Drug and Biologic Coverage Policy

Effective Date 4/1/2024
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Coverage Policy Number IP0273

Topical Antifungals

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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, Certificate 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.

Overview

This policy supports medical necessity review for the following non-covered topical antifungal products:

- **Ertaczo®** (sertaconazole nitrate 2% cream)
- **Exelderm®** (sulconazole nitrate 1% cream or solution)
- **Extina®** (ketoconazole 2% foam)
- **Jublia®** (efinaconazole 10% solution)
- **Kerydin®** (tavaborole 5% solution)
- **Loprox®** (ciclopirox 0.77% cream)
- **Loprox®** (ciclopirox 1% shampoo)
- **Luzu™** (luliconazole 1% cream)
- **miconazole-zinc-petrolatum ointment** 0.25%-15%-81.35%
- **oxiconazole** 1% cream
- **Oxistat®** (oxiconazole 1% cream or lotion)
- **sulconazole nitrate** 1% cream or solution
- **tavaborole** 5% solution
- **Vusion®** (miconazole-zinc-petrolatum 0.25%-15%-81.35% ointment)

- **Xolegel™** (ketoconazole 2% gel)

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

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Employer Plans:

Product	Criteria
Ertaczo (sertaconazole nitrate cream, 2%)	**Ertaczo** is considered medically necessary when there is documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to **FOUR** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel 2. For occluded infection (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to **TWO** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel
Exelderm (sulconazole nitrate cream or solution, 1.0%)	**Exelderm cream or solution** is considered medically necessary when there is documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to **FOUR** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel 2. For occluded infection (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to **TWO** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel
Extina (ketoconazole foam, 2%)	**Extina** is considered medically necessary when there is documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to **FOUR** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel 2. For occluded infection (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to **TWO** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel

<table>
<tr><th>Product</th><th>Criteria</th></tr>
<tr><td>Jublia
(efinaconazole solution, 10%)</td><td>Jublia is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ciclopirox 8% solution.</td></tr>
<tr><td>Kerydin
(tavaborole solution, 5%)</td><td>Kerydin is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ciclopirox 8% solution:</td></tr>
<tr><td>Loprox
(ciclopirox cream, 0.77%)</td><td>Loprox cream is considered medically necessary when there is documentation of ONE of the following:
1. Failure, contraindication, or intolerance to FOUR of the following:
A. ciclopirox cream <u>or</u> gel
B. econazole cream
C. ketoconazole cream <u>or</u> foam
D. naftifine cream <u>or</u> gel
2. For <u>occluded infection</u> (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to TWO of the following:
A. ciclopirox cream <u>or</u> gel
B. econazole cream
C. ketoconazole cream <u>or</u> foam
D. naftifine cream <u>or</u> gel</td></tr>
<tr><td>Loprox
(ciclopirox shampoo, 1%)</td><td>Loprox shampoo is considered medically necessary when there is documentation of failure, contraindication, or intolerance to BOTH of the following:
1. ciclopirox gel <u>or</u> shampoo
2. ketoconazole cream <u>or</u> 2% shampoo</td></tr>
<tr><td>Luzu
(luliconazole cream, 1%)</td><td>Luzu is considered medically necessary when there is documentation of ONE of the following:
1. Failure, contraindication, or intolerance to FOUR of the following:
A. ciclopirox cream <u>or</u> gel
B. econazole cream
C. ketoconazole cream <u>or</u> foam
D. naftifine cream <u>or</u> gel
2. For <u>occluded infection</u> (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to TWO of the following:
A. ciclopirox cream <u>or</u> gel
B. econazole cream
C. ketoconazole cream <u>or</u> foam
D. naftifine cream <u>or</u> gel</td></tr>
<tr><td>miconazole-zinc-petrolatum ointment, 0.25%-15%-81.35%</td><td>Miconazole-zinc-petrolatum ointment is considered medically necessary when there is documentation of BOTH of the following:
1. Presence of candida infection
2. Failure, contraindication, or intolerance to ONE of the following:
A. ketoconazole cream <u>or</u> foam
B. nystatin cream <u>or</u> ointment
[Approval duration will be limited to 7 days]</td></tr>
<tr><td>oxiconazole cream, 1%</td><td>Oxiconazole cream is considered necessary when there is documentation of ONE of the following:
1. Failure, contraindication, or intolerance to FOUR of the following:
A. ciclopirox cream <u>or</u> gel</td></tr>
</table>

Product	Criteria
	B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel 2. For occluded infection (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to **TWO** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel
Oxistat (oxiconazole cream or lotion, 1%)	**Oxistat cream or lotion** is considered necessary when there is documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to **FOUR** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel 2. For occluded infection (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to **TWO** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel
sulconazole nitrate cream or solution, 1.0%	**Sulconazole nitrate cream or solution** are considered necessary when there is documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to **FOUR** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel 2. For occluded infection (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to **TWO** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel
tavaborole solution, 5%	**Tavaborole solution** is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ciclopirox 8% solution:
Vusion (miconazole-zinc-petrolatum ointment, 0.25%-15%-81.35%)	**Vusion** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Presence of candida infection 2. Failure, contraindication, or intolerance to **ONE** of the following: A. ketoconazole cream or foam B. nystatin cream or ointment [Approval duration will be limited to 7 days]
Xolegel (ketoconazole gel, 2%)	**Xolegel** is considered medically necessary when there is documentation of **ONE** of the following:

Product	Criteria
	1. Failure, contraindication, or intolerance to **FOUR** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel 2. For occluded infection (for example, intertrigo or erosio interdigitalis blastomycetica): Failure, contraindication, or intolerance to **TWO** of the following: A. ciclopirox cream or gel B. econazole cream C. ketoconazole cream or foam D. naftifine cream or gel

Individual and Family Plans:

Product	Criteria
Jublia (efinaconazole solution, 10%)	**Jublia** is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ciclopirox 8% solution

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.

Reauthorization Criteria

Continuation of non-covered topical antifungals are considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.
Reauthorization approval duration: up to 12 months.

Background

OVERVIEW

Topical antifungal products are used to treat a variety of superficial fungal infections (e.g., tinea, candida) diaper dermatitis, and seborrheic dermatitis.[1-27] In general, the frequency of administration is typically once daily (QD) to two times daily (BID).[1-27] The duration of treatment varies depending on the fungus and condition being treated but is most often used for an initial 2 week period. In some cases, 4 weeks of treatment is recommended initially, in others, treatment can last for up to 4 weeks if no clinical improvement is seen after 2 weeks of treatment.

The quantity of topical antifungals is generally not specified in dosing instructions for these products. The SCORIng Atopic Dermatitis (SCORAD) index is the most widely used validated clinical tool to classify atopic dermatitis severity based on affected body surface area (BSA) and intensity of the lesions; this is also helpful to determine body surface area for other skin infecitons.[28-31] The head and neck are considered 9% of BSA, each upper limb is 9% of BSA (18% total), each lower limb is 18% BSA (36% total), anterior tuck is 18% of BSA, back is 18% of BSA, and genitals are 1% of BSA. When determining the amount of a topical product to apply, a standard measure, the fingertip unit (FTU), is often used.[29] One FTU is the amount of product that is squeezed out of a standard tube

along an adult's fingertip. One FTU is equivalent to approximately 0.5 grams and provides enough product to treat an area of skin that is twice the size of one adult hand, or approximately 2% of an adult's total BSA. Therefore, it is assumed that 1 gram of topical antifungal cream would cover 4% of the patient's BSA, approximately 63 grams is a quantity sufficient to apply a topical antifungal product to 9% of the BSA BID for 14 days.

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