MEDICAL MUTUAL®

Drug Policy

Policy:	**Antifungals (Topical) for Onychomycosis** **Preferred Step Therapy Policy**	**Annual Review Date: 12/21/2023** **Last Revised Date: 12/21/2023**
Affected Drugs:	• **Ciclodan 8% Kit** • **Tavaborole topical solution 5%**	

OVERVIEW

Ciclodan 8% Kit, Pedipirox-4 Nail Kit, and Penlac (generics) contain the same active ingredient, ciclopirox topical solution 8%. Ciclopirox topical solution 8% and Kerydin (tavaborole) are topical antifungals indicated for the treatment of onychomycosis. Onychomycosis is a general term that refers to nail infections caused by any fungus, including yeasts and nondermatophyte molds. While onychomycosis can affect both the toenails and the fingernails, it is approximately 4- to 25-times more widespread in toenails than in fingernails. Toenail onychomycosis is most commonly caused by dermatophytes, namely *Trichophyton rubrum* and *T. mentagrophytes*; these organisms account for up to 90% of all cases. Fingernail onychomycosis is more likely to be caused by yeast (*Candida albicans*). Nondermatophyte molds cause < 10% of cases of toenail onychomycosis and rarely cause fingernail onychomycosis. Accurate diagnosis is very important since the physical changes associated with onychomycosis may also be associated with other conditions (e.g., psoriasis, chronic nail trauma). A microscopy test using potassium hydroxide (KOH) is typically done to confirm infection; a fungal culture may also be used to identify the specific causative organism.

Treatment choice is dependent on several factors, including: infecting organism, clinical presentation, severity of the infection, comorbidities, and concerns about adverse events (AEs) and drug-drug interactions. Oral antifungals (e.g., azoles [itraconazole] and allylamines [terbinafine]) are the gold standard for the treatment of onychomycosis. They have been shown to be significantly more effective than topical antifungals for this condition, but they may be associated with systemic AEs (e.g., hepatotoxicity) and risk of drug-drug interactions. Thus, oral antifungals may not be appropriate for certain patient populations. Topical antifungals, although not as effective, generally do not cause systemic AEs or drug-drug interactions.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of a generic preferred (Step 1) product prior to the use of a non-preferred (Step 2) product. If the step therapy rule is not met for a non-preferred (Step 2) agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 12 months in duration.

Automation: Patients with a history of one preferred drug within the 130-day look-back period are excluded from step therapy.

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

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Non-preferred: Ciclodan 8% Kit, , tavaborole topical solution 5%

CRITERIA

1. If a patient has used one preferred product, then authorization for a non-preferred product may be given.

Initial Approval/ Extended Approval.
A) *Initial Approval:*1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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