Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Laser Treatment of Onychomycosis

Policy #: 528
Latest Review Date: December 2022
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **laser treatment of onychomycosis** as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

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

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. 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. 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.

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.

Characteristics of laser systems used to treat onychomycosis are listed in Table 1.

Table 1. Characteristics of Lasers for Treating Onychomycosis

Variables	Characteristics
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 are 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/cm2)	Fluence refers to the amount of energy delivered into the area

KEY POINTS:

This policy has been updated regularly with searches of the MEDLINE database. The most recent update with literature review covered the period through October 21, 2022.

Summary of Evidence

For individuals who have onychomycosis who receive treatment with laser therapy, the evidence includes small, randomized controlled trials. 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.

Practice Guidelines and Position Statements

No Practice Guidelines or Position Statements regarding issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE) were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Onychomycosis, laser treatment, laser therapy, nail fungus, PinPointe FootLaser, GenesisPlus™, VARIABreeze™, GentleMax Family of Laser Systems, Nordlys

APPROVED BY GOVERNING BODIES:

Multiple Nd:YAG laser systems have been cleared by the FDA for marketing for the temporary increase of clear nail in patients with onychomycosis (product code: GEX). 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, acquired by NuvoLase in 2011): 2010
- GenesisPlus™ (Cutera): 2011
- JOULE ClearSense™ (Sciton): 2011
- GentleMax Family of Laser Systems (Candela): 2014
- Nordlys (Ellipse A/S): 2016

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

- Q-Clear™ (Light Age, Inc.): 2011

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:
No comparable CPT code exists for this procedure, and would likely be reported using the following unlisted codes:

17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
96999	Unlisted special dermatological service or procedure

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POLICY HISTORY:

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Medical Policy Group, June 2014
Medical Policy Group, June 2015
Medical Policy Group, December 2015
Medical Policy Group, December 2016
Medical Policy Group, December 2017
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Medical Policy Group, December 2019
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