

FEP 2.01.89 Laser Treatment of Onychomycosis

Effective Date: April 15, 2018

Related Policies:
2.01.71 Nonpharmacologic Treatment of Rosacea

Laser Treatment of Onychomycosis

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.

FDA REGULATORY STATUS

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

POLICY STATEMENT

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

BENEFIT APPLICATION

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

FEP 2.01.89 Laser Treatment of Onychomycosis

RATIONALE

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. Some of the available randomized controlled trials have reported improvements in clinical outcomes with laser treatment, but these trials have mixed results and methodologic limitations. Clinical and mycologic 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 randomized controlled trials are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

British Association of Dermatologists

In 2014, the British Association of Dermatologists issued guidelines on the management of onychomycosis.¹³ 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-).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

REFERENCES

1. Rodgers P, Bassler M. Treating onychomycosis. *Am Fam Physician*. Feb 15 2001;63(4):663-672, 677-668. PMID 11237081
2. Boyko EJ, Ahroni JH, Cohen V, et al. Prediction of diabetic foot ulcer occurrence using commonly available clinical information: the Seattle Diabetic Foot Study. *Diabetes Care*. Jun 2006;29(6):1202-1207. PMID 16731996
3. Drake LA, Scher RK, Smith EB, et al. Effect of onychomycosis on quality of life. *J Am Acad Dermatol*. May 1998;38(5 Pt 1):702-704. PMID 9591814
4. Elewski BE. Onychomycosis. Treatment, quality of life, and economic issues. *Am J Clin Dermatol*. Jan-Feb 2000;1(1):19-26. PMID 11702301
5. Gupta A, Simpson F. Device-based therapies for onychomycosis treatment. *Skin Therapy Lett*. Oct 2012;17(9):4-9. PMID 23032936
6. Bristow IR. The effectiveness of lasers in the treatment of onychomycosis: a systematic review. *J Foot Ankle Res*. Aug 2014;7:34. PMID 25104974
7. Karsai S, Jager M, Oesterhelt A, et al. Treating onychomycosis with the short-pulsed 1064-nm-Nd:YAG laser: results of a prospective randomized controlled trial. *J Eur Acad Dermatol Venereol*. Jan 2017;31(1):175-180. PMID 27521028
8. Kim TI, Shin MK, Jeong KH, et al. A randomised comparative study of 1064 nm Neodymium-doped yttrium aluminium garnet (Nd:YAG) laser and topical antifungal treatment of onychomycosis. *Mycoses*. Jul 12 2016;59(12):803-810. PMID 27402466
9. El-Tatawy RA, Abd El-Naby NM, El-Hawary EE, et al. A comparative clinical and mycological study of Nd-YAG laser versus topical terbinafine in the treatment of onychomycosis. *J Dermatolog Treat*. Feb 11 2015:1-4. PMID 25669435

FEP 2.01.89 Laser Treatment of Onychomycosis

10. Xu Y, Miao X, Zhou B, et al. Combined oral terbinafine and long-pulsed 1,064-nm Nd: YAG laser treatment is more effective for onychomycosis than either treatment alone. *Dermatol Surg*. Nov 2014;40(11):1201-1207. PMID 25322165
11. Landsman AS, Robbins AH, Angelini PF, et al. Treatment of mild, moderate, and severe onychomycosis using 870- and 930-nm light exposure. *J Am Podiatr Med Assoc*. May-Jun 2010;100(3):166-177. PMID 20479446
12. Landsman AS, Robbins AH. Treatment of mild, moderate, and severe onychomycosis using 870- and 930-nm light exposure: some follow-up observations at 270 days. *J Am Podiatr Med Assoc*. Mar-Apr 2012;102(2):169-171. PMID 22461276
13. Ameen M, Lear JT, Madan V, et al. British Association of Dermatologists' guidelines for the management of onychomycosis 2014. *Br J Dermatol*. Nov 2014;171(5):937-958. PMID 25409999

POLICY HISTORY

Date	Action	Description
September 2013	New Policy	
September 2014	Update Policy	Policy updated with literature review through March 18, 2014. Policy statement unchanged. References 11-13 and 15-17 added.
September 2015	Update Policy	Policy updated with literature review. References 6-8 added. Policy statement unchanged.
March 2017	Update Policy	Policy updated with literature review, 2016; references 7-8 and 13 added. Policy statement unchanged.
March 2018	Update Policy	Policy updated with literature review through October 16, 2017; no references added. Policy statement unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.