Protocol

Low-Level Laser Therapy

(20156)

Medical Benefit		**Effective Date**: 10/01/11	**Next Review Date**: 07/15
Preauthorization	No	**Review Dates**: 04/07, 05/08, 05/09, 01/10, 01/11, 07/11, 07/12, 07/13, 07/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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

Background

Low-level laser therapy (LLLT) refers to the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and power from five to 500 MW. (In contrast, lasers used in surgery typically use 300 W.) 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 photobiostimulative effect. The exact mechanism of its effect on tissue healing is unknown; hypotheses have included improved cellular repair and stimulation of the immune, lymphatic, and vascular systems. LLLT is being evaluated to treat a wide variety of conditions, including soft tissue injuries, myofascial pain, tendinopathies, nerve injuries, and joint pain. LLLT has also been evaluated for lymphedema.

One of the disorders that LLLT has been evaluated for is the treatment of 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 lesion can compress the median nerve and produce the typical symptoms of carpal tunnel syndrome—pain, numbness, 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. 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. 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 (HSCT). Oral mucositis describes inflammation of the oral mucosa and typically manifests as erythema or ulcerations that appear seven 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 two to four weeks after cessation of cytotoxic chemotherapy.

Regulatory Status

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.

Related Protocols

Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions

Temporomandibular Joint Dysfunction

Treatment of Tinnitus

Policy (Formerly Corporate Medical Guideline)

Low-level laser therapy is considered **investigational** for all indications including but not limited to treatment of carpal tunnel syndrome.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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