Medical Coverage Policy | Laser Treatment for Onychomycosis

EFFECTIVE DATE: 02|07|2017
POLICY LAST UPDATED: 01|18|2023

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Laser treatment of onychomycosis is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Laser treatment of onychomycosis is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessity benefits/coverage.

BACKGROUND
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 (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. In addition, 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 ulcer. Moreover, onychomycosis, especially more severe cases, may adversely impact 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. These generally 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 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, requires less long-term patient compliance.

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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 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.

For individuals who have onychomycosis who receive treatment with laser therapy, the evidence includes small randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. Some of the available RCTs have reported improvements in clinical outcomes with laser treatment, but these trials have mixed results and methodologic limitations. Clinical and mycological outcomes sometimes differed in the trials, which may be due in part to lack of consistent blinding of outcome assessment. The published evidence to date does not permit determining whether laser treatment improves health outcomes in patients with onychomycosis. Additional well-designed, adequately powered, and well-conducted RCTs are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

There is no specific CPT code(s) for this treatment. It would likely be reported using an unlisted CPT code such as 17999 (Unlisted procedure, skin, mucous membrane and subcutaneous tissue) or 96999 (Unlisted special dermatological service or procedure).

RELATED POLICIES

Foot Care and Nail Debridement

PUBLISHED

Provider Update, March 2023
Provider Update, April 2022
Provider Update, March 2021
Provider Update, April 2020
Provider Update, July 2019

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