

STEP THERAPY CRITERIA

DRUG CLASS**TOPICAL ANTIFUNGAL AGENTS
BRAND PRODUCTS ONLY****BRAND NAME*
(generic)****ECOZA****(econazole)****ERTACZO****(sertaconazole)****EXELDERM****(sulconazole nitrate)****EXTINA****(ketoconazole)****LOPROX****(ciclopirox)****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. OTC products are not included unless otherwise stated.

FDA-APPROVED INDICATIONS

Ecoza

Ecoza 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 (sertaconazole nitrate) cream, 2%, 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 (sulconazole nitrate, USP) Cream, 1.0% is an antifungal agent 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 (sulconazole nitrate, USP) Solution, 1.0% is a broad-spectrum antifungal agent 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.

Extina

Extina (ketoconazole) Foam, 2% is indicated for the topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older.

Limitations of Use

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

Loprox

Loprox 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*, *Epidermophyton floccosum*, and *Microsporum canis*; candidiasis (moniliasis) due to *Candida albicans*; and tinea (pityriasis) versicolor due to *Malassezia furfur*.

Loprox (ciclopirox) Shampoo, 1% is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults.

Loprox Topical Suspension is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*; cutaneous candidiasis (moniliasis) due to *Candida albicans*; and tinea (pityriasis) versicolor due to *Malassezia furfur*.

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 (luliconazole) Cream, 1% 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 (butenafine HCl) Cream, 1% 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 Cream 2% is an allylamine antifungal indicated for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism *Trichophyton rubrum*.

Naftin Gel 1% 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 Gel 2% 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 Cream and Lotion are 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 Cream is indicated for the topical treatment of tinea (pityriasis) versicolor due to *Malassezia furfur*. Oxistat Cream may be used in pediatric patients for tinea corporis, tinea cruris, tinea pedis, and tinea (pityriasis) versicolor; however, these indications for which Oxistat Cream has been shown to be effective rarely occur in children below the age of 12.

Vusion

Miconazole nitrate, zinc oxide and white petrolatum 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.

Miconazole nitrate, zinc oxide and white petrolatum ointment 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. Miconazole nitrate, zinc oxide and white petrolatum ointment should not be used as a substitute for frequent diaper changes.

Limitations of Use

The safety and efficacy of miconazole nitrate, zinc oxide and white petrolatum ointment have not been demonstrated in immunocompromised patients, or in infants less than 4 weeks of age (premature or term).

The safety and efficacy of miconazole nitrate, zinc oxide and white petrolatum ointment have not been evaluated in incontinent adult patients. Miconazole nitrate, zinc oxide and white petrolatum ointment 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*

Include Rx and OTC products unless otherwise stated.

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 requested drug will not be used in a footbath

AND

- The patient experienced an inadequate treatment response to a generic topical antifungal agent

OR

- The patient experienced an intolerance to a generic topical antifungal agent

OR

- The patient has a contraindication that would prohibit a trial of a generic topical antifungal agent

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.

Since symptomatic relief and/or clinical improvement usually occurs within a week after starting topical antifungal treatment, the initial step therapy fill is set at 7 day supply.^{18,19} A 120 day look back is used due to the acute nature of fungal infections.

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 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 (sertaconazole nitrate) cream, 2%, 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 (sulconazole nitrate, USP) Cream, 1.0% is an antifungal agent 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 (sulconazole nitrate, USP) Solution, 1.0% is a broad-spectrum antifungal agent 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. Extina (ketoconazole) Foam, 2% is indicated for the topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older. Loprox 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*, *Epidermophyton floccosum*, and *Microsporum canis*; candidiasis (moniliasis) due to *Candida albicans*; and tinea (pityriasis) versicolor due to *Malassezia furfur*. Loprox (ciclopirox) Shampoo, 1% is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults. Loprox Topical Suspension is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*; cutaneous candidiasis (moniliasis) due to *Candida albicans*; and tinea (pityriasis) versicolor due to *Malassezia furfur*. 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 (luliconazole) Cream, 1% 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 (butenafine HCl) Cream, 1% is indicated for the topical treatment of the dermatologic infection, tinea (pityriasis) versicolor due to *M. furfur* (formerly *P. orbiculare*). Naftin Cream 2% is an allylamine antifungal indicated for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism *Trichophyton rubrum*. Naftin Gel 1% 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 Gel 2% is an allylamine antifungal indicated for the treatment of interdigital tinea pedis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*. Nizoral (ketoconazole) 2% Shampoo is indicated for the treatment of tinea (pityriasis) versicolor caused by or presumed to be caused by *Pityrosporum orbiculare* (also known as *Malassezia furfur* or *M. orbiculare*). Oxistat Cream and Lotion are 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 Cream is indicated for the topical treatment of tinea (pityriasis) versicolor due to *Malassezia furfur*. Miconazole nitrate, zinc oxide and white petrolatum 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.¹⁻¹⁷

The approach to treatment depends upon the anatomic location and extent of infection. Most infections can be managed with topical antifungals.¹⁹ There are numerous generic topical antifungal products available in various indications and dosage forms.^{18,19} Meta-analysis of various topical antifungal therapies shows no significant difference in efficacy between antifungal therapies.²⁰ For brand topical antifungals, coverage may be approved if the patient had an inadequate treatment response, intolerance, or has a contraindication to at least one generic topical antifungal drug.

The Post Limit prior authorization criteria do not approve topical antifungals for use in a footbath, as this is not an FDA-approved use.

The therapy duration is typically for acute treatment. The duration of approval will be 3 months to accommodate topical antifungals approved for 6 weeks use, or a re-infection or recurrence.

REFERENCES

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CRITERIA FOR APPROVAL

1	Has the patient experienced an inadequate treatment response to a generic topical antifungal agent? [If yes, then skip to question 4.]	Yes	No
2	Has the patient experienced an intolerance to a generic topical antifungal agent? [If yes, then skip to question 4.]	Yes	No

3	Does the patient have a contraindication that would prohibit a trial of a generic topical antifungal agent? [If no, then further questions.]	Yes	No
4	Is the requested drug being used in a footbath?	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Go to 4	Go to 2	
2.	Go to 4	Go to 3	
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried a generic topical antifungal agent and it either did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance or contraindication to a generic topical antifungal]
4.	Deny	Approve, 3 months	You do not meet the requirements of your plan. Your plan covers this drug when the requested drug is not being used in a footbath. Your request has been denied based on the information we have. [Short Description: No approvable use]