BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.01.89 Laser Treatment of Onychomycosis

Annual Effective Policy Date: April 1, 2024

Original Policy Date: September 2013

Related Policies:

None

Laser Treatment of Onychomycosis

Description

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.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of laser therapy improves net health outcomes in individuals with onychomycosis compared with topical and oral medications alone.

POLICY STATEMENT

Laser treatment of onychomycosis is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

The approach to laser treatment of onychomycosis will depend on benefit language related to definitions of medically necessary, reconstructive, and cosmetic services. Procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease, or congenital defect. Not all benefit contracts include benefits for reconstructive services. Benefit language supersedes this document.

FDA REGULATORY STATUS

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 1 lists select approved laser systems.

Table 1. Select Laser Systems Approved for Temporary Increase of Clear Nail in Patients with Onychomycosis

Device	Manufacturer	Approved
Nd:YAG 1064-nm laser systems		
PinPointe™ FootLaser™	PinPointe USA (acquired by NuvoLase 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 1064-nm and 532-nm laser system		
Q-Clear™	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

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 RCTs 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 RCTs are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

SUPPLEMENTAL INFORMATION

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.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2013	New policy	Laser systems for onychomycosis are considered investigational.
September 2014	Replace policy	Policy updated with literature review through March 18, 2014. Policy statement unchanged. References 11-13 and 15-17 added.
September 2015	Replace policy	Policy updated with literature review. References 6-8 added. Policy statement unchanged.
March 2017	Replace policy	Policy updated with literature review, 2016; references 7-8 and 13 added. Policy statement unchanged.
March 2018	Replace policy	Policy updated with literature review through October 16, 2017; no references added. Policy statement unchanged.
March 2019	Replace policy	Policy updated with literature review through October 1, 2018; no references added. Policy statement unchanged.
March 2020	Replace policy	Policy updated with literature review through October 14, 2019; no references added. Policy statement unchanged.
March 2021	Replace policy	Policy updated with literature review through October 21, 2020; references added. Policy statement unchanged.
March 2022	Replace policy	Policy updated with literature review through September 20, 2021; no references added. Policy statement unchanged.
March 2023	Replace policy	Policy updated with literature review through October 21, 2022; no references added. Policy statement unchanged.
March 2024	Replace policy	Policy updated with literature review through October 18, 2023; reference added. Policy statement unchanged.