PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

(ciclopirox topical solution 8%)

PENLAC NAIL LACQUER
(ciclopirox topical solution 8%)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 289-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Penlac, Ciclopirox nail lacquer

Ciclopirox topical solution, 8%, (Nail Lacquer) as a component of a comprehensive management program, is 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.
- Ciclopirox topical solution, 8%, should be used only under medical supervision as described above.
- The effectiveness and safety of Ciclopirox topical solution, 8%, in the following populations has not been studied. The clinical trials with use of Ciclopirox topical solution, 8%, 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 Ciclopirox topical solution, 8%, daily for greater than 48 weeks have not been established.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has onychomycosis of the nail due to dermatophytes

AND

- The patient's diagnosis has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)

AND

- The patient has experienced an inadequate treatment response to an oral antifungal therapy (e.g., terbinafine, itraconazole)

OR

- The patient has experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole)

OR

- The patient has a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole)

AND

- The requested drug is not being used in a footbath

AND

- If additional quantities are required, multiple nails are being treated

Quantity Limits Apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Ciclopirox topical solution, 8%, as a component of a comprehensive management program, is indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to *Trichophyton rubrum*.[1-4]

Onychomycosis may be diagnosed by the presence of fungi by culture, microscopy (Potassium hydroxide [KOH] stain), or histological examination of the nail plate.[6] Microscopy is a commonly used method because it is inexpensive and easy to perform; nail clippings or scrapings are placed in a drop of KOH and examined under a microscope for the presence of fungal elements.[7]

Per the CDC, oral antifungal therapy (terbinafine) is considered first line treatment for confirmed onychomycosis.[7] According to the Cochrane review, medication taken orally appears to cure the condition more quickly and effectively than topical treatment; there was high-quality evidence that oral azole (itraconazole) and terbinafine treatments were more effective for achieving mycological cure and clinical cure for onychomycosis compared to placebo, and when compared directly, terbinafine was probably more effective than azoles and likely not associated with excess adverse events (griseofulvin was associated with more adverse reactions than azoles and terbinafine).[6] Even though oral treatment is limited by drug interactions and risk of acute liver injury, topical lacquer treatments have negligible efficacy and low success rates due to the nail's physical properties.[5,6] Ciclopirox lacquer has a complete cure rate of 5.5% to 8.5%, and mycologic cure rates of 34%; while oral itraconazole and terbinafine report complete cure rates of 14% and 38%, and mycologic cure rates of 54% and 70%, respectively.[5]

The safety and efficacy of using Ciclopirox topical solution 8% daily for greater than 48 weeks have not been established.[1]

The prior authorization criteria do not approve ciclopirox topical solution 8% for use in a footbath, as this is not an FDA-approved use. Ciclopirox Topical Solution, 8%, is not for ophthalmic, oral, or intravaginal use. It is for use on nails and immediately adjacent skin only.[1,2]

Ciclopirox topical solution 8% is available as a solution supplied in 6.6 mL bottles.[1,2] Ciclopirox topical solution 8% is to be applied to all affected nails once daily (preferably before bedtime). The lacquer should be applied evenly over the entire nail and, if possible, the underside of the nail and the skin beneath it. Apply the ciclopirox topical solution 8% over the previous coat. Once a week, remove the ciclopirox topical solution 8% from the nail with rubbing alcohol and remove as much of the damaged nail as possible with scissors, nail clippers, or nail files.[1,2]

Based on the dosing of this product, there is no standard quantity used per nail treated. Another topical nail antifungal product, Jublia (efinaconazole), uses 1 drop per regular toenail and 2 drops per big toenail per application, which translates to approximately 4 mL needed per month to treat a big toenail and one smaller toenail.[8,9] Based on dosing of other topical nail antifungal products such as Jublia, the 6.6 mL bottle should be sufficient to treat one big toenail and another toenail or fingernail. If PA criteria are met, the quantity for approval will be one bottle (6.6 mL) per month. If additional quantities are needed, additional criteria will apply. The PA will allow additional quantities if the patient is treating multiple nails. The PA will allow a quantity that should allow treatment of all nails, 4 bottles (or 26.4 mL).

REFERENCES

1. Ciclodan Ciclopirox Solution [package insert]. Fairfield, NJ: Medimetriks Pharmaceutical, Inc.; October 2019.
2. Penlac Nail Lacquer [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2016.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed August 2021.
4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed August 2021.

5. Elewski BE, Rich,P, Pollak R, et al. Efinaconazole 10% solution in the treatment of toenail onychomycosis: Two phase III multicenter randomized, double-blind studies. *J Am Acad Dermatol.* 2013;68:600-8.
6. Kreijkamp-Kaspers S, Hawke K, Guo L, et al. Oral antifungal medication for toenail onychomycosis. Cochrane Database of Systematic Reviews 2017, Issue 7. Art. No.: CD010031. Accessed August 2021.
7. Centers for Disease Control (CDC) and Prevention. Fungal Nail infections. https://www.cdc.gov/fungal/nail-infections.html. Accessed August 2021.
8. Jublia [package insert]. Bridgewater, NJ: Bausch Health US LLC; July 2020.
9. Lipner SR, Scher RK. Efinaconazole in the treatment of onychomycosis. *Infect Drug Resist*. 2015;8:163–172.

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CRITERIA FOR APPROVAL

1	Does the patient have onychomycosis of the nail due to dermatophytes? [If no, then no further questions.]	Yes	No
2	Has the patient's diagnosis been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)? [If no, then no further questions.]	Yes	No
3	Has the patient experienced an inadequate treatment response to an oral antifungal therapy (e.g., terbinafine, itraconazole)? [If yes, then skip to question 6.]	Yes	No
4	Has the patient experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole)? [If yes, then skip to question 6.]	Yes	No
5	Does the patient have a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole)? [If no, then no further questions.]	Yes	No
6	Is the requested drug being used in a footbath? [If yes, then no further questions.]	Yes	No
7	Does the patient require MORE than the plan allowance of 6.6 mL (one bottle) per month? [Note: If higher quantities are needed, additional questions are required.] [If no, then no further questions.]	Yes	No
8	Are multiple nails being treated? [If no, then no further questions.] [RPh Note: If no, then deny and enter a partial approval for 6.6 mL / 21 days or 19.8 mL / 63 days.]	Yes	No

9	Does the patient require MORE than the plan allowance of 26.4 mL (four bottles) per month? RPh Note: If yes, then deny and enter a partial approval for 26.4 mL / 21 days or 79.2 mL / 63 days.]	Yes	No

Mapping Instructions				
	Yes	**No**	**DENIAL REASONS (Non-Medicaid, Non-Medicare Part D)**	**DENIAL REASONS (Medicaid)**
1.	Go to 2	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member is using the requested medication for onychomycosis of the nail due to dermatophytes. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you are not requesting the medication for onychomycosis of the nail due to dermatophytes. [Short Description: No approvable diagnosis]	You do not meet the requirements of your plan. Your plan covers this drug when you have a specific fungal infection of the nail(s). Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member is using the requested medication for onychomycosis due to dermatophytes that has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide preparation, fungal culture, or nail biopsy). Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you are not requesting the medication	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You have a specific fungal infection of the nail(s) - You had a test to confirm your toenail fungal infection Your request has been denied based on the information we have. [Short Description: No confirmation of diagnosis]

			for onychomycosis due to dermatophytes that has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide preparation, fungal culture, or nail biopsy). [Short Description: No confirmation of diagnosis]	
3.	Go to 6	Go to 4		
4.	Go to 6	Go to 5		
5.	Go to 6	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member has experienced an inadequate treatment response, intolerance, or a contraindication to an oral antifungal therapy (e.g., terbinafine, itraconazole). Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you have not experienced an inadequate treatment response, intolerance, or a contraindication to an oral antifungal therapy. [Short Description: No trial of oral antifungal]	You do not meet the requirements of your plan. Your plan covers this drug when you have tried an oral antifungal medicine first and it did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to oral antifungals]
6.	Deny	Go to 7	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member is not using this drug in a footbath. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you are using this drug in a footbath. [Short Description: Used in footbath]	You do not meet the requirements of your plan. Your plan covers this drug when it is not being used in a footbath. Your request has been denied based on the information we have. [Short Description: Used in footbath]
7.	Go to 8	Approve, 12 months, 6.6 mL / 21		

		days* or 19.8 mL / 63 days*		
8.	Go to 9	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that additional quantities of this medication may be approved when the member is using this drug to treat multiple nails. Current plan approved criteria cover up to 6.6 mL per month of the requested drug and strength. You have been approved for the quantity that your plan covers for a duration of 12 months. Based on the policy and the information we have, the request for additional quantities is denied. The request was denied because the information provided to us indicates that you are not using this drug to treat multiple nails. [Short Description: Not enough area affected]	You do not meet the requirements of your plan. Your plan covers additional quantities of this drug when multiple nails are being treated. Current plan approved criteria cover up to 6.6 mL per month of the requested drug and strength. You have been approved for the quantity that your plan covers for a duration of 12 months. Your request for additional quantities has been denied based on the information we have. [Short Description: Not enough area affected]
9.	Deny	Approve, 12 months, 26.4 mL / 21 days* or 79.2 mL / 63 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 26.4 mL per month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 26.4 mL per month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.*