

STEP THERAPY CRITERIA

DRUG CLASS	TOPICAL ANTIFUNGAL AGENTS (BRAND PRODUCTS ONLY)
BRAND NAME* (generic)	
	ECOZA (econazole)
	ERTACZO (sertaconazole)
	EXELDERM (sulconazole nitrate)
	LOPROX (ciclopirox shampoo)
	LOTRISONE (clotrimazole/betamethasone)
	LUZU (luliconazole)
	MENTAX (butenafine)
	NAFTIN (naftifine)
	OXISTAT (oxiconazole)
	VUSION (miconazole/zinc oxide/white petrolatum)
	XOLEGEL (ketoconazole)

Status: CVS Caremark Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization **Ref # 1380-D**

* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated

FDA-APPROVED INDICATIONS

Ecoza

Ecoza topical 1% foam is indicated for the treatment of interdigital tinea pedis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum* in patients 12 years of age and older.

Ertaczo

Ertaczo 2% cream is indicated for the topical treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older, caused by: *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*.

Exelderm

Exelderm 1% cream is indicated for the treatment of tinea pedis (athlete's foot), tinea cruris, and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*, and for the treatment of tinea versicolor.

Exelderm 1% solution is indicated for the treatment of tinea cruris and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*; and for the treatment of tinea versicolor.

Effectiveness has not been proven in tinea pedis (athlete's foot). Symptomatic relief usually occurs within a few days after starting Exelderm solution and clinical improvement usually occurs within one week.

Loprox

Loprox 1% shampoo is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults.

Lotrisone

Lotrisone cream is a combination of an azole antifungal and corticosteroid and is indicated for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton Floccosum*, *Trichophyton Mentagrophytes*, and *Trichophyton rubrum* in patients 17 years and older.

Luzu

Luzu cream is indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*.

Mentax

Mentax 1% cream is indicated for the topical treatment of the dermatologic infection, tinea (pityriasis) versicolor due to *M. furfur* (formerly *P. orbiculare*). Butenafine HCl cream was not studied in immunocompromised patients.

Naftin

Naftin 1% gel is indicated for the topical treatment of tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Trichophyton tonsurans*, *Epidermophyton floccosum*.

Naftin 2% cream is an allylamine antifungal indicated for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism *Trichophyton rubrum*.

Naftin 2% gel is an allylamine antifungal indicated for the treatment of interdigital tinea pedis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*.

Oxistat

Oxistat 1% lotion is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, or *Epidermophyton floccosum*.

Oxistat 1% cream is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, or *Epidermophyton floccosum*. Oxistat 1% cream is also indicated for the topical treatment of tinea (pityriasis) versicolor due to *Malassezia furfur*.

Vusion

Vusion ointment is indicated for the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast), in immunocompetent pediatric patients 4 weeks and older. A positive fungal culture for *Candida albicans* is not adequate evidence of candidal infection since colonization with *C. albicans* can result in a positive culture. The presence of candidal infection should be established by microscopic evaluation prior to initiating treatment.

Vusion should be used as part of a treatment regimen that includes measures directed at the underlying diaper dermatitis, including gentle cleansing of the diaper area and frequent diaper changes.

Vusion should not be used as a substitute for frequent diaper changes. Vusion should not be used to prevent the occurrence of diaper dermatitis, since preventative use may result in the development of drug resistance.

Limitations of Use

The safety and efficacy of Vusion have not been demonstrated in immunocompromised patients, or in infants less than 4 weeks of age (premature or term).

The safety and efficacy of Vusion have not been evaluated in incontinent adult patients. Vusion should not be used to prevent the occurrence of diaper dermatitis, such as in an adult institutional setting, since preventative use may result in the development of drug resistance.

Xolegel

Xolegel is indicated for the topical treatment of seborrheic dermatitis in immunocompetent adults and children 12 years of age and older.

Safety and efficacy of Xolegel for treatment of fungal infections have not been established.

INITIAL STEP THERAPY

If the patient has filled a prescription for at least a 7 day supply of a generic topical antifungal agent within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic topical antifungal agent (e.g., ciclopirox, clotrimazole, ketoconazole, naftifine, oxiconazole)

RATIONALE

If the patient has filled a prescription for at least a 7 day supply of a generic topical antifungal agent within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient does not meet the initial step therapy criteria, then prior authorization is required.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines.

Ecoza topical 1% foam is indicated for the treatment of interdigital tinea pedis in patients 12 years of age and older. Ertaczo 2% cream is indicated for the topical treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older. Exelderm 1% cream is indicated for the treatment of tinea pedis (athlete's foot), tinea cruris, and tinea corporis and for the treatment of tinea versicolor. Exelderm 1% solution is indicated for the treatment of tinea cruris and

tinea corporis and for the treatment of tinea versicolor. Loprox 1% shampoo is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults. Lotrisone cream is indicated for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis. Luzu cream is indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis. Mentax 1% cream is indicated for the topical treatment of the dermatologic infection, tinea (pityriasis) versicolor. Butenafine HCl cream was not studied in immunocompromised patients. Naftin 1% gel is indicated for the topical treatment of tinea pedis, tinea cruris, and tinea corporis. Naftin 2% cream is indicated for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis. Naftin 2% gel is indicated for the treatment of interdigital tinea pedis. Oxistat 1% cream and lotion are indicated for the topical treatment of tinea pedis, tinea cruris, and tinea corporis. Oxistat 1% cream is also indicated for the topical treatment of tinea (pityriasis) versicolor. Vusion ointment is indicated for the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast), in immunocompetent pediatric patients 4 weeks and older. Xolegel is indicated for the topical treatment of seborrheic dermatitis in immunocompetent adults and children 12 years of age and older.

Treatment for seborrheic dermatitis includes over-the-counter shampoos and topical antifungals, calcineurin inhibitors, and corticosteroids. For long-term control, antifungal shampoos containing ketoconazole 2% or ciclopirox 1% (Loprox) can be used daily or at least two or three times per week for several weeks.^{15,18} If a patient with seborrheic dermatitis shows no clinical improvement after 4 weeks of treatment, the diagnosis should be reviewed.¹⁵

Tinea corporis and tinea cruris generally can be effectively treated using a topical antifungal. Many clinicians consider topical imidazole derivative azole antifungals (e.g., clotrimazole, ketoconazole, oxiconazole) or topical allylamine antifungals (e.g., naftifine) the drugs of first choice for the topical treatment of tinea corporis or tinea cruris, although other antifungals agents (e.g., ciclopirox olamine) also can be effective in the treatment of these infections. Uncomplicated interdigital and vesiculobullous forms of tinea pedis generally can be treated effectively using topical therapy with an imidazole derivative azole antifungal (e.g., clotrimazole, ketoconazole, oxiconazole), an allylamine antifungal (e.g., naftifine), or other topical antifungal agents such as ciclopirox olamine. Like other imidazole derivatives (e.g., clotrimazole, ketoconazole) and ciclopirox olamine, oxiconazole has an advantage over some other topical antifungal agents (e.g., nystatin, tolnaftate) in the treatment of mixed infections or for empiric treatment pending identification of the causative organism, since the drug is active against both dermatophytes and *Candida*.^{15,17} If clinical improvement does not occur after 4 weeks of treatment with topical treatment, the diagnosis should be reevaluated.¹⁵

Pityriasis (tinea) versicolor generally can be treated topically with an imidazole derivative azole antifungal (e.g., clotrimazole, ketoconazole, oxiconazole), ciclopirox olamine.¹⁵ Pityriasis (tinea) versicolor should be treated for 2 weeks to reduce the possibility of recurrence. If clinical improvement does not occur after the recommended treatment period, the diagnosis should be reevaluated.¹⁵

Diaper dermatitis that has not responded to standard treatments may warrant the use of topical corticosteroids or further evaluation for other common causes of irritation in this area, such as allergic contact dermatitis and fungal or bacterial infection. Useful topical antifungal agents for the diaper area in cases of suspected or confirmed candidal dermatitis include clotrimazole, ketoconazole, miconazole, econazole, tioconazole, and ciclopirox.¹⁹ If symptoms do not improve by day 7, the diagnosis should be reevaluated.¹³

REFERENCES

1. Ecoza [package insert]. Florham Park, NJ: Exeltis USA Dermatology LLC. July 2016.
2. Ertaczo [package insert]. San Antonio, TX: DPT Laboratories, Ltd., November 2017.
3. Exelderm 1% cream [package insert]. Cranbury, NJ: Sun Pharmaceuticals, Inc. December 2017.
4. Exelderm 1% solution [package insert]. Cranbury, NJ: Sun Pharmaceuticals, Inc. December 2017.
5. Loprox 1% shampoo [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. June 2017.
6. Lotrisone [package insert]. Whitehouse Station, NJ: Merck & Co., Inc. July 2017.
7. Luzu cream [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2018.
8. Mentax [package insert]. Morgantown, WV: Mylan Pharmaceutical Inc. November 2013.
9. Naftin 1% gel [package insert]. Roswell, GA: Sebela Pharmaceuticals, Inc.; May 2018.
10. Naftin 2% cream [package insert]. Roswell, GA: Sebela Pharmaceuticals, Inc.; April 2018.
11. Naftin 2% gel [package insert]. Roswell, GA: Sebela Pharmaceuticals, Inc.; April 2018.
12. Oxistat 1% cream/lotion [package insert]. Melville, NY: Fougera Pharmaceuticals Inc., LLC; January 2012.

13. Vusion [package insert]. Newtown, PA: Prestium Pharma, Inc. October 2013.
14. Xolegel [package insert]. Exton, PA: Aqua Pharmaceuticals. September 2016.
15. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed June 2018.
16. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed June 2018.
17. Ely JW, Rosenfeld S, Seabury Stone M. Diagnosis and Management of Tinea Infections. *Am Fam Physician*. 2014;90(10):702-710.
18. Clark GW, Pope SM, Jaboori KA. Diagnosis and Treatment of Seborrheic Dermatitis. *Am Fam Physician*. 2015;91(3):185-190.
19. Clunk C, Domingues E, Wiss K. An Update on Diaper Dermatitis. *Clinics in Dermatology*. 2014;32(4):477-487. Available at: <http://dx.doi.org/10.1016/j.clindermatol.2014.02.003>

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CRITERIA FOR APPROVAL		
1	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to a generic topical antifungal agent (e.g., ciclopirox, clotrimazole, ketoconazole, naftifine, oxiconazole)?	Yes No

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 3 months	Deny	<p>You do not meet the requirements of your plan. Your plan covers this drug when you have tried a generic topical antifungal agent (e.g., ciclopirox, clotrimazole, ketoconazole, naftifine, oxiconazole) and it either did not work for you or you cannot use it.</p> <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No inadequate response, intolerance or contraindication to generic topical antifungals]</p>