Clinical Policy: Ciclopirox (Penlac)

Reference Number: CP.PMN.24
Effective Date: 09.01.07
Last Review Date: 02.22
Line of Business: Commercial, HIM, Medicaid

Revision Log

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.

Limitation(s) 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 (such as office chart notes, lab results or other clinical information) 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. If request is for brand Penlac, member must use generic ciclopirox 8% topical solution, unless contraindicated or clinically significant adverse effects are experienced;
4. If age ≥ 18 years, failure of a 12-week trial of oral terbinafine (for toenails) or a 6-week trial of oral terbinafine (for fingernails), at up to maximally indicated doses within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 6.6 mL (1 bottle) per claim.

Approval duration: 48 weeks

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Member has not received more than 48 weeks of treatment with ciclopirox 8% topical solution;
4. If request is for a dose increase, new dose does not exceed 6.6 mL (1 bottle) per claim.

Approval duration: up to 48 weeks of total treatment

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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 QD for 6 weeks Toenail onychomycosis: 250 mg PO QD 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.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to any of its components
- Boxed warning(s): none reported

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 (6.6 mL bottle): 8%

VII. References

1. Penlac Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2016. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9793245c-c3e0-4351-a2ab-b54b46aecb43. Accessed September 27, 2021.
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.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed September 27, 2021.
4. Lamisil Tablets Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020539s033lbl.pdf. Accessed September 27, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
1Q 2019 annual review: added quantity limit per claim; references reviewed and updated.	09.27.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.29.19	02.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: added Commercial and HIM lines of business; added requirement for use of generic Penlac; clarified redirection applies to age 18 or older similar to Jublia and Kerydin; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.17.20	02.21
1Q 2022 annual review: modified medical justification language to member must use language per template and clarified this applies to brand Penlac requests; for continued therapy added criteria to ensure member has not received more than 48 weeks of treatment; modified approval duration to allow up to 48 weeks of total treatment per prescribing information; references reviewed and updated.	09.27.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.20.22	

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.