercise. Patients were treated five days a week for three weeks with hotpack+ultrasound+exercise, hotpack+laser+exercise, or hotpack+exercise. All three groups showed improvement from baseline to posttreatment in pain at rest, ROM, and function. There were no significant differences between the groups.

In a 2011 publication, Abrisham et al randomized 80 patients with subacromial syndrome (rotator cuff and biceps tendinitis) to exercise plus pulsed LLLT or sham laser five times per week for two weeks. At the conclusion of the treatment period, both groups showed improvement in VAS for pain and shoulder ROM. The improvement was significantly better for the active LLLT group than the sham laser group for VAS (4.4 vs 2.9), and all measures of ROM (active and passive flexion, abduction, and external rotation). The durability of this effect was not assessed.

Frozen Shoulder

Sixty-three patients with frozen shoulder were included in an RCT 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 four weeks and eight weeks of treatment, and at the end of eight 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 eight weeks of treatment and at 16 weeks’ postrandomization; and a significant decrease in health assessment questionnaire scores was observed at four weeks and eight weeks of treatment.

**Temporomandibular (TMJ) Pain**

A meta-analysis of RCTs on low-level laser therapy for treating TMJ disorders was published in 2011. The investigators identified six randomized placebo-controlled trials that met the inclusion criteria. A pooled analysis of data from the six trials did not find a statistically significant difference in the primary outcome of interest, change in pain from baseline to endpoint. The pooled difference in pain, measured on a visual analogue scale (VAS), was a mean difference of 7.77 mm (95% confidence interval [CI], -2.49 to 18.02; p=0.14). All studies had small sample sizes (ranging from a total of 14 to 52 participants), and the confidence interval in the pooled analysis was wide.

Outcomes of individual trials of LLLT for TMJ pain are inconsistent. In a study from Brazil, 40 patients with TMJ were treated with LLLT or placebo. After four weeks of weekly treatment, patients were evaluated for pain on VAS and the Craniomandibular Index (CMI). Both groups improved on both measures (p<0.05), and there were no significant differences between groups. Emshoff et al. evaluated LLLT in the management of TMJ in a double-blinded RCT with 52 patients randomized equally to LLLT or sham treatment. After eight weeks of two to three treatments/week, both groups showed improvements in pain during function. Between-group differences were not significant.

Fikackova et al. treated 61 patients with TMJ or myofascial pain with LLLT at one of two densities (10 or 15 J/cm2) and 19 patients with sham LLLT (0.1 J/cm2). Outcomes were measured by self-administered questionnaire. The authors report significantly better outcomes in patients treated with 10 or 15 J/cm2 than in patients given sham treatment. There were no differences in outcomes between patients with TMJ and myofascial pain.

Carrasco et al. randomly assigned 60 patients with myofascial pain and one active trigger point in the anterior masseter and anterior temporal muscles to six groups. Three groups received laser treatment twice a week for four weeks using different energy levels for each group (25, 60, or 105 J/cm2). The other three groups received placebo treatment simulating the same parameters as the treated groups. Pain scores were assessed just before, immediately after the 4th and 8th applications, and at 15 days and one month after treatment. An analgesic effect was seen starting from the third evaluation in both the treated and placebo groups, and placebo was as effective as laser (p<0.05). Differences in pain VAS between groups treated at different energy levels were not significant.

Venezian et al. randomized 48 patients with myofascial pain to one of two doses of laser (25 or 60 J/cm2) or placebo twice a week for four weeks. Surface electromyography (EMG) at the conclusion of testing showed no difference between the groups. Pain with palpation was measured by VAS before, at the conclusion of, and 30 days after laser therapy. VAS scores declined in all groups and were more consistently decreased (more regions of the palpated muscles) after active laser therapy. However, there were no significant differences in VAS between the active and sham-controlled groups.
Marini et al compared superpulsed LLLT with NSAIDs for pain caused by temporomandibular joint disorders secondary to disc displacement without reduction or osteoarthritis. Ninety-nine patients were randomized to one of three groups: 39 received LLLT in ten sessions over two weeks, 30 received sham LLLT on the same schedule, and 30 patients received ibuprofen 800 mg twice/day. Pain intensity was measured at baseline and after 2, 5, 10, and 15 days of treatment. Mandibular function (active and passive mouth openings and right and left lateral motions) was evaluated at baseline, 15 days, and 1 month of treatment. Durability of pain relief beyond the end of treatment is not reported. Mandibular function was significantly better at one month after treatment in the active laser-treated group.

**Bell’s Palsy**

In 2013, Alayat et al reported on a randomized double-blind placebo-controlled trial of laser therapy for the treatment of 48 patients with Bell's palsy. Facial exercises and massage were given to all patients. Patients were randomized to one of three groups: high-intensity laser therapy, low-level laser therapy or exercise only. Laser treatment was given three times per week to eight points of the affected side for six weeks. At three and six weeks after treatment, outcomes were assessed using the facial disability scale (FDI) and the House-Brackmann scale (HBS). Significant improvements in recovery were seen in both laser therapy groups over exercise alone with the most improvement seen with high-intensity laser.

**Low Back Pain**

A 2007 update of the Cochrane Database System Review of LLLT for nonspecific low back pain concluded 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 for low-back pain.” Chou and Huffman assessed benefits and harms of nonpharmacologic therapies including LLLT for acute and chronic low back pain in a 2007 review of evidence and did not find good evidence of efficacy for LLLT for either indication.

In a large double-blind placebo-controlled study published in 2010, Konstantinovic et al randomized 546 patients with acute low back pain to three groups of 182 patients. 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 five 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. Durability of these outcomes was not measured.

In 2010, Ay et al randomized 80 patients with acute and chronic low back pain attributed to lumbar disc herniation (LDH) into four groups of 20. 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 three weeks. Outcome measures were pain on VAS, patients’ global assessment, physicians’ global assessment, and functional capacity and were measured after three weeks of treatment. After treatment, all groups had statistically significant improvements in
pain severity, patients’ and physicians’ global assessment, ROM, 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 the treatment effect was not reported.

In a 2007 study by Djavid et al, 61 patients were randomized to LLLT alone (n=20), LLLT with exercise (n=21), or sham laser treatment with exercise (n=20). Outcomes of pain on VAS, lumbar ROM, and disability were measured by blinded assessors after six weeks of treatment, after another six weeks and 12 weeks without treatment. By intention-to-treat (ITT) analysis, there were no between-group differences for any outcome measure immediately after the 6-week intervention. After six weeks without intervention, there was no difference between the LLLT alone group and the placebo laser therapy plus exercise group; however, in the LLLT plus exercise group, pain had reduced by 1.8 cm (95% CI, 0.1 to 3.3; p=0.03), lumbar ROM increased by 0.9 cm (95% CI, 0.2 to 1.8; p≤0.01) on the Schober test and by 15° (95% CI, 5 to 25; p<0.01) of active flexion, and disability reduced by 9.4 points (p=0.03) on the Oswestry Disability Index more than in the placebo laser therapy plus exercise group. The authors advised that larger trials are needed to detect differences between groups for some outcomes.

**Osteoarthritis (OA) Knee Pain**

In 2007, Bjordal et al published a systematic review of placebo-controlled RCTs to determine the short-term efficacy of physical interventions for OA knee pain. They concluded that transcutaneous electrical nerve stimulation (TENS) (including interferential currents) and LLLT offered clinically relevant pain-relieving effects on VAS scores compared to placebo control. Follow-up data up to 121 weeks were sparse, but positive effects seemed to persist for at least four weeks after the course of treatment.

In 2011, Alfredo et al reported a randomized double-blind sham-controlled trial of LLLT in 40 patients with knee OA. Laser or sham treatments were delivered three times per week for three weeks, and both groups received exercise sessions three times per week for eight weeks. The active laser group showed significant improvements from baseline in pain scores, activity, ROM, and functionality, but there were no significant differences between the active and sham laser groups.

Hegedus et al reported a randomized double-blind sham-controlled trial of LLLT in 35 patients with knee OA in 2009. Eight patients from the sham group left the experiment, leaving 18 patients in the active LLLT group and nine in the sham group. Treatments were delivered twice a week over a period of four weeks at a dose of 6 J/point (48 J/cm²). Follow-up was performed immediately, two weeks, and two months after completing the therapy. In the group treated with LLLT, a significant improvement was found in pain (5.75 to 1.18), pressure sensitivity (2.33 to 0.77), and flexion (105.83° to 122.94°) at two months. In the placebo group, baseline to posttreatment changes in joint flexion and pain were not significant. It was not reported if these changes were significantly improved in comparison with the sham group. Circumference of the joint was not significantly changed for either group. Thermographic measurements at two months showed an increase in temperature of equal to or greater than 0.5° in patients in the active laser group who experienced pain relief, suggesting an improvement in circulation.
**Meniscal Knee Pain**
In a 2013 study, Malliaropoulos et al reported on a randomized, double-blind, placebo-controlled study of LLLT in 64 patients with unilateral medial knee pain for more than six weeks that was related to meniscal pathology (i.e., Grade 3 tiny attenuation or intrasubstance tears on magnetic resonance imaging [MRI]). Pain improved significantly with LLLT than placebo (p<0.0001). However, four patients (12.5%) did not have improvement with LLLT. Pain returned in three patients at six months and in five patients after one year. Repeat MRIs were not performed.

**Medial Tibial Stress Syndrome**
In a 2013 systematic review by Winters et al. of treatments for medial tibial stress syndrome, LLLT was not found to be effective. Studies in the systematic review were all considered to have methodologic-bias.

**Rheumatoid Arthritis (RA)**
A 2005 Cochrane Review included five placebo-controlled RCTs and found that relative to a separate control group, LLLT reduced pain by 1.10 points on VAS compared to placebo, reduced morning stiffness duration by 27.5 minutes, and increased tip-to-palm flexibility by 1.3 cm.(48) Other outcomes, such as functional assessment, ROM, and local swelling, did not differ between groups. For RA, relative to a control group using the opposite hand (one 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 2010 randomized double-blind placebo-controlled trial comparing outcomes of pain reduction and improvement in hand function in 82 patients with RA treated with LLLT or placebo laser was reported by Meireles et al. 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 LLLT at the dosage used in the study was not effective for the treatment of hands among patients with RA.

**Elbow Pain**
Authors of a systematic review published in 2008 grouped trials by application technique and wave lengths and reported that seven of the 13 included trials had a narrowly defined regimen where lasers of 904 nm wavelength with low output (5-50 MW) were used to irradiate the tendon insertion at two to six points on the lateral elbow. Positive results in these trials were consistent on outcomes of pain and function, and significance persisted for at least three to eight weeks after the end of treatment. The authors noted that the conclusions of their review differed from conclusions of prior reviews of this topic.

**Achilles Tendinopathy**
Stergioulas et al. randomized 52 recreational athletes with chronic Achilles tendinopathy symptoms to an eight-week (12 sessions) program of eccentric exercises (EE) with LLLT or with sham LLLT. By ITT analysis, results for the primary outcome of pain during physical activity
on VAS were significantly lower in the EE with LLLT group at four weeks (p=0.0003), eight weeks (p=0.0002), and 12 weeks (p=0.007) after randomization. Results of EE with LLLT at four weeks were similar to results for the EE plus sham LLLT group after 12 weeks.

Tumilty et al reported a randomized double-blinded sham-controlled trial of LLLT as an adjunct to three months of EE in 40 patients with Achilles tendinopathy. Active or sham LLLT was administered three times per week for four weeks, and exercises were performed twice a day for 12 weeks. The primary outcome was the Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A) at 12 weeks. There was a trend for the active laser group to score lower on the VISA-A at baseline (p=0.051). Following treatment, the only significant difference between the groups on an ITT basis was at four weeks on the VISA-A and favored the sham-control group. The VISA-A and numerical rating scale for pain were not significantly different between the active and sham groups at 12 weeks or one-year follow-up.

**Plantar Fasciitis**

Kiritsi et al reported a randomized double-blind sham-controlled trial of LLLT in 30 subjects with plantar fasciitis in 2010. Twenty-five patients (83%) completed the study, with treatment three times per week over six weeks. At baseline, plantar fascia thickness measured by US was significantly greater in the symptomatic compared with asymptomatic feet (5.3 mm vs 3.0 mm). Plantar fascia thickness decreased in both LLLT and sham groups over the course of the study. Although plantar fascia thickness after six weeks of treatment was not significantly different between the two groups (3.6 mm LLLT and 4.4 mm sham), there was a significant difference between the groups in the change in thickness (1.7 mm LLLT vs 0.9 mm sham). VAS after night rest or daily activities was significantly improved in the LLLT group compared with the sham, with a 59% improvement in the active laser group and a 26% improvement for the sham-treated subjects. At baseline, pain after daily activities was rated as 67/100 by both groups. At the end of treatment, VAS after daily activities was rated as 28/100 for LLLT and 50/100 for sham.

**Oral Mucositis**

The Mucositis Study Group of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) published a systematic review of laser and other light therapy for the management of oral mucositis in 2012. A total of 24 trials were included for the review. Based on their review of the evidence, the MASCC/ISOO made a new recommendation for LLLT for the prevention of oral mucositis in adult patients receiving hematopoietic stem-cell transplantation (HSCT) conditioned with high-dose chemotherapy. This recommendation was based on what was considered to be one well-designed placebo-controlled randomized trial (described in more detail below), together with a series of studies classified at a lower level of evidence. Evidence was insufficient to provide a guideline for laser as a treatment of oral mucositis in HSCT patients.

The MASCC/ISOO made a new “suggestion” for low-level laser for the prevention of oral mucositis in patients undergoing radiotherapy, without concomitant chemotherapy, for head and neck cancer. This guideline was based on three studies that showed positive results but were considered to have major flaws. Evidence was considered encouraging but insufficient to recommend LLLT in other populations. The authors emphasized that due to the variety of laser
devices and the variation in individual protocols, results of each study apply exclusively to the cancer population studied and the specific wavelength and settings used.

The pivotal study for the MASCC/ISOO recommendation was a randomized double-blind sham-controlled trial with 70 patients who were undergoing HSCT. Patients were randomized to 650 nm laser, 780 nm laser, or placebo (randomization method not described). Patients in the 650 nm laser group were more likely to have received a total-body irradiation (TBI)-containing regimen compared to the other two groups; otherwise, the groups were comparable. LLLT began on the first day of conditioning and continued for three days posttransplant. Of the 70 patients, 47 (67%) had complete or nearly complete mucositis measurements over time; the average number of visits per patient was similar for the three groups. The difference between groups in mean oral mucositis scores was greatest at day 11 (placebo 24.3, 650 nm 16.7, 780 nm 20.6), and this difference between the 650 nm group and placebo approached statistical significance (p=0.06). Thus, there was no significant difference in mean oral mucositis scores between the 650 nm and placebo group at the other time points. Patient-specific oral mucositis scores were significantly different between the two groups only when adjusted for TBI exposure. Of the 70 patients in the study, 17 (24%) were assessed for oral pain. With group sizes of five and six, the 650-nm group had significantly lower patient-specific average pain scores (15.6) compared to placebo (47.2). No adverse events from LLLT were noted. This study, which formed the basis for the MASCC/ISOO recommendation, suffers from limitations that include not achieving statistical significance for the primary outcome measure and a very small percentage of patients with pain assessments.

In 2013, Figueiredo et al reported on a systematic review and meta-analysis of laser therapy for oral mucositis. In the systematic review of 12 studies and meta-analysis of seven studies, laser therapy was found to be more significantly more effective in preventing grade >3 oral mucositis than patients who did not receive laser treatment (p=0.0093). The authors noted that larger studies are needed.

Gautam et al. reported two double-blinded randomized sham-controlled trials in 2012. One of the studies reported LLLT for the prevention of chemoradiotherapy-induced oral mucositis in 121 oral cancer patients. The second publication reported LLLT for the prevention of chemoradiotherapy-induced oral mucositis in 221 head and neck cancer patients. There is an apparent overlap in patients in these two reports, with the head and neck cancer report including the 121 patients with a primary tumor site in the oral cavity. Patients in these studies received LLLT prior to radiation therapy at 66 Gy delivered daily in 33 fractions, five days per week and concurrent with cisplatin. LLLT was delivered at a wavelength of 632.8 nm, power density of 24mW/cm² and a dosage of 3 to 3.5 J. In the report on oral cancer, LLLT prior to radiation treatment led to significant reductions in the incidence of severe oral mucositis (29% vs 89%) and its associated pain (18% vs 71% with a VAS >7) opioid analgesic use (7% vs 21%) and total parenteral nutrition (30% vs 39%, all respectively) during the last weeks of chemoradiotherapy. LLLT also reduced the duration of severe oral mucositis (4.07 vs 13.96 days), severe pain (5.31 vs 9.89 days), and total parenteral nutrition (14.05 vs 17.93 days, all respectively). In the 221 patients treated for head and neck cancer, LLLT was reported to lead to significant reductions in the incidence and duration of severe oral mucositis (8.19 vs 12.86 days) and its associated pain (VAS of approximately 4 vs 7), total parenteral nutrition (45.0% vs 65.5%), and opioid analgesic
use (9% vs 26% for step III, all respectively). In 2013 Gautam et al reported on patient-reported outcomes from the same study of 220 head and neck cancer patients using the Oral Mucositis Weekly Questionnaire-Head and Neck (OMWQ-HN) and the Functional Assessment of Cancer Treatment- Head and Neck (FACT-HN) questionnaire. Patients in this study received LLLT prior to radiation therapy at 66 Gy delivered daily in 33 fractions, five days per week and concurrent with cisplatin. LLLT was delivered at a wavelength of 632.8 nm, power density of 24 mW/cm² and a dosage of 3.0 J. Patients in the LLLT group reported significantly better outcomes than the placebo group with lower scores on both the OMWQ-HN (p<0.001) and FACT-HN (p<0.05).

In 2013 Antunes et al also reported on LLLT to prevent oral mucositis in a double-blinded randomized sham-controlled trial of 94 head and neck squamous-cell carcinoma patients. Patients received LLLT prior to radiation therapy at 70.2 Gy delivered daily in 39 fractions, five days per week and concurrent with cisplatin. In this study, LLLT was delivered at a higher dose of 660 nm, 100 mW and 1 J–4 J/cm². Three patients (6.4%) in the LLLT group developed grade 3-4 oral mucositis, as measured by the World Health Organization oral mucositis scale compared to 19 patients (40.5%) in the placebo group (relative risk ratio: 0.158; 95% CI, 0.050 to 0.498). Additionally, 28 patients (59.6%) in the LLLT group did not develop ulcers compared to 10 patients (21.3%) in the placebo group (p<0.001). Incidence of severe pain, narcotic analgesic use and gastrostomy was also lower in the LLLT group. Differences in radiation and LLLT dosages and oral hygiene protocols used may influence outcomes in these studies.

Another randomized sham-controlled trial from 2012 evaluated the effect of LLLT on quality of life in 60 patients undergoing radiotherapy in the region of the major salivary glands. Quality of life (QOL) was measured by the University of Washington QOL questionnaire at baseline and after 15 and 30 treatment sessions. QOL decreased significantly in both groups over the 30 treatment sessions, but there was a smaller decrease in QOL in the LLLT group compared to the placebo group. The domains of appearance, activity, recreation, speech, taste, pain, chewing, and saliva were less affected in the LLLT group compared to the placebo group at either the mid-treatment or final assessment. More patients in the sham control group had an interruption of radiotherapy (25 vs 12), which was primarily due to mucositis.

**Fibromyalgia**
Matsutani et al randomized 20 patients with fibromyalgia to receive laser treatment and stretching exercises or stretching alone. Outcome measures were VAS and dolorimetry at tender points, quality of life on the Fibromyalgia Impact Questionnaire (FIQ), and the 36-item Short-Form Health Survey (SF-36). At the end of treatment, both groups demonstrated pain reduction, higher pain threshold at tender points (all p<0.01), lower mean FIQ scores, and higher SF-36 mean scores (all p<0.05). No significant differences were found between groups.

**Wound Healing**
A 2004 evidence report on vacuum-assisted and low-level laser wound therapies for treatment of chronic nonhealing wounds prepared for the Agency for Healthcare Research and Quality (AHRQ) 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 six 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.” No newer studies were identified in updated literature searches.

**Lymphedema**
Omar et al. published a qualitative systematic review of LLLT for the management of breast cancer-related lymphedema in 2012. They included eight studies with a total of 230 patients in the review. Five studies were graded as Sackett evidence Level II (small randomized trial with high false-positive or false-negative errors), two were graded as Level III (nonrandomized comparative study), and one study was graded as Level V evidence (case series). The authors noted major methodologic flaws and little uniformity in the design of the studies.

One of the studies included in the review was a 2011 publication by Omar et al. reporting a randomized double-blind sham controlled trial of LLLT in 50 patients with postmastectomy lymphedema. The average length of time that patients had swelling was 14 months (range, 12-36 month). Patients were treated with active or sham laser three times per week for 12 weeks over the axillary and arm areas. In addition, all participants were instructed to perform daily arm exercises and to wear a pressure garment. Limb circumference, shoulder mobility, and grip strength were measured before treatment and at four, eight, and 12 weeks. Limb circumference declined over time in both groups, with significantly greater reduction in limb circumference in the active laser group at eight (20.0 vs 16.4 cm), 12 (29 vs 21.8 cm), and 16 weeks (31 vs 23). Shoulder flexion and abduction were significantly better in the active laser group at eight and 12 weeks. Grip strength was significantly better in the active laser group after 12 weeks of laser therapy (26.2 vs 22.4 kg). The durability of these effects was not assessed.

**Summary**
Low-level laser therapy (LLLT), also called photo-biomodulation, is being evaluated to treat a variety of conditions including soft tissue injuries, myofascial pain, tendinopathies, nerve injuries, joint pain, lymphedema, and oral mucositis.

The available literature on low-level laser therapy as a treatment for lymphedema, prevention of oral mucositis, wound healing, or pain of various etiologies and in a variety of anatomical sites presents inconsistent results and methodologic weaknesses, including lack of follow-up evaluation, that prevent drawing firm conclusions regarding efficacy. Therefore, LLLT remains investigational for all indications.

**Practice Guidelines and Position Statements**
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.

The American Academy of Orthopaedic Surgeons (AAOS) 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.
The United Kingdom’s 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.

In 2010, the American Physical Therapy Association (APTA) published a guideline on the diagnosis and treatment of Achilles tendinitis. APTA gave a level B recommendation (based on moderate evidence) to consider the use of LLLT to decrease pain and stiffness in patients with Achilles tendinopathy. APTA states in their review of the evidence, that “given the limited number of studies employing LLLT in this population, additional study is warranted”.

**Key Words:**
Low-level laser therapy (LLLT), cold lasers, class III laser, carpal tunnel syndrome, micro-light laser, temporomandibular joint dysfunction, appetite suppression, weight loss, smoking cessation, trismus, Raynaud’s, photobiomodulation, high power laser therapy (HPLT), class IV therapeutic laser

**Approved by Governing Bodies:**
A number of low-level lasers have received clearance for marketing from the U.S. Food and Drug Administration (FDA) for the treatment of pain.

Data submitted to the FDA as part of the FDA 510(k) approval process for the MicroLight 830® Laser consisted of application of the laser over the carpal tunnel three times a week for five weeks. The labeling states that the "MicroLight 830 Laser is indicated for adjunctive used in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome."

In 2006, the FDA provided marketing clearance for the GRT LITE™, which listed the Tuco Erchonia PL3000, the Excalibur System, the Microlight 830 Laser, and the Acculaser Pro as predicate devices. Indications of the GRT LITE for carpal tunnel syndrome are similar to the predicate devices: “adjunctive use in providing temporary relief of minor chronic pain.”

The LightStream™ Low Level Laser device received 510(k) marketing clearance in 2009 for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice. A number of clinical trials of LLLT are underway in the United States, including studies of wound healing.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification requirements: Not applicable

**Current Coding:**

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

**References:**

83. Schubert MM, Eduardo FP, Guthrie KA et al. A phase III randomized double-blind placebo-controlled clinical trial to determine the efficacy of low level laser therapy for the


Policy History:
Medical Policy Group, May 2006 (3)
Medical Policy Administration Committee, June 2006
Available for comment July 5-August 18, 2006
Medical Policy Group, February 2007 (3)
Medical Policy Administration Committee, February 2007
Available for comment February 10-March 26, 2007
Medical Policy Group, March 2009 (4)
Medical Policy Administration Committee, April 2009
Available for comment March 18-May 1, 2009
Medical Policy Group, January 2010 (3)
Medical Policy Group, October 2010 (3)
Medical Policy Group, January 2010
Medical Policy Group, March 2011 (3)
Medical Policy Administration Committee March 2011
Available for comment April 4 – May 18, 2011
Medical Policy Group, December 2011 (3): Updated investigational list under Policy section, and updated Key Points, & References
Medical Policy Group, December 2012 (3): 2012 Updates to Description, Policy (added more indications), Key Points, and References
Medical Policy Administration Committee, January 2013
Available for comment December 12, 2012 through January 26, 2013
Medical Policy Panel, November 2013
Medical Policy Group, January 2014 (2): Policy statement unchanged. Description, Key Points, References updated with findings of literature review through September 2013. Outdated web references deleted.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.