

Corporate Medical Policy

Laser Treatment of Onychomycosis

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Description of Procedure or Service

Onychomycosis is a common fungal infection of the nail. Currently available treatments for onychomycosis, including systemic and topical antifungal medications, have relatively low efficacy and require a long course of treatment. Laser systems are proposed as another treatment option.

Onychomycosis is a common chronic fungal infection of the nail. It is estimated to cause up to 50% of all nail disease and 33% of cutaneous fungal infections. The condition can affect toenails or fingernails but is more frequently found in toenails. Primary infectious agents include dermatophytes (e.g., *Trichophyton* species), yeasts (e.g., *Candida albicans*) and non-dermatophytic molds. In temperate Western countries, infections are generally caused by dermatophytes.

Aging is the most common risk factor for onychomycosis, most likely due to decreased blood circulation, longer exposure to fungi, and slower nail growth. In addition, various medical conditions increase the risk of co-morbid onychomycosis. These include diabetes, obesity, peripheral vascular disease, immunosuppression and HIV infection. In certain populations, onychomycosis may lead to additional health problems. Although there is limited evidence of a causal link between onychomycosis and diabetic foot ulcers, at least one prospective study with diabetic patients found onychomycosis to be an independent predictor of foot ulcer. Moreover, onychomycosis, especially more severe cases, may adversely impact quality of life. Patients with onychomycosis have reported impacts such as pain, discomfort wearing shoes, nail pressure and embarrassment.

The diagnosis of onychomycosis can be confirmed by potassium hydroxide preparation, culture or histology. Treatments for onychomycosis include topical antifungals such as nail paints containing ciclopirox (ciclopiroxolamine) or amorolfine, and oral antifungals such as terbinafine and itraconazole. These generally have low to moderate efficacy and a high relapse rate. Topical antifungals and some long-available oral medications such as griseofulvin require a long course of treatment, which presents issues for patient compliance. Moreover, oral antifungal medications have been associated with adverse effects such as a risk of hepatotoxicity.

Several types of device-based therapies are under investigation for treatment of onychomycosis, including ultrasound, iontophoresis, photodynamic therapy and laser systems. A potential advantage of lasers is that they have greater tissue penetration than antifungal medication and thus may be more effective at treating infection embedded within the nail. Another potential advantage is that laser treatments are provided in a clinical setting in only one or several sessions and thus long-term patient compliance is less of an issue than with medications.

Laser treatment of onychomycosis uses the principle of selective photothermolysis. This is defined as the precise targeting of a tissue using a specific wavelength of light. The premise is that light is absorbed into the target area and heat generated by that energy is sufficient to damage the target area while sparing the surrounding area. The aim of laser treatment of onychomycosis is to heat the

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nail bed to temperatures required to disrupt fungal growth (approximately 40-60oC) and at the same time avoid pain and necrosis to surrounding tissues.

Characteristics of laser systems used to treat onychomycosis are as follows:

Wavelength: Lasers are single-wavelength light sources. There needs to be sufficient tissue penetration to adequately treat nail fungus. The near-infrared spectrum tends to be used because this is the part of the spectrum that has maximum tissue penetrance in the dermis and epidermis and the nail plate is similar to the epidermis. To date, most laser systems for treating onychomycosis have been Neodymium yttrium aluminum garnet (Nd: YAG) lasers that are typically operated at 1064nm; 940-1320nm and 1440nm wavelengths are also options.

Pulse duration: Pulses need to be short to avoid damage to the tissue surrounding the target area. For example, short-pulse systems have microsecond pulse durations and Q-switched lasers have nanosecond pulse durations.

Repetition rate (frequency of laser pulses, Hz): Selective photothermolysis requires that there be time between pulses to allow for dispersal of heat energy.

Spot size: This refers to the diameter of the laser beam. For treating onychomycosis, laser spot sizes range from 1 to 10 mm.

Fluence: This refers to the amount of energy delivered into the area and is measured in J/cm²).

A number of laser systems for treating onychomycosis have been cleared for marketing by the U.S. Food and Drug Administration (FDA). The FDA-cleared indications are for the temporary increase of clear nail; they are not cleared as a cure for onychomycosis.

Regulatory Status

A number of Nd: YAG laser systems have been cleared by the FDA for marketing for the temporary increase of clear nail in patients with onychomycosis. The FDA determined that these devices were substantially equivalent to existing devices. Cleared devices and year of FDA decision are as follows:

Nd:YAG 1064nm laser systems:

- PinPointe FootLaser (PinPointe USA, Inc.): 2010
- GenesisPlus (Cutera): 2011
- VARIABreeze (CoolTouch Inc.): 2011
- JOULE ClearSense (Sciton): 2011

Dual wavelength Nd:YAG 1064nm and 532nm laser system:

- Q-Clear (Light Age, Inc.): 2011

Related Policies

Nonpharmacologic Treatment of Rosacea
Laser Treatment of Port Wine Stains

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Laser Treatment of Onychomycosis is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

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Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Laser Treatment of Onychomycosis is covered

Not Applicable.

When Laser Treatment of Onychomycosis is not covered

Laser treatment of onychomycosis is considered investigational.

Policy Guidelines

The published evidence to date is insufficient to determine whether laser treatment improves health outcomes in patients with onychomycosis. Additional studies are needed that use FDA-cleared devices and compare outcomes to those obtained with a sham control or an alternative treatment for onychomycosis and conduct appropriate statistical analyses.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: There is no specific CPT code for this treatment. It would likely be reported using an unlisted CPT code such as 17999 or 96999.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Zhang RN, Wang DK, Zhuo FL et al. Long-pulse Nd:YAG 1064-nm laser treatment for onychomycosis. *Chin Med J (Engl)* 2012; 125(18):3288-91. Retrieved from <http://www.cmj.org/Periodical/paperlist.asp?id=LW2012917486313906660&linkintype=pubmed>

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.89, 5/9/13

Becker C, Bershaw A. Lasers and photodynamic therapy in the treatment of onychomycosis: a review of the literature. *Dermatol Online J*. 2013 Sep 14;19(9):19611. <http://escholarship.org/uc/item/0js6z1kw#page-3>

Specialty Matched Consultant Advisory Panel review 1/2014

Medical Director review 1/2014

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National Institutes of Health (NIH) Clinical Trial #NCT01528813. Erbium-doped Yttrium Aluminium Garnet Laser(Er:Yag)Associated With Amorolfine Lacquer in the Treatment of Onychomycosis. <http://clinicaltrials.gov/ct2/show/NCT01528813?term=NCT01528813&rank=1>

National Institutes of Health (NIH) Clinical Trial #NCT01920178. Evaluation Study for the Efficacy and Safety of PinPointe FootLaser in Treatment for Onychomycosis. <http://clinicaltrials.gov/ct2/show/NCT01920178?term=NCT01920178&rank=1>

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.89, 5/22/14

Specialty Matched Consultant Advisory Panel review 1/2015

Medical Director review 1/2015

Policy Implementation/Update Information

7/1/13 New policy developed. Laser treatment of onychomycosis is considered investigational. There is no specific CPT code for this treatment. Medical Director review 6/2013. (mco)

2/11/14 Specialty Matched Consultant Advisory Panel review 1/1024. Medical Director review 1/2014. References updated. No changes to Policy Statement. (mco)

7/15/14 References updated. No changes to Policy Statement. (mco)

2/24/15 References updated. Specialty Matched Consultant Advisory Panel review 1/2015. Medical Director review 1/2015. Policy Statement unchanged. (td)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.