Pharmacy Benefit Coverage Criteria

Effective Date .................................................. 1/1/2020
Next Review Date............................................... 1/1/2021
Coverage Policy Number ................................. P0046

Antifungals, Topical

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

For Employer Group Plans:
Non covered topical antifungals are considered medically necessary when the following criteria are met:

<table>
<thead>
<tr>
<th>Standard Drug List Plan</th>
<th>Value Drug List Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance Drug List Plan</td>
<td>Advantage Drug List Plan</td>
</tr>
<tr>
<td><strong>Ertaczo® cream, 2%</strong></td>
<td><strong>ALL of the following:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Individual is 12 years of age and older</strong></td>
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<tr>
<td></td>
<td><strong>Documented diagnosis of interdigital tinea pedis</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Documented failure/inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: clotrimazole cream, econazole cream, naftifine cream</strong></td>
</tr>
</tbody>
</table>

<p>| <strong>Exelderm® cream, 1.0%</strong> | <strong>ALL of the following:</strong> |
| | <strong>Individual is 18 years of age and older</strong> |
| | <strong>Documented diagnosis of tinea corporis, tinea cruris, tinea pedis, or tinea versicolor</strong> |
| | <strong>Documented failure/inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: ciclopirox cream/lotion, econazole cream, ketoconazole cream, naftifine cream, oxiconazole cream</strong> |</p>
<table>
<thead>
<tr>
<th><strong>Brand Name</strong></th>
<th><strong>Standard Drug List Plan</strong></th>
<th><strong>Value Drug List Plan</strong></th>
</tr>
</thead>
</table>
| **Exelderm® solution, 1.0%**    | **ALL** of the following:  
• Individual is 18 years of age and older  
• Documented diagnosis of tinea corporis, tinea cruris, or tinea versicolor  
• Documented failure/inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: ciclopirox cream/lotion, econazole cream, ketoconazole cream/shampoo, naftifine cream, oxiconazole cream |                                                                                                                                                                                                                          |
| **Extina® foam, 2%**            | **ALL** of the following:  
• Individual is 12 years of age and older  
• Documented diagnosis of seborrheic dermatitis  
• Documented intolerance to (1) generic formulation of Extina 2% foam  
• Documented failure/inadequate response, contraindication per FDA label, intolerance, or not a candidate for BOTH of the following: ciclopirox shampoo, sulfaacetamide sodium shampoo |                                                                                                                                                                                                                          |
| **Jublia® topical solution, 10%** | **ALL** of the following:  
• Individual is 18 years of age and older  
• Documented diagnosis of onychomycosis of the toenail(s)  
• Documented failure/inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: ciclopirox nail lacquer solution, itraconazole capsules, terbinafine tablets |                                                                                                                                                                                                                          |
| **Kerydin® topical solution, 5%** | **ALL** of the following:  
• Individual is 6 years of age and older  
• Documented diagnosis of onychomycosis of the toenail(s)  
• Documented failure/inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: ciclopirox nail lacquer solution, itraconazole capsules, terbinafine tablets |                                                                                                                                                                                                                          |
| **Loprox® cream, 0.77%**       | **BOTH** of the following:  
• Documented intolerance to (1) generic formulation of Loprox 0.77% cream  
• Documented failure/inadequate response, contraindication per FDA label, intolerance, or not a candidate for FOUR of the following: clotrimazole cream, econazole cream, ketoconazole cream, naftifine cream, oxiconazole cream |                                                                                                                                                                                                                          |
| **Loprox® shampoo, 1%**        | **ALL** of the following:  
• Individual is 18 years of age and older  
• Documented diagnosis of seborrheic dermatitis  
• Documented intolerance to (1) generic formulation of Loprox 1% shampoo  
• Documented failure/inadequate response, contraindication per FDA label, intolerance, or not a candidate for BOTH of the following: ketoconazole foam, sulfaacetamide sodium shampoo |                                                                                                                                                                                                                          |
| **Luzu™ cream, 1%**            | **BOTH** of the following:  
• Documented diagnosis of tinea corporis, tinea cruris, or tinea pedis  
• Documented failure/inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following: ciclopirox cream/lotion, econazole cream, ketoconazole cream, naftifine cream, oxiconazole cream |                                                                                                                                                                                                                          |
| **miconazole/zinc oxide/white petrolatum ointment, 0.25%-15%-81.35%** | **ALL** of the following:  
• Pediatric individual 4 weeks of age or older  
• Documented diagnosis of diaper dermatitis  
• Presence of candida infection  
The approval will be limited to a (7) day supply. |                                                                                                                                                                                                                          |
| **Oxistat® cream, 1%**         | **BOTH** of the following:  
• Documented intolerance to (1) generic formulation of Oxistat 1% cream |                                                                                                                                                                                                                          |
For Individual and Family Plans:

Jublia (efinaconazole 10% solution) is covered as medically necessary when ALL of the following are met:

- Individual is an adult (18 years of age and older)
- Documented diagnosis of onychomycosis of the toenail(s)
- Documented inadequate response, contraindication per FDA label, intolerance, or not a candidate for itraconazole capsules, terbinafine tablets, and ciclopirox nail lacquer solution

Initial and reauthorization is up to 12 months (unless otherwise stated).

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Topical antifungals are considered experimental, investigational or unproven for ANY other use.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

*If you’re a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

**FDA Approved Indications**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Tinea corporis</th>
<th>Tinea cruris</th>
<th>Tinea pedis</th>
<th>Tinea versicolor</th>
<th>Diaper Dermatitis</th>
<th>Seborrheic dermatitis</th>
<th>Cutaneous candidiasis</th>
<th>Onychomycosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertaczo</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(sertaconazole)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Exelderm</td>
<td>✓</td>
<td>✓</td>
<td>✓†</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(sulconazole)</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Extina</td>
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<td></td>
<td></td>
<td></td>
<td>✓*</td>
<td></td>
</tr>
<tr>
<td>(ketoconazole)</td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>
### Recommended Dosing

<table>
<thead>
<tr>
<th>Drug</th>
<th>Available Formulations</th>
<th>Usual Recommended Frequency</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertaczo (sertaconazole)</td>
<td>Topical cream</td>
<td>Apply twice daily for 4 weeks.</td>
<td>Topical use only; not for oral, ophthalmic, or intravaginal use.</td>
</tr>
</tbody>
</table>
| Exelderm (sulconazole) | Topical cream, Topical solution | **Cream**  
Corporis, cruris, versicolor: Apply once or twice daily for 3 weeks  
**Solution**  
Corporis, cruris, versicolor: Apply once or twice daily for 3 weeks | Topical use only; not for ophthalmic use. |
| Extina (ketoconazole) | Topical foam           | Apply twice daily for 4 weeks. | Topical use only; not for oral, ophthalmic, or intravaginal use. |
| Jublia (efinaconazole) | Topical solution       | Apply to affected toenails once daily for 48 weeks. | Topical use only; not for oral, ophthalmic, or intravaginal use. |
| Kerydin (tavaborole)  | Topical solution       | Apply to affected toenails once daily for 48 weeks. | Topical use only; not for oral, ophthalmic, or intravaginal use. |
| Loprox (ciclopirox)   | Topical cream, Topical shampoo | **Cream**  
Apply twice daily for up to 4 weeks.  
**Shampoo** | Topical use only; not for oral, ophthalmic, or intravaginal use. |
<table>
<thead>
<tr>
<th><strong>Luzu</strong>&lt;br&gt;(luliconazole)</th>
<th>Topical cream</th>
<th><strong>Interdigital tinea pedis:</strong> Apply once daily for 2 weeks&lt;br&gt;<strong>Corporis, cruris:</strong> Apply once daily for 1 week</th>
<th>Topical use only; not for oral, ophthalmic, or intravaginal use.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oxistat</strong>&lt;br&gt;(oxiconazole) ***</td>
<td>Topical cream&lt;br&gt;Topical lotion</td>
<td><strong>Corporis and cruris:</strong> Apply once or twice daily for 2 weeks.&lt;br&gt;<strong>Versicolor:</strong> Apply once daily for 2 weeks.&lt;br&gt;<strong>Pedis:</strong> Apply once or twice daily for one month.</td>
<td>Topical use only; not for oral, ophthalmic, or intravaginal use.</td>
</tr>
<tr>
<td><strong>Penlac</strong>&lt;br&gt;(ciclopirox)</td>
<td>Topical solution&lt;br&gt;(nail lacquer)</td>
<td>Apply once daily (at bedtime or 8 hours prior to washing) to all affected nails, evenly over the entire nail plate. Daily applications should be made over the previous coat and removed with alcohol every 7 days.</td>
<td>Topical use only; not for oral, ophthalmic, or intravaginal use.</td>
</tr>
<tr>
<td><strong>Vusion</strong>&lt;br&gt;(miconazole/zinc oxide/white petrolatum)</td>
<td>Topical ointment</td>
<td>Apply with each diaper change for 7 days.</td>
<td>Topical use only; not for oral, ophthalmic, or intravaginal use.</td>
</tr>
</tbody>
</table>

### Background

**Professional Societies/Organizations**

The American Academy of Dermatology (AAD) and World Health Organization (WHO) discuss the management of fungal infections with a focus primarily to superficial mycotic infections. Recommendations list topical antifungal products and do not give preference to one agent over another. The guidelines note mycological and clinical cure of noninvasive fungal infections are usually achieved with topical monotherapy. Recommendations do affirm oral therapy is preferred to treat extensive or severe infections or to treat onychomycosis. (Drake [a] [b] [c], 1996; WHO, 2014)

**Off Label Uses**

AHFS Drug Information 2019 Edition supports the following off-label uses for Ertaczo: Tinea corporis, Tinea cruris, and Tinea manuum.

**Generics**

The FDA’s generic drug approval process does not require the drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Generic drugs must establish the following for approval:

- contain the same active ingredients as the innovator drug (inactive ingredients may vary)
- be identical in strength, dosage form, and route of administration
- have the same use indications
- be bioequivalent
- meet the same batch requirements for identity, strength, purity, and quality
- be manufactured under the same strict standards of FDA’s good manufacturing practice regulations required for innovator products

A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs. Not every brand-name drug has a generic drug. When new drugs are first
made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, doesn’t allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the FDA must approve it.

References


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