



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)
 - Ciclopirox topical solution 8% (generic only)
 - Jublia® (efinaconazole topical solution 10% – Valeant)
 - Kerydin™ (tavaborole topical solution 5% – PharmaDerm/Sandoz, generic)

REVIEW DATE: 12/06/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Ciclopirox topical solution 8%, Ciclodan, Jublia, and Kerydin are topical antifungals indicated for the **treatment of onychomycosis**.¹⁻⁴

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, 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.

Topical Antifungals for Onychomycosis product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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, generic tavaborole topical solution 5%

CRITERIA

1. If a patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Ciclopirox topical solution [prescribing information]. Gurnee, IL: Akorn; July 2022
2. Ciclodan® topical solution [prescribing information]. Fairfield, NJ: Medimetriks; October 2019.
3. Jublia® topical solution [prescribing information]. Bridgewater NJ: Bausch Health; Valeant; March 2022.
4. Kerydin™ topical solution [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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/30/2022
Annual Revision	Penlac was removed from Step 2 (obsolete).	12/06/2023

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