| Reference number(s) |
| --- |
| 289-C |

# Initial Prior Authorization with Quantity Limit
# Ciclopirox Topical Solution 8 Percent

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| ciclopirox topical solution 8% (brand unavailable) | ciclopirox topical solution 8% |

## Indications

### FDA-approved Indications

#### Ciclopirox Nail Lacquer

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. 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

## Onychomycosis

Authorization may be granted for the requested drug when the patient has onychomycosis of the nail due to dermatophytes when ALL of the following criteria are met:

- The patient's diagnosis has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy).
- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to an oral antifungal therapy (e.g., terbinafine, itraconazole).
  - The patient has experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole).
  - The patient has a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole).
- The requested drug is NOT being used in a footbath.
- If additional quantities are required, multiple nails are being treated.

# Quantity Limits Apply

Treatment of a single nail: 6.6 mL per 21 days or 19.8 mL per 63 days

Treatment of multiple nails: 26.4 mL per 21 days or 79.2 mL per 63 days

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.

| Reference number(s) |
| --- |
| 289-C |

# Duration of Approval (DOA)

- 289-C: DOA: 12 months

# References


1. Ciclodan Ciclopirox Solution [package insert]. Fairfield, NJ: Medimetriks Pharmaceutical, Inc.; October 2019.
2. Ciclopirox solution [package insert]. Allegan, MI: Padagis; March 2022.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed September 10, 2024.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/10/2024).
5. Frazier WT, Santiago-Delgado ZM, Stupka KC. Onychomycosis: Rapid Evidence Review. American Academy of Family Physicians. 2021;104:359-368.
6. Centers for Disease Control (CDC) and Prevention. Treatment of Ringworm and Fungal Nail infections. Available at: https://www.cdc.gov/ringworm/treatment/index.html. Accessed September 10, 2024.


# Document History

Written by: UM Development (CT)

Date Written: 11/2006

Revised: UM Development (NB) 07/2007, (CT/MS) 07/2008, (SE) 07/2009, (TM) 07/2010, 08/2011, 07/2012, 08/2012; (MS) 08/2013, 12/2013; (CT) 08/2014; (MS) 05/2015; (KM) 05/2016 (removed kits), (SF) 05/2017 (combined questions); (DS) 04/2018 (no clinical changes), (ME) 02/2019 (no clinical changes); (RP) 02/2020 (Removed MDC designation; no clinical changes); (JH/TS) 08/2020 (updated denial reasons); (KC) 12/2020 (added footbath question, quantity limits); (DS) 09/2021 (no clinical changes), (CJC/MRS) 09/2022 (removed brand Penlac); (DRS) 09/2023 (no clinical changes); (OA/DFW) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (MM) 12/2006, (WLF) 07/2008, 07/2009, (KP) 07/2010, (KP) 08/2011, (KP) 07/2012, (LS) 08/2012; (DC) 08/2013; (SS) 12/2013; (LCB) 08/2014; (DC) 05/2015; (ME) 05/2016; (LMS) 05/2017; (CHART) 02/27/2020, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 02/2007; 02/2008; 10/2008, 10/2009, 12/2010, 12/2011, 12/2012, 12/2013, 10/2014, 10/2015, 08/2017, 06/2018, 06/2019, 06/2020, 04/2021, 12/2021, 12/2022, 12/2023, 12/2024

**CRITERIA FOR APPROVAL**

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| 1 | Does the patient have onychomycosis of the nail due to dermatophytes?<br>[If Yes, then go to 2. 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)?<br>[If Yes, then go to 3. 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)?<br>[If Yes, then go to 6. If No, then go to 4.] | Yes | No |
| 4 | Has the patient experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole)?<br>[If Yes, then go to 6. If No, then go to 5.] | Yes | No |
| 5 | Does the patient have a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole)?<br>[If Yes, then go to 6. If No, then no further questions.] | Yes | No |
| 6 | Is the requested drug being used in a footbath?<br>[If Yes, then no further questions. If No, then go to 7.] | 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.]<br>[If Yes, then go to 8. If No, then no further questions.] | Yes | No |
| 8 | Are multiple nails being treated?<br>[If Yes, then go to 9. If No, then no further questions.]<br><br>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?<br>[No further questions]<br><br>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 | | | |
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| | **Yes** | **No** | **DENIAL REASONS** |
| **1.** | Go to 2 | Deny | Your plan only covers this drug when it is used for certain health conditions. Covered use is for a fungal infection on your nail(s). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Diagnosis] |
| **2.** | Go to 3 | Deny | Your plan only covers this drug when you have a fungal diagnostic test. We denied your request because we did not receive your results, or your test result did not show a positive test result. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Lab/test] |
| **3.** | Go to 6 | Go to 4 | |
| **4.** | Go to 6 | Go to 5 | |
| **5.** | Go to 6 | Deny | Your plan only covers this drug if you have tried an oral antifungal therapy (e.g., terbinafine, itraconazole), and it did not work well for you. We have denied your request because: A) You have not tried it, or B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Step therapy] |

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| **6.** | Deny | Go to 7 | Your plan only covers this drug if it is not being used in a footbath. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Footbath Use] |
| **7.** | Go to 8 | [PA approved for 12 months. Approve 6.6 mL / 21 days or 19.8 mL / 63 days]. Approve, 12 Months | |
| **8.** | Go to 9 | Deny | We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (6.6 mL [one bottle] per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Quantity, Post limit criteria not met, Partial denial] |
| **9.** | Deny | [PA approved for 12 | We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for |

 

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| | | months. Approve 26.4 mL / 21 days or 79.2 mL / 63 days]. Approve, 12 Months | this drug up to the amount your plan covers (26.4 mL [four bottles] per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Quantity, Exceeds max limit, Partial denial] |