

STEP THERAPY POLICY

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

REVIEW DATE: 11/11/2020

OVERVIEW

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

Onychomycosis, a fungal infection of the nail unit, is the most common nail disease; it accounts for at least 50% of all nail diseases.⁵ The overall prevalence of onychomycosis in the general population is approximately 5.5%. Dermatophytes (*Trichophyton mentagrophytes* and *T. rubrum*) cause approximately 90% of toenail and 75% of fingernail onychomycosis. Non-dermatophyte molds and yeasts can also cause onychomycosis.

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, generics). 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 history 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), ciclopirox 8% topical solution, ciclopirox 8% treatment kit

Step 2: Ciclodan 8% Kit, Jublia, Kerydin, Penlac, 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.

REFERENCES

1. Penlac[®] [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2016.
2. Ciclodan[®] Kit [prescribing information]. Available at: <https://www.medimetriks.com/prescription-brands/ciclodan-kit-ciclodan-topical-solution>. Accessed on November 3, 2020.
3. Jublia[®] [prescribing information]. Bridgewater NJ: Bausch Health US LLC; Valeant; July 2020.
4. Kerydin[™] [prescribing information]. New York, NY: Pfizer Labs, Division of Pfizer; January 2015.
5. Leung AKC, Lam JM, Leong KF, et al. Onychomycosis: an updated review. *Inflamm Allergy Drug Targets*. 2020;14(1):32-45.