

Laser Treatment of Onychomycosis

Policy # 00371

Original Effective Date: 07/17/2013

Current Effective Date: 09/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Laser Treatment of Skin Conditions is addressed separately in medical policy 00162.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers laser treatment of onychomycosis to be **investigational**.*

Background/Overview

Onychomycosis

Onychomycosis is a common chronic fungal infection of the nail. It is estimated to cause up to 50% of all nail diseases 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.

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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 one 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° to 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 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 mm.
Fluence (in J/cm ²)	Fluence refers to the amount of energy delivered into the area.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Multiple Nd:YAG laser systems have been cleared by the U.S. Food and Drug Administration (FDA) for marketing for the temporary increase of clear nail in patients with onychomycosis. The FDA has determined that these devices were substantially equivalent to existing devices. Table 2 lists select approved laser systems.

Table 2. Select Laser Systems Approved for Temporary Increase of Clear Nail in Patients with Onychomycosis

Device	Manufacturer	Approved
Nd:YAG 1064-nm laser systems		
PinPointe ^{TM‡} FootLaser ^{TM‡}	PinPointe USA (acquired by NuvoLase 2011)	2010
GenesisPlus ^{TM‡}	Cutera	2011
JOULE ClearSense ^{TM‡}	Sciton	2011
GentleMax Family of Laser Systems	Candela	2014
Nordlys	Ellipse A/S	2016
Dual-wavelength Nd:YAG 1064-nm and 532-nm laser system		
Q-Clear ^{TM‡}	Light Age	2011

Nd:YAG 1064-nm laser systems (FDA product code: GEX); dual-wavelength Nd:YAG 1064-nm and 532-nm laser system (FDA product code: PDX).

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

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 systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. The RCTs

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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. A systematic review reported favorable outcomes for laser therapy; however, wide confidence intervals suggest uncertainty in the precision of the results. 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 RCTs are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of clinicaltrials.gov did not yield any ongoing or unpublished trials that might influence this review.

References

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Policy History

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06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2015	Medical Policy Committee review
08/19/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/19/2019	Coding update
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Extensive policy revisions with no change to coverage criteria.
08/01/2024	Medical Policy Committee review

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08/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/07/2025 Medical Policy Committee review

08/13/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/06/2026 Medical Policy Committee review

08/12/2026 Medical Policy Implementation Committee review

08/20/2026 Medical Quality Management Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	17999, 96999
HCPCS	No codes
ICD-10 Diagnosis	B35.1, L60.0-L60.9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.