FEP 2.01.89 Laser Treatment for Onychomycosis

Effective Date: April 1, 2019
Related Policies: None

Laser Treatment for 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.

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.

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

FDA REGULATORY STATUS
Multiple Nd:YAG laser systems have been 510(k) 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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nd:YAG 1064-nm laser systems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PinPointe™ FootLaser™</td>
<td>PinPointe USA (acquired by NuvoLase 2011)</td>
<td>2010</td>
</tr>
<tr>
<td>GenesisPlus™</td>
<td>Cutera</td>
<td>2011</td>
</tr>
<tr>
<td>VariaBreeze™</td>
<td>CoolTouch</td>
<td>2011</td>
</tr>
</tbody>
</table>
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**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


**RATIONALE**

**Summary of Evidence**

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

The British Association of Dermatologists (2014) 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**


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.
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POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2013</td>
<td>New Policy</td>
<td>Laser systems for onychomycosis are considered investigational.</td>
</tr>
<tr>
<td>March 2019</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 1, 2018; no references added. Policy statement unchanged.</td>
</tr>
</tbody>
</table>

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