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Medicare Advantage Policy Manual

Low-Level Laser Therapy

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Medicare Link(s) Revised: N/A

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Low-level laser therapy (LLLT; aka, photobiomodulation) refers to the use of red-beam or near-infrared lasers with a wavelength between 600 and 1000 nm and power from 5 to 500 milliwatts. This contrasts with surgical lasers, which typically use 300 watts. When applied to the skin, low level lasers produce no sensation and do not burn the skin. Because of the low absorption by human skin, it is hypothesized that the laser light can penetrate deeply into the tissues where it has a photobiostimulative effect.

The exact mechanism of its effect is unknown, but LLLT has been proposed as a treatment of carpal tunnel syndrome, painful musculoskeletal disorders such as temporomandibular joint disfunction and low back pain, soft tissue injuries, tendinopathies, and osteoarthritis. LLLT has been used outside the U.S. to treat oral mucositis associated with radiation and chemotherapy,

stimulate healing of chronic wounds, treat nerve injuries, and as an adjunct to antituberculosis drug treatment.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This Medicare Advantage medical policy does not address the application of infrared therapy (CPT code 97026), which is considered non-covered under the Medicare NCD for *Infrared Therapy Devices* (270.6).

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None ^[1]
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	Medicare coverage guidance is not available for low-level laser therapy (LLLT). Therefore, the health plan's medical policy is applicable. Low-Level Laser Therapy, Medicine, Policy No. 105 (see "NOTE" below)

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an *objective*, *evidence-based process*, *based on authoritative evidence*. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below <u>must</u> be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- History and Physical/Chart Notes;
- Current symptomology and indication; and
- Documentation of need for prevention of oral mucositis in cancer patients with high risk of developing oral mucositis including cancer treatment causing this risk.

REGULATORY STATUS

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

- Super Pulsed Laser (Multi Radiance Medical)
- MicroLight ML830® (MicroLight Corporation of America)
- GRT LITE™ PRO-8A (GRT Solutions, Inc.)
- LightStream[™] Low Level Laser (RJ Laser Canada Corp.)
- TouchOne[™] (OTC)

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

<u>Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149</u>

REFERENCES

1. NCD for Laser Procedures (140.5) (This NCD can be accessed directly from the <u>Medicare</u> <u>Coverage Database</u> website) Coverage of procedures performed with a laser is at contractor discretion.

CODING

NOTE: HCPCS code S8948 is a Medicare Status "I" code, and therefore, is not valid for Medicare or Medicare Advantage use.

Codes	Number	Description
CPT	0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional
	97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non-ablative) for post-operative pain reduction
	97039	Unlisted modality (specify type and time if constant attendance)
HCPCS	S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low level laser, each 15 minutes (Not valid for Medicare purposes)

*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.