



MASSACHUSETTS

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Medical Policy Laser Treatment of Onychomycosis

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Policy Number: 562

BCBSA Reference Number: 2.01.89 (For Plan internal use only)

NCD/LCD: NA

Related Policies

- Nonpharmacologic Treatment of Rosacea, #[462](#)
- Plastic Surgery, #[068](#)

Policy

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members**

Laser treatment of onychomycosis is [INVESTIGATIONAL](#).

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO BlueSM	This is not a covered service.
Medicare PPO BlueSM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

Description

Onychomycosis

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.¹ The condition can affect toenails or fingernails but is more frequently found in toenails. Primary infectious agents include dermatophytes (eg, Trichophyton species), yeasts (eg, Candida albicans), and nondermatophytic 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. Also, various medical conditions increase the risk of comorbid onychomycosis. They 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 1 prospective study with diabetic patients found onychomycosis to be an independent predictor of foot ulcers.² Moreover, onychomycosis, especially more severe cases, may adversely impact the quality of life. Patients with onychomycosis have reported pain, uncomfortable nail pressure, embarrassment, and discomfort wearing shoes.^{3,4}

Diagnosis

The diagnosis of onychomycosis can be confirmed by potassium hydroxide preparation, culture, or histology.

Treatment

Treatments for onychomycosis include topical antifungals such as nail paints containing ciclopirox (ciclopiroxolamine), efinaconazole, tavaborole, or amorolfine (not available in the US) and oral antifungals such as terbinafine and itraconazole. These have low-to-moderate efficacy and a high relapse rate. Topical antifungals and some long-available oral medications (eg, 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 the 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 1 or several sessions and, thus, require less long-term patient compliance.

Laser treatment of onychomycosis uses the principle of selective photothermolysis, defined as the precise targeting of 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 for onychomycosis is to heat the nail bed to temperatures required to disrupt fungal growth (approximately 40°-60°C) and at the same time avoid pain and necrosis to surrounding tissues.⁵

Characteristics of laser systems used to treat onychomycosis are listed in Table 1.⁵

Table 1. Characteristics of Lasers for Treating Onychomycosis

Variables	Characteristics
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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 part of the spectrum 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 typically operate at 1064 nm; 940- to 1320-nm and 1440-nm wavelengths are also options.
Pulse duration	Pulses need to be short to avoid damaging 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 pulses, in hertz)	Spot size to the diameter of the laser beam. For treating onychomycosis, laser spot sizes range from 1 to 10 nm.
Fluence (in J/cm ²)	Fluence refers to the amount of energy delivered into the area

Summary

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.

Summary of Evidence

For individuals who have onychomycosis who receive treatment with laser therapy, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. The randomized controlled trials reported inconsistent results and had methodologic limitations. Clinical and mycologic outcomes differed across the trials, lacked consistent blinding of outcome assessments, and often reported outcomes on a per-nail basis without accounting for correlated measurements. The published evidence to date does not permit determining whether laser treatment improves health outcomes in patients with onychomycosis. Additionally, some registered clinical trials are completed without publication of results, indicating potential publication bias. Additional well-designed, adequately powered, and well-conducted randomized controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Policy History

Date	Action
1/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2017	Annual policy review. New references added.
7/2015	Annual policy review. New references added.
9/2014	Annual policy review. New references added.
11/2013	New medical policy describing investigational indications. Effective 11/1/2013.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

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