Clinical Policy: Ciclopirox (Penlac)

Reference Number: CP.PMN.24
Effective Date: 09.01.07
Last Review Date: 02.18 Revision Log
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ciclopirox (Penlac®) is a synthetic antifungal agent.

FDA Approved Indication(s)

Penlac is a nail lacquer indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to Trichophyton rubrum.

Limitations of use:

- No studies have been conducted to determine whether ciclopirox might reduce the effectiveness of systemic antifungal agents for onychomycosis. Therefore, the concomitant use of 8% ciclopirox topical solution and systemic antifungal agents for onychomycosis is not recommended.
- Penlac should be used only under medical supervision.
- The effectiveness and safety of Penlac in the following populations has not been studied. The clinical trials with use of Penlac excluded patients who: were pregnant or nursing, planned to become pregnant, had a history of immunosuppression (e.g., extensive, persistent, or unusual distribution of dermatomycoses, extensive seborrheic dermatitis, recent or recurring herpes zoster, or persistent herpes simplex), were HIV seropositive, received organ transplant, required medication to control epilepsy, were insulin dependent diabetics, or had diabetic neuropathy. Patients with severe plantar (moccasin) tinea pedis were also excluded.
- The safety and efficacy of using Penlac daily for greater than 48 weeks have not been established.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Penlac is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Onychomycosis (must meet all)**:**

1. Diagnosis of onychomycosis;
2. Age ≥ 12 years;

3. Failure of a trial of oral terbinafine for 12 weeks (for toenails) or 6 weeks (for fingernails), at up to maximally indicated doses within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 48 weeks

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Onychomycosis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 48 weeks

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 48 weeks (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
terbinafine (Lamisil®)	Fingernail onychomycosis: 250 mg PO once daily for 6 weeks Toenail onychomycosis: 250 mg PO once daily for 12 weeks	250 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Onychomycosis	Apply once daily (preferably at bedtime or eight hours before washing) to all affected nails with the applicator brush provided. Daily applications should be made over the previous coat and removed with alcohol every seven days. This cycle should be repeated throughout the duration of therapy. The safety and efficacy of using ciclopirox daily for > 48 weeks have not been established.	See dosing regimen

VI. Product Availability

Topical solution: 8%

VII. References

1. Penlac Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2016. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed October 31, 2017.
2. Westerberg DP and Voyack MJ. Onychomycosis: current trends in diagnosis and treatment. Am Fam Physician. 2013; 88(11): 762-770.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Updated Criteria for Approval oral terbinafine section. Revised age criteria to reflect Prescribing Information recommendations. Revised approval duration to reflect Prescribing Information guidelines. Added specific population exclusions in Special Instructions. Added pediatric considerations consistent with Prescribing Information in Special Instructions. Restrict the concomitant use of ciclopirox topical solution and systemic agents for onychomycosis in Special Instructions. Updated reference section to reflect current literature search.	02.13	02.13
Updated reference section to reflect current literature search.	02.14	02.14
Updated reference section to reflect current literature search.	02.15	02.15
Converted into new policy template and added reference number;	11.15	02.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Modified approval criteria by adding patient is immunocompetent to conform with FDA labeling, additional testing options (fungal culture or PAS stain) to confirm diagnosis; intolerance to oral terbinafine; Modified approval criteria by removing: a) infection associated with pain as this is a subjective measure b) patient has concomitant diagnosis of diabetes mellitus or peripheral vascular disease c) treatment is part of comprehensive management program; d) use as monotherapy as it would be difficult to enforce Revised continued approval to reflect Prescribing information recommendations; Updated reference section to reflect current literature search.		
Converted to new integrated template. Combined requirements for diagnosis of onychomycosis and documentation of T. rubrum infection confirmed by testing into one criterion. Modified trial/failure requirement to: 1) require terbinafine be trialed at maximum indicated dose of 250 mg/day and 2) include option for clinically significant adverse effects. On re-auth, added that member must be responding positively to therapy. Added workflow document. Updated references.	11.16	02.17
1Q18 annual review: - Converted to new template. Removed laboratory testing related to confirmation of diagnosis and requirement that member is immunocompetent; modified dosing requirement of terbinafine 250 mg/day to “at up to maximally indicated doses” and specified a time frame of trial within the past 12 months. - Re-auth: removed requirement that member has not used ciclopirox daily ≥48 weeks as this would be difficult to verify objectively; modified approval duration from “up to 48 weeks total” to 48 weeks. - References reviewed and updated.	10.31.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.