

STEP THERAPY POLICY

- POLICY:** Topical Antifungals for Onychomycosis Step Therapy Policy
- Ciclodan® 8% Kit (ciclopirox topical solution 8% – Medimetriks)
 - Ciclodan 8% (ciclopirox topical solution 8% - Medimetriks, generic)
 - Ciclopirox 8% treatment kit (generic only)
 - Jublia® (efinaconazole topical solution 10% – Valeant)
 - Kerydin™ (tavaborole topical solution 5% – PharmaDerm/Sandoz, generic)
 - Penlac® (ciclopirox topical solution 8% – Valeant, generic)

REVIEW DATE: 11/30/2022

OVERVIEW

Ciclopirox topical solution 8%, Jublia, and Kerydin are topical antifungals indicated for the **treatment of onychomycosis**.¹⁻⁴ Ciclodan 8% and Penlac (generic) contain the same active ingredient, ciclopirox 8%.^{1,2}

Treatment options include oral and topical antifungals.⁵ Oral antifungals are the gold standard as they are significantly more effective than topical antifungals. However, they may be associated with significant adverse effects (e.g., hepatotoxicity, ventricular dysfunction) and risk of drug-drug interactions. Commonly used topical antifungals include ciclopirox topical solution (Ciclodan, Penlac, generics), Jublia, and tavaborole topical solution (Kerydin, generic). Some patients require both an oral and a topical antifungal for treatment.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: Ciclodan 8% topical solution (branded generic), generic ciclopirox 8% topical solution, generic ciclopirox 8% treatment kit

Step 2: Ciclodan 8% Kit, Jublia, Kerydin, Penlac, generic tavaborole topical solution 5%

CRITERIA

1. If a patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

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REFERENCES

1. Penlac® [prescribing information]. Bridgewater, NJ: Valeant; June 2016.
2. Ciclodan® topical solution [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals; October 2019.
3. Jublia® [prescribing information]. Bridgewater NJ: Bausch Health; Valeant; March 2022.
4. Kerydin™ [prescribing information]. New York, NY: Pfizer; August 2018.
5. Leung AKC, Lam JM, Leong KF, et al. Onychomycosis: an updated review. *Inflamm Allergy Drug Targets*. 2020;14(1):32-45.