



Penlac[®]/CNL8/ciclopirox solution Prior Authorization Criteria

Brand	Generic	Dosage Form
Penlac [®]	ciclopirox	8% topical solution*
CNL8 [™]	ciclopirox	Kit with 8% topical solution and miconazole emulsion 2%

* available as a generic and included in the program

PROGRAM OBJECTIVES

The intent of the prior authorization (PA) criteria for Penlac/CNL8/ciclopirox Nail Lacquer is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical trials and to discourage cosmetic utilization. The PA defines appropriate use as confirmed fungal nail infections that are considered medically necessary to treat (patient has comorbid condition such as diabetes, peripheral vascular insufficiency, immune deficiency, secondary bacterial skin condition, or pain limiting normal activity) and cannot be treated with an oral antifungal agent.

PROGRAM FUNCTIONALITY

Electronic Edits

The overall process for a prior authorization will not allow the targeted drugs to adjudicate through the claims system. When a patient requests a targeted drug listed in Table 1 below, the system will reject the claim with the message indicating that prior authorization is necessary. The Prior Authorization (PA) Criteria for Approval would then be applied to requests submitted by the patient's practitioner for evaluation.

Table 1: Targeted Agents for Penlac/ciclopirox Prior Authorization

Agent	GPI (multisource code)
Penlac (ciclopirox)^a	
topical solution 8%	90150030002020 (M, N, O, or Y)
topical solution 8% and Vitamin E 5% topical, kit	90150030506420 (M, N, O, or Y)
CNL8 (ciclopirox with miconazole emulsion)	
topical solution 8% and miconazole emulsion 2%, kit	90159902736420 (M, N, O, or Y)

^a generic available and included in the program

Prior Authorization (PA) Criteria for Approval

No claims for Penlac/CNL8/ciclopirox will be automatically paid at the point of sale. The Prior Authorization (PA) Criteria for Approval provide the manual review process for all claims for targeted agents in this PA program.

Appropriate candidates for therapy must have the diagnosis of onychomycosis that requires treatment, i.e. the patient has comorbid condition such as diabetes, peripheral vascular insufficiency, immune deficiency, secondary bacterial skin condition, or pain limiting normal activity. Use of Penlac/CNL8/ciclopirox solution for nail infection will be considered if fungal infection of the nail(s) is confirmed, oral treatment is contraindicated or declined by the patient, or oral therapy has failed. Treatment must include nail care including removal of the unattached affected nail by an appropriate health professional as recommended in product labeling.¹ Approvals for the use of Penlac/CNL8/ciclopirox will be given for twelve months for both initial and renewal therapy.

Penlac/CNL8/ciclopirox

Initial and Renewal Evaluation

1. Does the patient have a diagnosis of onychomycosis AND one of the following conditions?
 - a. Diabetes mellitus
 - b. Peripheral vascular insufficiency
 - c. Immune deficiency due to medical condition or treatment (e.g. cancer chemotherapy, HIV/AIDS, anti-rejection therapy post organ transplant)
 - d. Pain limiting normal activity
 - e. Secondary bacterial infection in the surrounding skin or systemic dermatosis with impaired skin integrityIf yes, continue to 2. If no, deny.

2. Has the fungal nail infection been confirmed by laboratory testing (e.g., KOH preparation, fungal culture, or nail biopsy)?
If yes, continue to 3. If no, deny.

3. Does the patient have a contraindication to oral agents or has the patient declined oral therapy, or failed treatment with an oral agent?
If yes, continue to 4. If no, deny.

4. Will treatment with Penlac/CNL8/ciclopirox solution include removal of the unattached, infected nail(s) by an appropriate health care professional?
If yes, approve for 12 months. If no, deny.

CLINICAL RATIONALE

Penlac Nail Lacquer and CNL8 Nail kit are approved for the treatment of mild to moderate onychomycosis of fingernails and toenails when the lunula of the nail is not involved and is intended to be a component of a comprehensive management program.¹ A comprehensive management program includes periodic removal of the unattached infected nail by a health care professional with special competence in the diagnosis and treatment of nail disorders.¹ Mild to moderate onychomycosis is defined in the clinical trial data for Penlac and CNL8 as 20% to 65% involvement of the affected nail plate.^{1,5}

The PA criteria for Penlac/CNL8/ciclopirox solution allows for the treatment of onychomycosis when treatment is not solely for cosmetic reasons. Onychomycosis typically causes no symptoms other than an undesirable appearance of the nail. Guidelines recommend consideration of treatment if walking is uncomfortable, abnormal looking nails are causing significant psychological distress, or if the patient has diabetes, vascular disease, or a connective tissue disorder. Treatment may be necessary if the nail infection is the source of a fungal skin infection or if the person is, or may become, severely immunocompromised.²

Verification of infection is required for approval. Onychomycosis can be difficult to distinguish from other causes of nail dystrophy and because of slow nail growth (six months for fingernails and twelve months for toenails) evidence of treatment failure may not be apparent for several months or more.² If the diagnosis is not confirmed and improvement does not occur, it is impossible to ascertain if treatment failure has occurred or if the initial diagnosis was incorrect. Guidelines on the treatment of fungal and candidal infections of the nail recommend laboratory confirmation of the diagnosis before initiation of treatment.^{2,3}

When topical therapy is used, combining use with vigorous debridement (filing the upper surface of the nail, which diminishes the amount of infected nail to treat) may increase the likelihood of successful therapy.³ Penlac and CNL8 labeling recommends removal of the unattached, infected nails as frequently as monthly, by a health care professional who has experience in the diagnosis and treatment of nail disorders.^{1,5}

Oral treatment is considered more effective than topical treatment for most individuals.^{2,3} Topical treatment may be appropriate when oral treatment is contraindicated or declined.³ There is a possible association of serious cardiac adverse events with the administration of the oral agent, itraconazole, and hepatic adverse events with the administration of both itraconazole and terbinafine.⁴ Combination therapy with an oral and topical agent is not currently recommended due to insufficient evidence of benefit.^{2,3} Some treating physicians may consider combination therapy if nails are severely infected or monotherapy has failed.² The PA criteria for Penlac will not address combination therapy.

FDA APPROVED INDICATIONS^{1,5}

Penlac Nail Lacquer (ciclopirox) Topical Solution, 8%, and CNL8 Nail Kit (topical solution 8%) as a component of a comprehensive management program, are indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to *Trichophyton rubrum*. The comprehensive management program includes removal of the unattached, infected nails as frequently as monthly, by a health care professional who has special competence in the diagnosis and treatment of nail disorders, including minor nail procedures.

- 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 Nail Lacquer and CNL8 Nail Kit should be used only under medical supervision as described above.
- The effectiveness and safety of Penlac Nail Lacquer and CNL8 Nail Kit in the following populations has not been studied. The clinical trials with use of Penlac Nail Lacquer excluded patients who: were pregnant or nursing, planned to become pregnant, had a history of immunosuppression (e.g., extensive, persistent, or unusual distribution of dermatomycosis, 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 Nail Lacquer and CNL8 Nail Kit daily for greater than 48 weeks have not been established.

REFERENCES

1. Penlac Nail Lacquer (ciclopirox) Topical Solution, 8% prescribing information. Dermik Laboratories. July 2006.
2. CKS Fungal Nail Infection May 2009. Available at: http://www.cks.nhs.uk/print_preview?pageid=370861001&pagepath=/fungal_nail_infection/view_whole_topic&rootcontainerelement=topicreview&viewtype=full. Accessed September 1, 2009.
3. de Becker D. Fungal nail disease. *N Engl J Med*. 2009;360:2108-2116.
4. FDA Public Health Advisory: The safety of Sporanox[®] capsules and Lamisil[®] tablets for the treatment of onychomycosis. Available at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm172622.htm>. Accessed September, 2009.
5. CNL8 Nail Kit/Nail Lacquer (ciclopirox, miconazole). JSJ Pharmaceuticals, Inc. December 2007.

Document History

Original Prime Standard Approved by UMC 08/2005
Annual Review with changes approved by External UM Committee 08/09/2006
Annual Review with changes approved by External UM Committee 11/2007
Initial Client Review Client-Specific criteria approved by HCSC Corporate Clinical Committee 09/2008
Annual Review without changes reviewed and approved by Prime National P&T Committee: UM Review 11/2008
Annual Review with changes approved by P&T UM Committee 11/2009
Client Specific Annual Review Client Specific criteria approved by HCSC Corporate Clinical Committee 01/2010
Administrative Addition, CNL8 Nail Kit as target, 04/2010