

Medical and Behavioral Health Policy

Section: Medicine

Policy Number: II-153

Effective Date: 09/24/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

LASER AND PHOTODYNAMIC THERAPY FOR ONYCHOMYCOSIS

Description: Onychomycosis, a fungal infection of the fingernails and toenails, may be caused by dermatophytes (i.e., *Trichophyton rubrum* and *T. mentagrophytes*), nondermatophyte molds, and yeasts (e.g., *Candida albicans*). The infection slowly attacks the nail plate and, in its final stages, may completely destroy the nail. The prevalence of onychomycosis ranges between 2% and 28%, with higher prevalence in specific populations such as the elderly and patients with immune suppression or diabetes mellitus.

Current treatments include mechanical and chemical debridement, oral and topical antifungals, or a combination of those therapies. Recurrence is frequent, however, with cure rates ranging from 21% to 53% after long-term treatment.

Because laser and ultraviolet light have the potential to eradicate microorganisms without destroying surrounding tissue, several different treatments have been proposed for onychomycosis. Photodynamic therapy (PDT) involves the application of a topical photosensitizer followed by irradiation of the treatment site with a light source (e.g., laser energy or ultraviolet light). Pretreatment with the photosensitizer may take up to 10 hours; multiple sessions of pretreatment and irradiation are generally required. Laser treatment, without the addition of a photosensitizing agent, involves direct application of laser energy to the treatment site. Treatment sessions last approximately one hour and multiple treatments may be required.

A number of laser devices used to treat onychomycosis have received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for "the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.)." Approved devices include, but are not limited to the PinPointe™

FootLaser™, GenesisPlus™, VARIABreeze™, JOULE ClearSense™, and Q-Clear™.

Policy: Use of the following therapies for onychomycosis is considered **INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes:

- Laser treatment; and
- Photodynamic therapy.

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

CPT:

96567 Photodynamic therapy by external application of light to destroy pre-malignant and/or malignant lesions of the skin and adjacent mucosa (e.g., lip) by activation of photosensitive drug(s), each phototherapy exposure session

HCPCS:

J7308 Aminolevulinic acid HCl for topical administration, 20%, single unit dosage form (354 mg)

J7309 Methyl aminolevulinate (mal) for topical administration, 16.8%, 1 gram

**Policy
History:**

Developed September 14, 2011

Most recent history:

Reviewed September 12, 2012

Reviewed/Updated, no policy statement changes Sept. 11, 2013

Reviewed September 10, 2014

**Cross
Reference:**

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