

PRIOR AUTHORIZATION CRITERIA

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

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Antifungal Topical PA Aligned Policy UDR 04-2024.docx

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Ecoza

Ecoza (econazole nitrate) topical foam, 1%, 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 cream, 2%, is indicated for the topical treatment of interdigital tinea pedis in immunocompetent adult and pediatric 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.

*Efficacy for this organism in the organ system was studied in fewer than ten infections.

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*.

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 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**.

*Efficacy for this organism in this organ system was studied in fewer than 10 infections.

Naftin 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 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

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.

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.

COVERAGE CRITERIA

Authorization may be granted for the requested drug when the following criteria is met:

- The requested drug is being used for an FDA-Approved indication.

DURATION OF APPROVAL (DOA)

- 1376-A: DOA: 3 months

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