

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	TOPICAL ANTIFUNGALS
BRAND NAME (generic)	<p>(ciclopirox gel)</p> <p>(clotrimazole cream, solution)</p> <p>(econazole)</p> <p>ECOZA (econazole)</p> <p>ERTACZO (sertaconazole)</p> <p>EXELDERM (sulconazole)</p> <p>EXTINA (ketoconazole)</p> <p>(ketoconazole)</p> <p>LOPROX (ciclopirox)</p> <p>LUZU (luliconazole)</p> <p>MENTAX (butenafine HCl)</p> <p>(naftifine)</p> <p>NAFTIN (naftifine)</p> <p>(nystatin cream, ointment, topical powder)</p> <p>OXISTAT (oxiconazole)</p> <p>VUSION (miconazole-zinc oxide-white petrolatum)</p>

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XOLEGEL (ketoconazole)

Status: CVS Caremark® Criteria

Type: Quantity Limit; Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Butenafine

Mentax (butenafine cream)

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.

Ciclopirox

Loprox (ciclopirox cream)

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*.

Ciclopirox gel

Superficial Dermatophyte Infections

Ciclopirox gel is indicated for the topical treatment of interdigital tinea pedis and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, or *Epidermophyton floccosum*.

Seborrheic Dermatitis

Ciclopirox gel is indicated for the topical treatment of seborrheic dermatitis of the scalp.

Loprox (ciclopirox shampoo)

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

Loprox (ciclopirox suspension/lotion)

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*.

Clotrimazole

Clotrimazole cream

Clotrimazole cream USP is indicated for the topical treatment of candidiasis due to *Candida albicans* and tinea versicolor due to *Malassezia furfur*.

Clotrimazole is also available as a nonprescription item which 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*.

Clotrimazole solution

Prescription Clotrimazole Topical Solution product is indicated for the topical treatment of candidiasis due to *Candida albicans* and tinea versicolor due to *Malassezia furfur*.

This formulation is also available as a nonprescription product which 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*.

Econazole

Econazole cream

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Econazole nitrate cream is indicated for topical application in the treatment of tinea pedis, tinea cruris, and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Trichophyton tonsurans*, *Microsporum canis*, *Microsporum audouinii*, *Microsporum gypseum*, and *Epidermophyton floccosum*, in the treatment of cutaneous candidiasis, and in the treatment of tinea versicolor.

Ecoza (econazole foam)

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.

Ketoconazole

Ketoconazole cream

Ketoconazole Cream, 2% is indicated for the topical treatment of tinea corporis, tinea cruris and tinea pedis caused by *Trichophyton rubrum*, *T. mentagrophytes* and *Epidermophyton floccosum*; in the treatment of tinea (pityriasis) versicolor caused by *Malassezia furfur* (*Pityrosporum orbiculare*); in the treatment of cutaneous candidiasis caused by *Candida spp.* and in the treatment of seborrheic dermatitis.

Extina (ketoconazole foam)

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.

Xolegel (ketoconazole gel)

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

Ketoconazole shampoo

Ketoconazole shampoo, 2%, 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*).

Note: Tinea (pityriasis) versicolor may give rise to hyperpigmented or hypopigmented patches on the trunk which may extend to the neck, arms and upper thighs. Treatment of the infection may not immediately result in normalization of pigment to the affected sites. Normalization of pigment following successful therapy is variable and may take months, depending on individual skin type and incidental sun exposure. Although tinea versicolor is not contagious, it may recur because the organism that causes the disease is part of the normal skin flora.

Luliconazole

Luzu (luliconazole cream)

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*.

Miconazole

Vusion (miconazole-zinc oxide-white petrolatum ointment)

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.

Naftifine

Naftifine cream

Naftifine Hydrochloride Cream USP, 1% is indicated for the topical treatment of tinea pedis, tinea cruris and tinea corporis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*.

Naftifine Hydrochloride Cream, 2% is indicated for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism *Trichophyton rubrum*.

Naftin (naftifine gel)

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**, and *Epidermophyton floccosum**.

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

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*.

Nystatin

Nystatin cream

Nystatin cream, is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

Nystatin ointment

Nystatin Ointment, USP is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

Nystatin topical powder

Nystatin topical powder is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

Oxiconazole

Oxistat (oxiconazole)

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.

Sertaconazole

Ertaczo (sertaconazole cream)

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*.

Sulconazole

Exelderm Cream (sulconazole cream)

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 Solution (sulconazole solution)

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.

Compendial Uses

Seborrheic Dermatitis – Ketoconazole 2% Shampoo^{27,28}

INITIAL QUANTITY LIMIT**

INITIAL LIMIT QUANTITY		
Limits should accumulate across same chemical entity up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.		
PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.		
Drug	1 Month Limit*	3 Month Limit*
BUTENAFINE		
Mentax (butenafine cream)	60 gm / 25 days	Does Not Apply*
CICLOPIROX		
ciclopirox gel	120 gm / 25 days	Does Not Apply*
Loprox Cream (ciclopirox cream)	120 gm / 25 days	Does Not Apply*
Loprox Shampoo (ciclopirox shampoo)	120 mL / 25 days	Does Not Apply*
Loprox Suspension/Lotion (ciclopirox suspension/lotion)	120 mL / 25 days	Does Not Apply*
CLOTRIMAZOLE		
clotrimazole cream	120 gm / 25 days	Does Not Apply*
clotrimazole solution	120 mL / 25 days	Does Not Apply*
ECONAZOLE		
econazole cream	60 gm / 25 days	Does Not Apply*
Ecoza (econazole foam)	70 gm / 25 days	Does Not Apply*
KETOCONAZOLE		
Extina (ketoconazole foam)	100 gm / 25 days	Does Not Apply*
ketoconazole cream	120 gm / 25 days	Does Not Apply*
ketoconazole shampoo	120 mL / 25 days	Does Not Apply*
Xolegel (ketoconazole gel)	45 gm / 25 days	Does Not Apply*
LULICONAZOLE		
Luzu (luliconazole cream)	60 gm / 25 days	Does Not Apply*
MICONAZOLE		
Vusion (miconazole-zinc oxide-white petrolatum ointment)	100 gm / 25 days	Does Not Apply*
NAFTIFINE		
naftifine cream	60 gm / 25 days	Does Not Apply*
Naftin 1% Gel (naftifine 1% gel)	120 gm / 25 days	Does Not Apply*
Naftin 2% Gel (naftifine 2% gel)	60 gm / 25 days	Does Not Apply*
NYSTATIN		

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nystatin cream	120 gm / 25 days	Does Not Apply*
nystatin ointment	120 gm / 25 days	Does Not Apply*
nystatin topical powder	120 gm / 25 days	Does Not Apply*
OXICONAZOLE		
Oxistat Cream (oxiconazole cream)	60 gm / 25 days	Does Not Apply*
Oxistat Lotion (oxiconazole lotion)	60 mL / 25 days	Does Not Apply*
SERTACONAZOLE		
Ertaczo (sertaconazole cream)	60 gm / 25 days	Does Not Apply*
SULCONAZOLE		
Exelderm Cream (sulconazole cream)	60 gm / 25 days	Does Not Apply*
Exelderm Solution (sulconazole solution)	60 mL / 25 days	Does Not Apply*
* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.		
* These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.		

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

Candidiasis/Candida

Authorization may be granted when the requested drug is being prescribed for the treatment of Candidiasis/Candida when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The requested drug is ANY of the following:
 - ciclopirox cream, suspension/lotion (Loprox cream, suspension/lotion)
 - clotrimazole cream, solution
 - econazole cream
 - ketoconazole cream
 - miconazole-zinc oxide-white petrolatum ointment (Vusion)
 - nystatin cream, ointment, powder

Seborrheic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the treatment of Seborrheic Dermatitis when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The requested drug is ANY of the following:
 - ciclopirox gel, ciclopirox shampoo (Loprox shampoo)
 - ketoconazole cream, ketoconazole foam (Extina), ketoconazole gel (Xolegel), ketoconazole shampoo

Tinea Corporis

Authorization may be granted when the requested drug is being prescribed for the treatment of Tinea Corporis when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The requested drug is ANY of the following:
 - ciclopirox cream, ciclopirox gel, suspension/lotion (Loprox cream, suspension/lotion)
 - clotrimazole cream, solution
 - econazole cream
 - ketoconazole cream
 - luliconazole cream (Luzu)

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- o naftifine cream, 1% gel (Naftin 1% gel)
- o oxiconazole cream, lotion (Oxistat)
- o sulconazole cream, solution (Exelderm)

Tinea Cruris

Authorization may be granted when the requested drug is being prescribed for the treatment of Tinea Cruris when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The requested drug is ANY of the following:
 - o ciclopirox cream, suspension/lotion (Loprox cream, suspension/lotion)
 - o clotrimazole cream, solution
 - o econazole cream
 - o ketoconazole cream
 - o luliconazole cream (Luzu)
 - o naftifine cream, 1% gel (Naftin 1% gel)
 - o oxiconazole cream, lotion (Oxistat)
 - o sulconazole cream, solution (Exelderm)

Tinea Pedis

Authorization may be granted when the requested drug is being prescribed for the treatment of Tinea Pedis when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The requested drug is ANY of the following:
 - o ciclopirox cream, ciclopirox gel, suspension/lotion (Loprox cream, suspension/lotion)
 - o clotrimazole cream, solution
 - o econazole cream, econazole foam (Ecoza)
 - o ketoconazole cream
 - o luliconazole cream (Luzu)
 - o naftifine cream, gel (Naftin)
 - o oxiconazole cream, lotion (Oxistat)
 - o sertaconazole cream (Ertaczo)
 - o sulconazole cream (Exelderm cream)

Tinea (Pityriasis) Versicolor

Authorization may be granted when the requested drug is being prescribed for the treatment of Tinea (Pityriasis) Versicolor when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The requested drug is ANY of the following:
 - o butenafine cream (Mentax)
 - o ciclopirox cream, suspension/lotion, (Loprox cream, suspension/lotion)
 - o clotrimazole cream, solution
 - o econazole cream
 - o ketoconazole cream, ketoconazole shampoo
 - o oxiconazole cream (Oxistat cream)
 - o sulconazole cream, solution (Exelderm)

QUANTITY LIMITS APPLY

POST LIMIT QUANTITY		
Drug	1 Month Limit*	3 Month Limit*
econazole foam (Ecoza)	140 gm / 25 days	Does Not Apply*
ketoconazole gel (Xolegel)	90 gm / 25 days	Does Not Apply*
ketoconazole foam (Extina)	200 gm / 25 days	Does Not Apply*
miconazole-zinc-petrolatum ointment (Vusion)		
luliconazole cream (Luzu)	120 gm or mL / 25 days	Does Not Apply*
butenafine cream (Mentax)		
naftifine gel 2% (Naftin 2% gel)		
naftifine cream		

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sertaconazole cream (Ertaczo) oxiconazole cream/lotion (Oxistat) econazole cream sulconazole solution/cream (Exelderm)		
Naftifine gel 1% (Naftin 1% gel) ciclopirox cream/gel/lotion/suspension/shampoo (Loprox) clotrimazole cream/solution ketoconazole cream nystatin cream/ointment/topical powder 100000 ketoconazole shampoo	240 gm / 25 days	Does Not Apply*
<p>* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.</p> <p>* These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.</p>		

DURATION OF APPROVAL (DOA)

- 3172-HJ: DOA: 3 months

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