| 2.01.89 | Laser Treatment of Onychomycosis | | |
|---|---|---|---|
| **Original Policy Date:** | December 4, 2015 | **Effective Date:** | February 1, 2024 |
| **Section:** | 2.0 Medicine | **Page:** | Page 1 of 14 |

## Policy Statement

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

**NOTE**: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

There is no specific CPT code for this treatment. It would likely be reported using the unlisted CPT codes:

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

## 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.

## Related Policies

- Nonpharmacologic Treatment of Rosacea

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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 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™ FootLaser™** | PinPointe USA (acquired by NuvoLase 2011) | 2010 |

| Device | Manufacturer | Approved |
|---|---|---|
| **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

### Background

#### 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.[1,] The condition can affect toenails or fingernails but is more frequently found in toenails. Primary infectious agents include dermatophytes (e.g., *Trichophyton* species), yeasts (e.g., *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.[2,] 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.[3,4,]

#### 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 (e.g., 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°to 60°C) and at the same time avoid pain and necrosis to surrounding tissues.[5,]

Characteristics of laser systems used to treat onychomycosis are listed in Table 1.[5,]

**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 nm. |
| **Fluence (in J/cm²)** | Fluence refers to the amount of energy delivered into the area |

## Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude e of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

## Laser treatment for Onychomycosis

### Clinical Context and Therapy Purpose

The purpose of laser treatment in individuals who have onychomycosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

*Populations*
The relevant population of interest is individuals with onychomycosis.

*Interventions*
The therapy being considered is laser treatment. Laser treatment allows for precise targeting of the fungal areas with enough heat to disrupt growth while avoiding damage to surrounding tissues. Two types of lasers have been developed to treat onychomycosis: neodymium-doped:yttrium aluminum garnet (Nd:YAG) and diode lasers.

*Comparators*
Current treatments for onychomycosis include topical antifungal nail lacquer and oral antifungal therapy. These treatments typically require long courses, which result in poor patient compliance and high relapse rates. Nail lacquers available in the US contain ciclopirox, efinaconazole, or tavaborole. Oral medications are terbinafine and itraconazole, which have been associated with a risk of hepatotoxicity.

*Outcomes*
The general outcomes of interest are symptom relief (e.g., clear nail growth), change in disease status (e.g., mycologic remission or Onychomycosis Severity Scale scores), reduction in medication use, and treatment-related morbidity.

Clinical response can be measured after laser treatment (3-6 months). To determine remission rates, follow-up may last a year or more.

## Study Selection Criteria
To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.

## Review of Evidence
### Systematic Reviews
A systematic review by Bristow et al (2014) identified 12 published studies on laser treatment for onychomycosis in a literature search conducted in June 2014.[6,] Two were RCTs, 4 were nonrandomized comparative studies with no placebo or control group, and 6 were case series. Bristow et al (2014) did not pool study findings, concluding the evidence was limited and of poor methodologic quality.

### Randomized Controlled Trials
Representative RCTs published after the systematic review, with the largest sample sizes, and comparing laser treatment with placebo or a different intervention are described next and in Tables 3 through 6.

Several representative RCTs published after the systematic review compared laser treatment with placebo or a different intervention.[7,8,9,10,11,12,13,14,15,] These RCTs have generally compared laser therapy with either systemic or topical therapy, and often a combination laser and systemic/topical regimen.

The primary outcomes evaluated in these trials have varied and generally were not uniformly or explicitly defined. Many trials report on clinical or mycological cure or improvement, the results of which have been conflicting. Moreover, follow-up duration has varied, ranging from 12 weeks in Kim et al to 12 months in Karsai et al and Nijenhuis-Rosien et al (LASER-1: Laser Therapy for Onychomycosis in Patients With Diabetes at Risk for Diabetic Foot Complications).[10,12,11,] Various methodologic limitations are also present. For example, Sabbah et al (2019) did not recruit the prespecified sample required to be adequately powered, and reported outcomes only for the most

severely affected greater toenail, which may not be representative of less severely affected nails.[13,] Additionally, Xu et al (2014) reported outcomes on a per-nail basis, which did not account for correlated measurements.[14,] All trials employed laser therapy with 1064-nm Nd:YAG laser therapy.

**Table 3. Characteristics of RCTs of Laser Treatment of Onychomycosis**

| Study; Trial | Countries | Sites | Dates | Participants | Interventions | |
|---|---|---|---|---|---|---|
| | | | | | *Active* | *Comparator* |
| **Nasif et al (2023)[15,]** | Egypt | 1 | NR | 40 adults with onychomycosis | Laser therapy (6 sessions) | Itraconazole pulse therapy only (200 mg twice daily for 1 week per month over 3 months) |
| **Hamed Khater et al (2020)[9,]** | Egypt | 1 | NR | 30 adults with onychomycosis | Laser therapy (every 2 weeks for 3 months) + itraconazole pulse therapy (200 mg twice daily for 1 week per month over 3 months) | Itraconazole pulse therapy only |
| **Bunyaratavej et al (2020 )[7,]** | Thailand | 1 | 2015-2019 | 60 adults with mycologically proven onychomycosis | Laser therapy only (4 sessions at 1-month intervals)<br><br>Laser therapy + topical amorolfine | Topical amorolfine only |
| **Nijenhuis-Rosien et al (2019); LASER-1[12,]** | Netherlands | 1 | 2015-2016 | 63 adults at risk for diabetic foot ulcer and with suspected onychomycosis | Laser therapy (4 sessions) | Sham laser therapy |
| **Sabbah et al (2019)[13,]** | Canada | 1 | 2013-2014 | 51 adults with mycologically confirmed onychomycosis involving at least 25% of 1 great toenail | Laser therapy (3 sessions) | Sham laser therapy |
| **Karsai et al (2017)[10,]** | Germany | 1 | 2013-2015 | 20 adults with mycologically proven onychomycosis | Laser therapy (4 treatments at 4- to 6-week intervals) | No laser therapy |
| **Kim et al (2016)[11,]** | Korea | 1 | 2014-2015 | 56 patients with mycologically proven onychomycosis | Laser therapy only (3 sessions at 4-week intervals; 4th session permitted if <50% clinical response)<br><br>Laser therapy + topical naftifine | Topical naftifine only |
| **El-Tatawy et al (2015)[8,]** | Egypt | 1 | NR | 40 adult females with onychomycosis | Laser therapy (4 sessions at 1-week intervals) | Topical terbinafine |

| Study; Trial | Countries | Sites | Dates | Participants | Interventions | |
|---|---|---|---|---|---|---|
| **Xu et al (2014)[14,]** | China | 1 | 2011-2012 | 53 adults with onychomycosis | Laser therapy only (once weekly)<br><br>Laser + oral terbinafine | Oral terbinafine only |

RCT: randomized controlled trial; NR: not reported.

**Table 4. Results of RCTs of Laser Treatment of Onychomycosis**

| Study; Trial | Onychomycosis Severity Index | Clinical response | Mycological cure | Improvement | Clearance |
|---|---|---|---|---|---|
| **Nasif et al (2023)[15,]** | N=40 | N=40 | N=40 | | |
| **Laser therapy only** | Reduction %, median (IQR) = 100 (90 to 100) | No: 0<br>Mild: 0<br>Moderate: 1<br>Marked: 19 | Negative: 19<br>Positive: 1 | | |
| **Itraconazole pulse therapy alone** | Reduction %, median (IQR) = 100 (90 to 100) | No: 0<br>Mild: 0<br>Moderate: 5<br>Marked: 15 | Negative: 15<br>Positive: 5 | | |
| **p-value** | .721 | | .181 | | |
| **Hamed Khater et al (2020)[9,]** | | | | N=30 | |
| **Laser therapy + itraconazole pulse therapy** | | | | Clinical improvement at 6 to 9 months:<br>Mild: 1/15 (6.7%)<br>Moderate: 1/15 (6.7%)<br>Good: 3/15 (19.9%)<br><br>Mycological improvement at 6 to 9 months:<br>Mild: 5/15 (33.3%)<br>Moderate: 6/15 (40%)<br>Excellent: 10/15 (66.7%) | |
| **Itraconazole pulse therapy alone** | | | | Clinical improvement at 6 to 9 months:<br>Mild: 2/15 (13.3%)<br>Moderate: 5/15 (33.3%)<br>Good: 6/15 (40%)<br><br>Mycological improvement at 6 to 9 months:<br>Mild: 5/15 (33.3%)<br>Moderate: 6/15 (40%)<br>Excellent: 2/15 (13.3%) | |
| **p-value** | | | | Clinical improvement:.001<br><br>Mycological improvement: NS | |
| **Bunyaratavej et al (2020 )[7,]** | | | N=60 | | |
| **Laser therapy only** | | | 7/20 (35%) at mean 5.9 months | | |
| **Laser therapy + topical amorolfine** | | | 12/20 (60%) at mean 5.2 months | | |

| Study; Trial | Onychomycosis Severity Index | Clinical response | Mycological cure | Improvement | Clearance |
|---|---|---|---|---|---|
| **Topical amorolfine only** | | | 13/20 (65%) at mean 4.8 months | | |
| **p-value** | | | p=.05 for combination therapy vs. laser therapy alone; p=NS for combination therapy vs. topical amorolfine | | |
| **Nijenhuis-Rosien et al (2019); LASER-1[12,]** | | | N=63 | | |
| **Laser therapy** | | | 52 weeks: 14/32 (43.8%) | | |
| **Sham laser therapy** | | | 52 weeks: 13/31 (41.9%) | | |
| **p-value** | | | 1.00 | | |
| **Sabbah et al (2019)[13,]** | | | N=51 | | |
| **Laser therapy** | | | 52 weeks: 0/25 | | |
| **Sham laser therapy** | | | 52 weeks: 2/26 (7.7%) | | |
| **p-value** | | | .49 | | |
| **Karsai et al (2017)[10,]** | N=20 | | N=20 | | |
| **Laser therapy** | 52 weeks: 2.0-point increase | | 52 weeks: 0/20 | | |
| **No laser therapy** | 52 weeks: 3.6-point increase | | 52 weeks: 0/20 | | |
| **Difference (95% CI); p-value** | -1.6 (-0.7 to +3.9); p=.5531 | | | | |
| **Kim et al (2016)[11,]** | | N=56 | N=56 | | |
| **Laser therapy alone** | | 12 weeks: 70.9%<br>24 weeks: 76.0% | 12 weeks: 8.9%<br>24 weeks: 15.2% | | |
| **Laser + topical antifungal therapy** | | 12 weeks: 73.2%<br>24 weeks: 71.8% | 12 weeks: 14.1%<br>24 weeks: 22.5% | | |
| **Topical therapy alone** | | 12 weeks: 14.9%<br>24 weeks: 20.9% | 12 weeks: 6.0%<br>24 weeks: 4.5% | | |
| **p-value** | | p<.05 for both groups vs. topical therapy alone | p<.05 for both groups vs. topical therapy alone | | |
| **El-Tatawy et al (2015)[8,]** | | | | N=40 | |
| **1064-nm Nd:YAG laser** | | | | 6 months:<br>Marked: 20/20 (100%) | |
| **Topical terbinafine** | | | | 6 months:<br>Marked: 0<br>Moderate: 2/20 (10%)<br>Mild: 8/20 (40%)<br>None: 10/20 (50%) | |
| **p-value** | | | | .002 | |
| **Xu et al (2014)[14,]** | | | | | N=54 |

| Study; Trial | Onychomycosis Severity Index | Clinical response | Mycological cure | Improvement | Clearance |
|---|---|---|---|---|---|
| **Laser therapy** | | | | | 24 weeks: 20 (64.5%) of 31 nails[1] |
| **Topical terbinafine** | | | | | 24 weeks: 22 (73.3%) of 30 nails[1] |
| **Laser therapy + topical terbinafine** | | | | | 24 weeks: 28 (96.6%) of 29 nails[1] |
| **p-value** | | | | | p<.05 for both groups vs. combination therapy |

CI: confidence interval; NS: not significant
[1]≤5% nail plate involvement in onychomycosis

**Table 5. Study Relevance Limitations**

| Study; Trial | Population[a] | Intervention[b] | Comparator[c] | Outcomes[d] | Follow-Up[e] |
|---|---|---|---|---|---|
| **Nasif et al (2023)[15],** | | | | 5. Clinically significant difference not prespecified | |
| **Hamed Khater et al (2020)[9],** | | | | 5. Clinically significant difference not prespecified | |
| **Bunyaratavej et al (2020)[7],** | | 1. Topical therapy regimen not described | 2. Patient applied | 5. Clinically significant difference not prespecified | |
| **Nijenhuis-Rosien et al (2019); LASER-1[12],** | | | | | |
| **Sabbah et al (2019)[13],** | | | | | |
| **Karsai et al (2017)[10],** | | | 2. Patient applied | 5. Clinically significant difference not prespecified | |
| **Kim et al (2016)[11],** | | | 2. Patient applied | 5. Clinically significant difference not prespecified | |
| **El-Tatawy et al (2015)[8],** | | | 2. Patient applied | 5. Clinically significant difference not prespecified | |
| **Xu et al (2014)[14],** | | | | 5. Clinically significant difference not prespecified | |

IQR: interquartile range.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as

intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

### Table 6. Study Design and Conduct Limitations

| Study; Trial | Allocation[a] | Blinding[b] | Selective Reporting[c] | Data Completeness[d] | Power[e] | Statistical[f] |
|---|---|---|---|---|---|---|
| **Nasif et al (2023)[15],** | 3. Allocation concealment method not reported | 1. Blinding methods not described | | | 1. Power calculations not performed | |
| **Hamed Khater et al (2020)[9],** | 3. Allocation concealment method not reported | 1. Blinding methods not described | | | 1. Power calculations not performed | |
| **Bunyaratavej et al (2020 )[7],** | 3. Allocation concealment method not reported | 1. Blinding methods not described | | | 1. Power calculations not performed | |
| **Nijenhuis-Rosien et al (2019); LASER-1[12],** | | | | | | |
| **Sabbah et al (2019)[13],** | | 1. Patients, not clinicians, were blinded | | | | |
| **Karsai et al (2017)[10],** | 3. Allocation concealment method not reported | 1. Patients, not clinicians, were blinded | | | 1. Power calculations not performed | |
| **Kim et al (2016)[11],** | 3. Allocation concealment method not reported | 1. Blinding not reported | | | 1. Power calculations not performed | |
| **El-Tatawy et al (2015)[8],** | 3. Allocation concealment method not reported | 1. Blinding not reported | | | 1. Power calculations not performed | |
| **Xu et al (2014)[14],** | 3. Allocation concealment method not reported | 1. Blinding not reported | | | 1. Power calculations not performed | |

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2.

Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

### 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

Some currently ongoing and unpublished trials that might influence this review are listed in Table 7.

**Table 7. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| *Ongoing* | | | |
| NCT05415852 | Comparison Between Different Types of LASER in the Treatment of Onychomycosis, a Randomized Controlled Trial | 40 | Sept 2022 |
| *Unpublished* | | | |
| NCT01915355 | Pulsed Dye Laser Treatment of Onychomycosis | 11 | Jul 2015 (completed) |
| NCT02019446 | Laser Treatment for Onychomycosis in Diabetes[a] | 60 | Dec 2021 |

NCT: national clinical trial; Nd:YAG: neodymium yttrium aluminum garnet
a Denotes industry-sponsored or cosponsored trial

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## Documentation for Clinical Review

- No records required

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

| Type | Code | Description |
|---|---|---|
| CPT® | 17999 | Unlisted procedure, skin, mucous membrane and subcutaneous tissue |
| | 96999 | Unlisted special dermatological service or procedure |
| HCPCS | None | |

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action |
|---|---|
| 12/04/2015 | BCBSA Medical Policy Adoption |
| 02/01/2017 | Policy revision without position change |
| 02/01/2018 | Policy revision without position change |
| 02/01/2019 | Policy revision without position change |
| 02/01/2020 | Annual review. No change to policy statement. Literature review updated. |
| 02/01/2024 | Policy reactivated. Previously archived from 09/01/2020 to 01/31/2024. |

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

## Appendix A

| POLICY STATEMENT | |
|---|---|
| **BEFORE** | **AFTER**<br>**Blue font: Verbiage Changes/Additions** |
| **Reactivated Policy**<br><br>**Policy Statement:**<br>N/A | **Laser Treatment of Onychomycosis 2.01.89**<br><br>**Policy Statement:**<br>I. Laser treatment of onychomycosis is considered **investigational**. |