### STEP THERAPY CRITERIA

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

**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.

**COVERED 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 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. If a patient with seborrheic dermatitis shows no clinical improvement after 4 weeks of treatment, the diagnosis should be reviewed. If a patient with seborrheic dermatitis presents with lesions that are resistant to treatment or if the diagnosis is in doubt, a skin biopsy or the use of a potassium hydroxide (KOH) preparation should be considered. If the causative organism, since the drug is active against both dermatophytes and Candida. If clinical improvement does not occur after 4 weeks of treatment with topical treatment, the diagnosis should be reevaluated.

Pityriasis (tinea) versicolor generally can be treated topically with an imidazole derivative azole antifungal (e.g., clotrimazole, ketoconazole, oxiconazole), ciclopirox olamine. 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.

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, toconazole, and ciclopirox. If symptoms do not improve by day 7, the diagnosis should be reevaluated.

REFERENCES
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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>DENIAL REASONS – DO NOT USE FOR MEDICARE PART D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td>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. Your request has been denied based on the information we have.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[Short Description: No inadequate response, intolerance or contraindication to generic topical antifungals]</td>
</tr>
</tbody>
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