

Clinical Policy: Topical Agents: Anti-Fungals

Reference Number: OH.PHAR.PPA.90

Effective Date: 01/01/2020

Last Review Date:

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CICLOPIROX cream, gel, topical suspension, shampoo (generic of Loprox®)	CICLOPIROX kit (generic of CNL® Nail lacquer kit)
CICLOPIROX solution (generic of Penlac®)	ERTACZO® (sertaconazole)
CLOTRIMAZOLE (generic of Lotrimin®)	EXELDERM® (sulconazole)
CLOTRIMAZOLE/BETAMETHASONE (generic of Lotrisone®)	JUBLIA® solution (efinaconazole)
ECONAZOLE (generic of Spectazole®)	KERYDIN® solution (tavaborole)
KETOCONAZOLE cream & shampoo (generic of Kuric®, Nizoral®)	KETOCONAZOLE foam (generic of Extina®)
MICONAZOLE	LUZU® (luliconazole)
NYSTATIN	MENTAX® (butenafine)
NYSTATIN/TRIAMCINOLONE	NAFTIFINE CREAM
TERBINAFINE (generic of Lamisil®)	NAFTIN® GEL (naftifine)
TOLNAFTATE (generic of Tinactin®)	OXICONAZOLE (generic of OXISTAT®)
	PEDIADERM AF® cream (nystatin)
	VUSION® ointment (miconazole/zinc)

FDA approved indication(s)

Ciclopirox is indicated for:

- Topical treatment of mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to *Trichophyton rubrum* in immunocompetent patients (Penlac®, Ciclodan Nail Lacquer®)
- Topical treatment of seborrheic dermatitis of the scalp (Loprox®)
- Topical treatment of tinea corporis, tinea cruris, or tinea pedis (*Epidermophyton floccosum*; *Microsporum canis*; *Trichophyton mentagrophytes*; *Trichophyton rubrum*); tinea versicolor (*Malassezia furfur*); or cutaneous candidiasis due to *Candida albicans* (Loprox®)

Clotrimazole is indicated for:

- Treatment of cutaneous candidiasis
- Treatment of tinea corporis, tinea cruris, tinea pedis, and tinea versicolor

Clotrimazole/betamethasone is indicated for:

- Treatment of tinea corporis, tinea cruris, and tinea pedis infections caused by *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, or *Trichophyton rubrum*
- Secondary treatment of topical candidiasis with inflammation due to susceptible strains of *Candida sp.* including *Candida albicans*

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Econazole is indicated for:

- Treatment of tinea cruris, tinea corporis, tinea pedis, or tinea versicolor caused by susceptible fungi
- Treatment of cutaneous candidiasis

Sertaconazole is indicated for:

- Topical treatment of interdigital tinea pedis in immunocompetent patients

Sulconazole is indicated for:

- Treatment of tinea corporis, tinea cruris, tinea pedis, or tinea versicolor
- Treatment of cutaneous candidiasis

Ketoconazole is indicated for:

- Treatment of mucocutaneous candidiasis
- Treatment of dandruff, to control flaking, scaling, or itching
- Treatment of seborrheic dermatitis
- Treatment of tinea corporis, tinea cruris, tinea pedis, or tinea versicolor

Miconazole is indicated for:

- Treatment of tinea corporis, tinea cruris, tinea pedis, or tinea versicolor
- Treatment of diaper dermatitis complicated by candidiasis

Nystatin is indicated for:

- Treatment of cutaneous and mucocutaneous candidiasis, including candidal diaper dermatitis

Nystatin/triamcinolone is indicated for:

- Short-term (i.e., less than 2 weeks) treatment of inflammatory cutaneous candidiasis caused by *Candida albicans* and other *Candida sp.*

Terbinafine is indicated for:

- Treatment of tinea corporis, tinea cruris, tinea pedis, or tinea versicolor due to *Malassezia furfur*

Tolnaftate is indicated for:

- Treatment of tinea cruris, tinea corporis, tinea manuum, tinea pedis, tinea barbae, and tinea capitis caused by *T. rubrum*, *T. mentagrophytes*, *T. tonsurans*, *M. canis*, *M. audouinii*, and *E. floccosum*; also effective in the treatment of tinea versicolor infections due to *M. furfur*

Efinaconazole is indicated for:

- Treatment of onychomycosis of the toenail(s) caused by *Trichophyton rubrum* and *Trichophyton mentagrophytes*

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Tavaborole is indicated for:

- Treatment of onychomycosis of the toenail(s) caused by *Trichophyton rubrum* and *Trichophyton mentagrophytes*

Luliconazole is indicated for:

- Treatment of interdigital tinea pedis, tinea cruris, and tinea corporis

Butenafine is indicated for:

- Topical treatment of tinea corporis, tinea cruris, interdigital tinea pedis, and tinea versicolor due to susceptible organisms such as *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, *Trichophyton rubrum*, *Trichophyton tonsurans*, or *Malassezia furfur*

Naftifine is indicated for:

- Treatment of tinea cruris, interdigital tinea pedis, and tinea corporis
- Treatment of distal subungual onychomycosis or white superficial onychomycosis (tinea unguium) due to susceptible dermatophytes (i.e., *Trichophyton rubrum*) or *Candida* species in patients unable to tolerate oral antifungal therapy

Oxiconazole is indicated for:

- Topical treatment of the following dermal infections: tinea corporis, tinea cruris, and tinea pedis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, or *Trichophyton rubrum*
- Topical treatment of tinea versicolor due to *Malassezia furfur*

Miconazole/zinc is indicated for:

- Adjuvant treatment of diaper dermatitis complicated by documented candidiasis in immunocompetent pediatric patients

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation[®] that Topical Agents: Anti-Fungals are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Failure of two medications not requiring prior approval, each for ≥ 14 days, unless member meets one of the following (a, b, c, or d):
 - a. Allergy to at least two medications not requiring prior approval;
 - b. Contraindication to all medications not requiring prior approval;

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- c. History of unacceptable/toxic side effects to at least two medications not requiring prior approval;
- d. Infection is caused or presumed to be caused by an organism resistant to medications not requiring prior approval.

Approval Duration: 180 days

II. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy - CP.PMN.53 or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

- Dosing varies by drug product. See FDA approved dosing and administration.

Appendix C: Contraindications/Boxed Warnings

- Refer to Clinical Pharmacology or other appropriate clinical resource.

IV. Dosage and Administration

- A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

- A. Varies by drug product. Please refer to Clinical Pharmacology or other appropriate clinical resource for product availability.

VI. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice

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current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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