Laser Treatment for Nail Fungus

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

Onychomycosis is a common fungal infection of the nail. Typically the nail becomes thickened and discolored. Aging is the most common risk factor for onychomycosis, most likely due to decreased blood circulation, longer exposure to fungi, and slower nail growth Additional risk factors include swimming, tinea pedis, psoriasis, diabetes, immunodeficiency, obesity, peripheral vascular disease, genetic predisposition, and living with family members who have onychomycosis. 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.

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. Because the infection is embedded within the nail and is difficult to reach, full resolution of symptoms is slow and may take a year or more,

since a new nail must grow and entirely replace the infected nail. These have low-to-moderate efficacy and a high relapse rate. Topical antifungals and some long-available oral medications (e.g., griseofulvin) require a long course of treatment, which presents issues for patient compliance. Also, some of the medications used to treat onychomycosis are associated with serious adverse events, including hepatotoxicity.

Several types of device-based therapies are under investigation for the treatment of onychomycosis, including ultrasound, iontophoresis, photodynamic therapy, and laser systems. Research suggests that fungi are sensitive to heat. Laser therapy heats the nail bed typically to 40-60 degrees Celsius to disrupt fungal growth. 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.

Clinical Context and Therapy Purpose
The purpose of laser treatment in patients who have onychomycosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of laser treatment improve the net health outcome compared with topical antifungal nail lacquer or oral antifungal therapy in patients who have onychomycosis?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with onychomycosis.

Interventions
The therapy being considered is laser treatment. Laser treatment allows for precise targeting of the fungal areas with enough heat to disrupt growth while avoiding damage to surrounding tissues. Two types of lasers have been developed to treat onychomycosis: neodymium-doped:yttrium aluminum garnet (Nd:YAG) and diode lasers.

Comparators
Current treatments for onychomycosis include topical antifungal nail lacquer and oral antifungal therapy. These treatments typically require long courses, which result in poor

patient compliance and high relapse rates. Nail lacquers contain ciclopirox or amorolfine. Oral medications are terbinafine and itraconazole, which have been associated with a risk of hepatotoxicity.

Outcomes
The general outcomes of interest are symptom relief (e.g., clear nail growth), change in disease status (e.g., mycologic remission or Onychomycosis Severity Scale scores), reduction in medication use, and treatment-related morbidity.

Clinical response can be measured after laser treatment (3-6 months). To determine remission rates, follow-up may last a year or more.

Study Selection Criteria
To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.

Literature
(2021) Gupta et al completed a systematic review of literature on lasers for treating dermatophyte onychomycosis included clinical studies of laser monotherapy that evaluated the great toenail as the target nail, reported mycological confirmation of onychomycosis and included a clear definition of efficacy. A total of nine studies met the review's inclusion criteria. Outcome measures and definitions of efficacy varied among studies. Clinical cure defined as 100% clear nail was reported in one study and clinical cure defined as less than 10% clinical involvement was reported in four studies. Mycological cure defined as both negative microscopy and negative fungal culture was reported in two studies, mycological cure defined as negative microscopy only was evaluated in three studies, and mycological cure defined as negative fungal culture only was reported in five studies. The authors did not pool study results.

(2020) Bunyaratavej et al did a double-blind study and did not find that Nd:YAG laser treatment of onychomycosis had superior outcomes to topical treatment alone or the combination of the two treatments. The study included 60 individuals, 20 per group. Individuals assigned to laser treatment received 4 sessions, with a month between each session. After treatment, mycological cure rates were 35%, 60% and 65% in the laser, topical treatment and combination treatment groups, respectively. Rates in the topical and combination treatment groups were similar to one another and both were better than rates in the laser treatment group alone (p=0.05). Clinical cure rates were 10% in the laser group, 30% in the topical treatment group, and 30% in the combination treatment group; p-values for this analysis were not reported.

(2020) Hamed et al conducted an RCT of 30 adults with onychomycosis. Interventions included laser therapy (every 2 weeks for 3 months) plus itraconazole pulse therapy (200 mg twice daily for 1 week per month over 3 months) compared to itraconazole pulse therapy only. Laser therapy plus itraconazole pulse therapy resulted in clinical improvement at 6 to 9 months of Mild 1/15 (6.7%); Moderate: 1/15 (6.7%): and Good:

3/15 (19.9%), and in mycological improvement at 6 to 9 months of Mild 5/15 (33.3%); Moderate 6/15 (40%); and Excellent: 10/15 (66.7%). Itraconazole pulse therapy alone resulted in clinical improvement at 6 to 9 months of Mild: 2/15 (13.3%); Moderate: 5/15 (33.3%); and Good: 6/15 (40%), and mycological improvement at 6 to 9 months of Mild: 5/15 (33.3%); Moderate: 6/15 (40%); and Excellent: 2/15 (13.3%). The conclusion noted the use of combined long-pulsed Nd-Yag laser and itraconazole pulse therapy gives the best clinical results and patient's satisfaction.

(2019) Nijenhuis-Rosien et al conducted the LASER-1 trial between 2015-2016. In a single-center, randomized (1:1), quadruple-blind, sham-controlled trial, patients and microbiological confirmation with diabetes mellitus, at risk for developing diabetic foot ulcers (Sims classification score 1, 2) and a clinical suspicion on onychomycosis, were randomized to either four sessions neodymium-doped yttrium aluminum garnet (Nd-YAG) 1064 nm laser or sham treatment. The primary outcome was clinical and microbiological cure of onychomycosis after 1-year follow-up. 64 patients were randomized; 63 could be analyzed. Trichophyton rubrum was the most detected pathogen. There was no difference in the primary outcome between laser and sham treatment. With the exception of a subungual hematoma in the fifth toenail occurring 2 weeks after laser treatment, the results suggested that treatment with Nd-YAG 1064 nm laser is safe. In conclusion, at this moment, there is no evidence of any effect of laser treatment for onychomycosis in patients with diabetes at increased risk for foot ulcers, at least not within 1 year after treatment.

(2020) UptoDate notes for Onychomycosis: Management report the following: Neodymium-doped:yttrium aluminum garnet (Nd:YAG) and diode lasers have emerged as treatment options for onychomycosis, data on the efficacy of these interventions are limited, and the mechanisms of action and optimal regimens for these treatments remain unclear [59-61]. Until more robust data supporting the efficacy of laser therapy for onychomycosis are available, we cannot recommend the routine use of this modality.

Support for the efficacy of such laser devices is primarily limited to uncontrolled studies that document clinical improvement in varying proportions of patients. One small, randomized trial found improvement in onychomycosis following the use of a dual wavelength near-infrared diode laser.

Randomized trials of Nd:YAG lasers in onychomycosis have yielded poor results. A randomized trial in which 27 patients with onychomycosis involving 125 nails were randomly assigned to two treatments with a 1064 nm Nd:YAG laser (17 patients) or no treatment (10 patients) did not find a statistical difference in the proportion of patients with mycologic clearance of all affected nails after three months. In addition, a nonsignificant trend towards greater proximal nail clearance in the active treatment group detected at the three-month time point dissipated by 12 months. Of note, responses could not be assessed in 5 of the 17 patients in the laser treatment group because of a failure to return for follow-up. Moreover, a separate randomized trial compared a series of four treatments with a short-pulsed 1064 nm Nd:YAG laser to no laser treatment in 20 patients

with 82 onychomycotic nails. The trial found laser treatment ineffective for achieving mycologic remission or clinical improvement.

Proposed mechanisms of action for laser therapy for onychomycosis include direct fungicidal effects, inhibition of fungus by laser-induced changes in the tissue environment, and laser-induced immunologic effects, though an in vitro study evaluating the effects of a submillisecond Nd:YAG laser on fungal nail pathogens did not find support for a laser-induced direct fungicidal effect. Further study with randomized trials that compare laser devices with placebo and other onychomycosis treatments as well as long-term, follow-up studies will be useful for clarifying the efficacy, mechanisms, optimal regimens, and indications for laser therapy.

Additional study will also be useful for determining whether combination therapy with an ablative fractional laser and a topical antifungal agent is effective for onychomycosis. In an uncontrolled study in which 24 patients with onychomycosis underwent three treatment sessions with an ablative fractional carbon dioxide (CO2) laser and once-daily application of topical amorolfine for 12 weeks, complete responses (normal-appearing nail and negative microscopic examination for fungus) were documented in 50 percent of patients after 12 weeks. This included all four patients with superficial white onychomycosis, 8 of 14 patients with distolateral subungual onychomycosis (57 percent), and none of six patients with total dystrophic onychomycosis. The authors of the study postulated that ablative fractional laser therapy might induce direct fungicidal effects, and the numerous vertical columns of tissue damage created by these lasers might increase penetration of a topical antifungal agent. Topical amorolfine is not available in the United States. (*Literature review current through December 2021*)

(2019) Yeung completed a meta-analysis of 24 prospective randomized and non-randomized trials evaluating laser treatment of onychomycosis found a pooled complete clinical cure rate of 7.2% (95% confidence interval [CI], 1.9-23.5%), clinical improvement rate of 67.2% (95% CI, 43.2-84.7%) and mycological cure rate of 70.4% (95% CI, 52.5-82.8%). The authors noted a high rate of heterogeneity among studies. The study did not report rates for any comparison intervention.

(2019) Sabbah et al conducted a double-blind RCT comparing treatment with Nd:YAG 1064 nm short-pulse lasers and sham in 51 individuals with toenail onychomycosis. Individuals received treatments at 0, 12 and 24 weeks. The primary endpoint was the proportion of individuals with complete cure, defined as clear nail and negative mycology, at 52 weeks. The primary endpoint was achieved by none of the individuals in the laser group and 2 (7.7%) individuals in the sham group, p=0.49. Secondary endpoints also did not differ significantly between groups. For example, 24% of individuals in the laser group and 42% of individuals in the sham group had negative mycology at 52 weeks, p=0.17. In conclusion, the study demonstrated that laser was not effective in treating onychomycosis, with results trending in favor of placebo sham laser.

(2018) Bonhert et al did not find a significant difference between groups in the primary outcome, complete cure, but did find a significant benefit of laser therapy for the outcome, improvement in onychomycosis. The trial randomized 30 individuals with toenail onychomycosis to treatment with 48 weeks of daily topical antifungal solution or antifungal solution plus 6 sessions of a 1064 nm Nd:YAG laser spaced 4 weeks apart. Outcome evaluation was blinded, and all participants completed the study. The primary outcome was complete cure at week 52, defined as negative mycological culture, negative potassium hydroxide (KOH) test and no nail onychomycosis. The primary outcome did not differ significantly between groups. At 52 weeks, there were no statistically significant differences between groups in mycological cure or KOH test results and thus the proportion of individuals experiencing complete cure did not differ. Onychomycosis severity was assessed by a 30-point Scoring Clinical Index for Onychomycosis (SCIO Index). The laser group had significantly lower SCOI scores at weeks 36, 48 and 52 compared with the comparison group. Moreover, overall improvement rated by blinded investigators was significantly higher in the laser group at 48 and 52 weeks.

(2017) Karsai et al completed a prospective randomized controlled pilot study, we analyzed the effect of the short-pulsed 1064-nm-Nd:YAG laser on the rate of mycological remission and clinical improvement after excluding relevant confounders with regard to our previous studies. Twenty patients with a total of 82 mycotic toenails were randomized to the treatment group (short-pulsed 1064-nm-Nd:YAG laser) or control group (no laser treatment). We conducted four laser treatments at 4- to 6-week intervals. In both groups, a local antimycotic agent was applied to the sole of the foot, the area between the toes and the skin directly surrounding the nails. The primary endpoint was complete remission of the onychomycosis after 12 months (fungal culture and histology); secondary endpoints included clinical improvement (Onychomycosis Severity Index, OSI) and the occurrence of pain or other adverse events. Mycological remission was not achieved in either study group. A comparison of both groups yielded no difference in the OSI score, both at the beginning of the trial (P = 0.9873) and after 12 months (P = 0.4317). In the treatment group, the OSI score worsened by a mean 2.0 points, and in the control group, by a mean 3.5 points. On a visual analogue scale (0 = 'no pain' to 10 = 'most intense pain'), pain in the treatment group was indicated at a mean score of five. Other adverse events were not reported. The short-pulsed 1064-nm-Nd:YAG laser shows no long-term efficacy as a monotherapy. Its role as an adjuvant therapy should be investigated in upcoming trials.

(2017) Park et al noted 128 individuals were randomized to 16 weeks of treatment with topical antifungal treatment alone (n=64) or topical treatment plus 1064 nm Nd:YAG laser treatment at 4 week intervals (n=64). The authors stated that outcome assessment was objective and independently assessed by two dermatologists. One of the primary efficacy outcomes, percent change in the lesion-free area over 16 weeks, did not differ significantly between groups. Change in the lesion-free area was 33.7% in the combined treatment group and 23% in the control group (p=0.07). However, there was a large and statistically significant difference between groups in another primary efficacy outcome,

cumulative cure rate, defined as the achievement of clinically normal nail or negative mycology, with nail plate involvement of less than 10%. Cure rates were 72% in the combined treatment group and 20% in the topical treatment-only group, p<0.00001.

Summary of Evidence
For individuals who have onychomycosis who receive treatment with laser therapy, the evidence includes small, randomized controlled trials and systemic reviews. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. The randomized controlled trials reported inconsistent, mixed 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.

Practice Guidelines and Position Statements

The British Association of Dermatologists (BAD)
(2014) The British Association of Dermatologists issued guidelines on the management of onychomycosis. Due to the limited nature of the evidence, the Association concluded that "lasers are showing promising results in the treatment of onychomycosis, but recommendations cannot be made at this stage" (level of evidence 1-). (*Accessed January 2022*).

Regulatory Status
The US Food and Drug Administration (FDA) has approved seven laser systems for the "temporary increase of clear nail onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)". The FDA has approved these devices based on "substantial equivalence" to predictive devices with similar technical specifications and applications. Laser therapy appears to be promising alternative to traditional pharmacotherapy, but these systems have tested in limited clinical trials; therefore, it is not possible to compare their efficacy to the oral and topical drugs currently used in the treatment of onychomycosis. Although neodymium-doped: yttrium aluminum garnet (Nd:YAG) and diode lasers have emerged as treatment options for onychomycosis, data on the efficacy of these interventions are limited, and the mechanisms of action and optimal regimens for these treatments remain unclear. Approved devices include, but are not limited to the following:

YAG 1064-nm Laser Systems		
Device	**Manufacturer**	**Approved**

GentleMax Family of Laser Systems™	Candela	2014
GenesisPlus™	Cutera	2011
JOULE ClearSense™	Sciton	2011
Nordlys	Ellipse A/S	2016
PinPointe™ FootLaser™	PinPointe USA (acquired by NuvoLase 2011)	2010
VARIABreeze™	CoolTouch	2011

Dual-wavelength:YAG 1064-nm and 532-nm Laser System		
Device	**Manufacturer**	**Approved**
Q-Clear™	Light Age	2011

PRIOR APPROVAL

Not applicable.

POLICY

Laser treatment is considered **investigational** for the treatment of nail fungus (onychomycosis).

The published evidence to date is insufficient to determine whether laser treatment improves health outcomes in patients with onychomycosis. Further study with randomized trials that compare laser devices with placebo and other onychomycosis treatments as well as long-term, follow-up studies will be useful for clarifying the efficacy, mechanisms, optimal regimens, and indications for laser therapy. There is an inability to draw conclusion of health benefits with the currently available information.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 17999 Unlisted procedure, skin, mucous membrane and subcutaneous tissue (when specified as laser treatment of onychomycosis)
- 96999 Unlisted special dermatological services or procedures (when specified as laser treatment of onychomycosis)

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POLICY HISTORY

Date	Reason	Action
January 2022	Annual Review	Policy Renewed
January 2021	Annual Review	Policy Revised
January 2020	Annual Review	Policy Renewed
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January 2018	Annual Review	Policy Renewed
January 2017	Annual Review	Policy Renewed

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March 2014	Annual Review	Policy Revised

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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