



## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Topical Antifungals Drug Quantity Management Policy – Per Days

Product	Manufacturer
<b>Butenafine Product</b>	
• Mentax® (butenafine HCl 1% cream)	Mylan
<b>Ciclopirox Products</b>	
• Loprox® and Loprox® Cream Kit (ciclopirox olamine 0.77% cream, generic for 90 g tube only, not kit)	Medimetriks
• ciclopirox 0.77% gel	Generic only
• Loprox® (ciclopirox 1% shampoo, generic)	Bausch
• Loprox® and Loprox® Suspension Kit (ciclopirox olamine 0.77% suspension, generic for 60 mL bottle only, not kit)	Medimetriks
<b>Clotrimazole Products</b>	
• clotrimazole 1% solution	Generic only
• clotrimazole 1% cream (prescription)	Generic only
• clotrimazole/betamethasone cream	Generic only
• clotrimazole/betamethasone lotion	Generic only
<b>Econazole Products</b>	
• econazole nitrate 1% cream	Generic only
• Ecoza® (econazole nitrate 1% foam)	Excelltis
<b>Ketoconazole Products</b>	
• ketoconazole 2% cream	Generic only
• Extina® (ketoconazole 2% foam, generic)	Mylan
• Xolegel® (ketoconazole 2% gel)	Almirall
• ketoconazole 2% shampoo	Generic only
<b>Luliconazole Product</b>	
• Luzu® (luliconazole 1% cream, authorized generic)	Bausch
<b>Miconazole Product</b>	
• Vusion® (miconazole nitrate/zinc oxide/white petrolatum 0.25%/15%/81.35% ointment, generic)	Mylan
<b>Naftifine Products</b>	
• naftifine HCl 1% cream	Generic only
• naftifine HCl 2% cream,	Generic only
• Naftin® 1% gel (naftifine HCl 1% gel, generic) [brand is obsolete 6/14/24 and generic is obsolete 2/22/2022]	Sebela
• Naftin® 2% gel (naftifine HCl 2% gel, generic)	Sebela
<b>Nystatin Products</b>	
• nystatin 100,000 units per gram cream	Generic only
• nystatin 100,000 units per gram ointment	Generic only
• nystatin/triamcinolone acetonide 100,000 units per gram/0.1% cream	Generic only
• nystatin/triamcinolone acetonide 100,000 units per gram/0.1% ointment	Generic only
<b>Oxiconazole Products</b>	
• Oxistat® (oxiconazole nitrate 1% cream, generic) [brand is obsolete 2/16/23]	PharmaDerm
• Oxistat® (oxiconazole nitrate 1% lotion)	PharmaDerm
<b>Sertaconazole Product</b>	
• Ertaczo® (sertaconazole nitrate 2% cream)	Bausch
<b>Sulconazole Products</b>	
• Exelderm® (sulconazole nitrate 1% cream, authorized generic)	Journey
• Exelderm® (sulconazole nitrate 1% solution, authorized generic)	Journey

**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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. 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.*

## **Cigna National Formulary Coverage:**

### **OVERVIEW**

Topical antifungal products are used to treat a variety of superficial fungal infections (e.g., tinea, candida) diaper dermatitis, and seborrheic dermatitis.<sup>1-27</sup> For specific indications for the topical antifungals consult the Drug Quantity Limits table.

### **Dosing/Availability**

The approved dosing and availability of each of the topical antifungal product is outlined in the Drug Quantity Limits table. In general, the frequency of administration is typically once daily (QD) to twice daily (BID).<sup>1-27</sup> 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 infections.<sup>28-31</sup> 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.<sup>29</sup> 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.

## POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of topical antifungals. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

## Drug Quantity Limits

The Express Scripts initial quantity limit for topical antifungal products is outlined in the table below. The quantity limits allow for a sufficient quantity of each of the topical antifungal products to treat approximately 9% of a patient's BSA when applied up to BID for 14 days. For prescription clotrimazole 1% cream, the quantity limit is sufficient to treat approximately 7% of a patient's BSA when applied up to BID for 14 days (3.2 grams/day). For patients treating a larger surface area or treating for a longer duration than 14 days, additional quantities are available through coverage review.

## Drug Quantity Limits (continued)

Brand (generic)	FDA-Approved Indication and Dosing	Availability	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity per 84 days
Mentax® (butenafine HCl 1% cream)	<u>Indication:</u> For the topical treatment of <b>tinea (pityriasis) versicolor</b> due to <i>M. furfur</i> (formerly <i>P. orbiculare</i> ). <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply a sufficient quantity to affected areas and immediately surrounding skin <b>QD for 2 weeks</b>.</li> <li>If a patient shows no clinical improvement after the treatment period, review the diagnosis/therapy.</li> </ul>	15 gram tube	30 grams	90 grams
		30 gram tube		
Loprox® cream and Loprox® cream kit (ciclopirox olamine 0.77% cream, generic for 90 g tube only, not kit)	<u>Indication:</u> For the topical treatment of the following dermal infections: <b>tinea pedis, tinea cruris, and tinea corporis</b> due to <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , <i>Epidermophyton floccosum</i> , and <i>Microsporum canis</i> ; <b>cutaneous candidiasis</b> (moniliasis) due to <i>Candida albicans</i> ; and <b>tinea (pityriasis) versicolor</b> due to <i>Malassezia furfur</i> . <u>Dosing:</u> <ul style="list-style-type: none"> <li>Massage cream into the affected and surrounding skin areas <b>BID</b>. Patients</li> </ul>	90 gram tube	90 grams*	270 grams

	<p>with tinea versicolor usually exhibit clinical and mycological clearing after <b>2 weeks</b> of treatment.</p> <ul style="list-style-type: none"> <li>• Clinical improvement usually occurs within 1 week of treatment.</li> <li>• If a patient shows no clinical improvement after 4 weeks, the diagnosis should be reviewed.</li> </ul>			
ciclopirox 0.77% gel	<p><u>Indications:</u></p> <ul style="list-style-type: none"> <li>• For the topical treatment of superficial dermatophyte infections (<b>interdigital tinea pedis and tinea corporis</b>) due to <i>Trichophyton rubrum</i>, <i>Trichophyton mentagrophytes</i>, <i>Epidermophyton floccosum</i>.</li> <li>• For the topical treatment of <b>seborrheic dermatitis of the scalp</b>.</li> </ul> <p><u>Dosing:</u></p> <ul style="list-style-type: none"> <li>• Superficial dermatophyte infections: Massage into the affected areas and surrounding skin <b>BID for 4 weeks</b>. If a patient shows no clinical improvement after 4 weeks the diagnosis should be reviewed.</li> <li>• Seborrheic dermatitis of the scalp: Apply to affected scalp areas <b>BID for 4 weeks</b>. Clinical improvement usually occurs within 1 week with continuing resolution of signs and symptoms through the 4<sup>th</sup> week of treatment. If a patient shows no clinical improvement after 4 weeks, the diagnosis should be reviewed.</li> </ul>	30 grams	100 grams*	300 grams
		45 grams		
		100 grams		

Brand (generic)	FDA-Approved Indication and Dosing	Availability	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity Per 84 days
Loprox® (ciclopirox 1% shampoo, generic)	<p><u>Indication:</u> For topical treatment of <b>seborrheic dermatitis</b> of the scalp in adults.</p> <p><u>Dosing:</u></p> <ul style="list-style-type: none"> <li>• Apply approximately 1 teaspoon (5 mL) to the scalp. Up to 2 teaspoons (<b>10 mL</b>) may be used for long hair. Treatment should be repeated <b>twice per week for 4 weeks</b>, with a minimum of 3 days between applications.</li> <li>• If no clinical improvement after 4 weeks, the diagnosis should be reviewed.</li> </ul>	120 mL bottle	120 mL*	360 mL

Loprox® suspension and Loprox® Suspension Kit (ciclopirox olamine 0.77% suspension, generic for 60 mL bottle only, not kit; 30 mL bottle is only available as the generic)	<u>Indication:</u> For the topical treatment of the following dermal infections: <b>tinea pedis, tinea cruris, and tinea corporis</b> due to <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , <i>Epidermophyton floccosum</i> , and <i>Microsporum canis</i> ; <b>cutaneous candidiasis</b> (moniliasis) due to <i>Candida albicans</i> ; and <b>tinea (pityriasis) versicolor</b> due to <i>Malassezia furfur</i> . <u>Dosing:</u> <ul style="list-style-type: none"> <li>Gently massage into the affected and surrounding skin areas <b>BID</b>. Clinical improvement with relief of pruritus and other symptoms usually occurs within 1 week of treatment. If a patient shows no clinical improvement after 4 weeks of treatment, the diagnosis should be reviewed.</li> <li>Patients with tinea versicolor usually exhibit clinical and mycological clearing after 2 weeks of treatment.</li> </ul>	30 mL bottle	60 mL	180 mL
		60 mL bottle		
clotrimazole 1% solution	<u>Indications:</u> <ul style="list-style-type: none"> <li>For the topical treatment of cutaneous <b>candidiasis</b> due to <i>Candida albicans</i> and <b>tinea versicolor</b> due to <i>Malassezia furfur</i>.</li> <li>The non-prescription product is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to <i>Trichophyton rubrum</i>, <i>Trichophyton mentagrophytes</i>, <i>Epidermophyton fluoccosum</i>, and <i>Microsporum canis</i>.</li> </ul> <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply sufficient quantity into the affected and surrounding skin areas <b>BID</b>.</li> <li>Clinical improvement, with relief of pruritus, usually occurs within 1 week of treatment. If the patient shows no clinical improvement after 4 weeks, the diagnosis should be reviewed.</li> </ul>	10 mL bottle	60 mL	180 mL
		30 mL bottle		

Brand (generic)	FDA-Approved Indication and Dosing	Availability	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity Per 84 days
clotrimazole 1% cream	<u>Indications:</u> <ul style="list-style-type: none"> <li>For the topical treatment of cutaneous <b>candidiasis</b> due to <i>Candida albicans</i> and <b>tinea versicolor</b> due to <i>Malassezia furfur</i>.</li> <li>The non-prescription product is indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to</li> </ul>	15 gram tube	45 grams	135 grams
		30 gram tube		

	<p><i>Trichophyton rubrum</i>, <i>Trichophyton mentagrophytes</i>, <i>Epidermophyton floccosum</i>, and <i>Microsporum canis</i>.</p> <p><u>Dosing:</u></p> <ul style="list-style-type: none"> <li>• Apply sufficient quantity to the affected and surrounding skin areas <b>BID</b>.</li> <li>• Clinical improvement, with relief of pruritus, usually occurs within 1 week of treatment. If the patient shows no clinical improvement after 4 weeks, the diagnosis should be reviewed</li> </ul>	45 gram tube		
Clotrimazole 1%/betamethasone 0.05% cream	<p><u>Indication:</u> For the topical treatment of symptomatic inflammatory <b>tinea pedis</b>, <b>tinea cruris</b>, and <b>tinea corporis</b> due to <i>Epidermophyton floccosum</i>, <i>Trichophyton mentagrophytes</i>, and <i>Trichophyton rubrum</i> in patients ≥ 17 years of age.</p> <p><u>Dosing:</u></p> <ul style="list-style-type: none"> <li>• Tinea corporis or tinea cruris: Apply a thin film to the affected skin areas <b>BID for 1 week</b>. Do not use more than 45 grams per week. If a patient shows no clinical improvement after 1 week the diagnosis should be reviewed. Do not use longer than 2 weeks.</li> <li>• Tinea pedis: Gently massage a sufficient amount into the affected skin areas <b>BID for 2 weeks</b>. Do not use more than 45 grams per week. If a patient shows no clinical improvement after 2 weeks of treatment, the diagnosis should be reviewed. Do not use longer than 4 weeks.</li> </ul>	15 gram tube	90 grams*	270 grams
		45 gram tube		
Clotrimazole 1%/betamethasone 0.05% lotion	<p><u>Indication:</u> For the topical treatment of symptomatic inflammatory <b>tinea pedis</b>, <b>tinea cruris</b>, and <b>tinea corporis</b> due to <i>Epidermophyton floccosum</i>, <i>Trichophyton mentagrophytes</i>, and <i>Trichophyton rubrum</i> in adults ≥ 17 years of age.</p> <p><u>Dosing:</u></p> <ul style="list-style-type: none"> <li>• Gently massage a sufficient amount into the affected skin areas BID. <b>Amounts &gt; 45 mL/week should not be used.</b></li> <li>• For tinea corporis or tinea cruris, do not use for &gt; 2 weeks (review after 1 weeks if no improvement). For tinea pedis do not use &gt; 4 weeks (review after 2 weeks if no improvement).</li> </ul>	30 mL bottle	60 mL	180 mL

Brand (generic)	FDA-Approved Indication and Dosing	Availability	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity Per 84 days
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econazole nitrate 1% cream	<u>Indications:</u> <ul style="list-style-type: none"> <li>For the topical treatment of <b>tinea pedis, tinea cruris, and tinea corporis</b> caused by <i>Trichophyton rubrum</i>, <i>Trichophyton mentagrophytes</i>, <i>Trichophyton tonsurans</i>, <i>Microsporum canis</i>, <i>Microsporum audouini</i>, <i>Microsporum gypseum</i>, and <i>Epidermophyton floccosum</i>.</li> <li>For the treatment of <b>cutaneous candidiasis</b>.</li> <li>For the treatment of <b>tinea versicolor</b>.</li> </ul> <u>Dosing:</u> <ul style="list-style-type: none"> <li>For tinea pedis, tinea cruris, tinea corporis, and tinea versicolor apply a sufficient quantity <b>QD</b>. Tinea cruris should be treated for <b>2 weeks</b>. Tinea pedis should be treated for <b>1 month</b>. Patients with tinea versicolor usually have clinical and mycological clearing after <b>2 weeks</b> of treatment.</li> <li>For cutaneous candidiasis, apply a sufficient quantity <b>BID for 2 weeks</b>.</li> <li>If a patient shows no clinical improvement after the treatment period, the diagnosis should be reviewed.</li> </ul>	15 gram tube	85 grams	255 grams
		30 gram tube		
		85 gram tube		
Ecoza® (econazole nitrate 1% foam)	<u>Indication:</u> For the treatment of <b>interdigital tinea pedis</b> caused by <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , and <i>Epidermophyton floccosum</i> in patients $\geq 12$ years of age. <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply to cover affected areas <b>QD for 4 weeks</b>.</li> </ul>	70 gram canister	70 grams	210 grams
ketoconazole 2% cream	<u>Indications:</u> <ul style="list-style-type: none"> <li>For the topical treatment of <b>tinea corporis, tinea cruris, and tinea pedis</b> caused by <i>Trichophyton rubrum</i>, <i>T. mentagrophytes</i> and <i>Epidermophyton floccosum</i></li> <li>For the treatment of <b>tinea (pityriasis) versicolor</b> caused by <i>Malassezia furfur</i> (<i>Pityrosporum orbiculare</i>).</li> <li>For the treatment of <b>cutaneous candidiasis</b> caused by <i>Candida spp.</i></li> <li>For treatment of <b>seborrheic dermatitis</b>.</li> </ul> <u>Dosing:</u> <ul style="list-style-type: none"> <li>For cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis, and tinea (pityriasis) versicolor apply <b>QD</b> to cover the affected and immediate surrounding area. Candidal infections and tinea cruris and corporis should be treated for <b>2 weeks</b>. Patients with tinea versicolor usually require <b>2 weeks</b> of treatment. Patients with tinea pedis require <b>6 weeks</b> of treatment.</li> </ul>	15 gram tube	60 grams	180 grams
		30 gram tube		
		60 gram tube		

	<ul style="list-style-type: none"> <li>For seborrheic dermatitis apply to the affected area <b>BID for 4 weeks</b> or until clinical clearing.</li> <li>If a patient shows no clinical improvement after the treatment period, the diagnosis should be reviewed.</li> </ul>			
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Brand (generic)	FDA-Approved Indication and Dosing	Availability	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity Per 84 days
Extina® (ketoconazole 2% foam, generic)	<u>Indication:</u> For the topical treatment of <b>seborrheic dermatitis</b> in immunocompetent patients ≥ 12 years of age. <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply to the affected area(s) <b>BID for 4 weeks</b>.</li> </ul>	50 gram canister 100 gram canister	100 grams	300 grams
Xolegel® (ketoconazole 2% gel)	<u>Indication:</u> For the topical treatment of <b>seborrheic dermatitis</b> in immunocompetent adults and children ≥ 12 years of age. <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply to the affected area <b>QD for 2 weeks</b>.</li> </ul>	45 gram tube	90 grams*	270 grams
ketoconazole 2% shampoo	<u>Indication:</u> For the treatment of <b>tinea (pityriasis) versicolor</b> caused by or presumed to be caused by <i>Pityrosporum orbiculare</i> (also known as <i>Malassezia furfur</i> or <i>M. orbiculare</i> ). <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply to the damp skin of the affected area and a wide margin surrounding this area.</li> <li><b>One application</b> of the shampoo should be sufficient</li> </ul>	120 mL bottle	120 mL	360 mL
Luzu® (luliconazole 1% cream, generic)	<u>Indication:</u> For the topical treatment of <b>interdigital tinea pedis, tinea cruris, and tinea corporis</b> caused by the organisms <i>Trichophyton rubrum</i> and <i>Epidermophyton floccosum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> <li>For interdigital tinea pedis, apply a thin layer of cream to the affected area and approximately 1 inch of the immediate surrounding area(s) <b>QD for 2 weeks</b>.</li> <li>For tinea cruris or tinea corporis, apply to the affected area and approximately 1 inch of the immediate surrounding area(s) <b>QD for 1 week</b>.</li> </ul>	60 gram tube	60 grams	180 grams
Vusion® (miconazole nitrate/zinc oxide/white petrolatum 0.25%/15%)	<u>Indication:</u> For the adjunctive treatment of <b>diaper dermatitis only when complicated by documented candidiasis</b> (microscopic evidence of pseudohyphae and/or budding yeast), in	50 gram tube	100 grams*	300 grams



/81.35% ointment, generic)	immunocompetent pediatric patients $\geq$ 4 weeks. <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply a thin layer of ointment to the diaper area with each diaper change for <b>7 days</b>. Continue treatment for the full 7 days, even if there is improvement.</li> <li>Do not use for &gt; 7 days.</li> </ul>			
naftifine HCl 1% cream	<u>Indication:</u> For the topical treatment of <b>tinea pedis, tinea cruris, and tinea corporis</b> caused by the organisms <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , and <i>Epidermophyton floccosum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply a sufficient quantity of to the affected and surrounding skin areas <b>QD</b>. If no clinical improvement is seen after 4 weeks the patient should be re-evaluated.</li> </ul>	60 gram tube	90 grams*	270 grams
		90 gram tube		

Brand (generic)	FDA-Approved Indication and Dosing	Availability	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity Per 84 days
naftifine HCl 2% cream	<u>Indication:</u> For the treatment of <b>interdigital tinea pedis, tinea cruris, and tinea corporis</b> caused by the organism <i>Trichophyton rubrum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply a thin layer <b>QD</b> to the affected areas plus a ½ inch margin of healthy surrounding skin for <b>2 weeks</b>.</li> </ul>	45 gram tube	60 grams	180 grams
		60 gram tube		
Naftin® 1% gel (naftifine HCl 1% gel, generic) [brand is obsolete 6/14/24 and generic is obsolete 2/22/2022]	<u>Indication:</u> For the topical treatment of <b>tinea pedis, tinea cruris, and tinea corporis</b> caused by the organisms <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , <i>Trichophyton tonsurans</i> , <i>Epidermophyton floccosum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply a sufficient quantity of to the affected and surrounding skin areas <b>BID</b>. If no clinical improvement is seen after 4 weeks of treatment, the patient should be re-evaluated.</li> </ul>	40 gram tube	90 grams*	270 grams
		60 gram tube		
		90 gram tube		
Naftin® 2% gel (naftifine HCl 2% gel, generic)	<u>Indication:</u> For the treatment of <b>interdigital tinea pedis</b> caused by the organisms <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , and <i>Epidermophyton floccosum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> <li>Apply <b>QD</b> to the affected areas plus an approximate ½ inch margin of healthy surrounding skin for <b>2 weeks</b>.</li> </ul>	45 gram tube	60 grams	180 grams
		60 gram tube		
nystatin 100,000	<u>Indication:</u> For the treatment of <b>cutaneous or mucocutaneous mycotic</b>	15 gram tube	60 grams	180 grams

units per gram cream	<b>infections</b> caused by <i>Candida albicans</i> and other susceptible <i>Candida</i> species. <u>Dosing:</u> • Apply liberally to affected areas <b>BID</b> or as indicated until healing is complete.	30 gram tube		
nystatin 100,000 units per gram ointment	<u>Indication:</u> For the treatment of <b>cutaneous or mucocutaneous mycotic infections</b> caused by <i>Candida albicans</i> and other susceptible <i>Candida</i> species. <u>Dosing:</u> • Apply liberally to affected areas <b>BID</b> or as indicated until healing is complete.	15 gram tube 30 gram tube	60 grams	180 grams
nystatin/triamcinolone acetate 100,000 units per gram/0.1% cream	<u>Indication:</u> For the treatment of <b>cutaneous candidiasis</b> . <u>Dosing:</u> • Apply to the affected areas <b>BID</b> . Discontinue if symptoms persist after 25 days of therapy.	15 gram tube 30 gram tube 60 gram tube	60 grams	180 grams
nystatin/triamcinolone acetate 100,000 units per gram/0.1% ointment	<u>Indication:</u> For the treatment of <b>cutaneous candidiasis</b> . <u>Dosing:</u> • Apply to the affected areas <b>BID</b> . Discontinue if symptoms persist after 25 days of therapy.	15 gram tube 30 gram tube 60 gram tube	60 grams	180 grams

Brand (generic)	FDA-Approved Indication and Dosing	Availability	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity Per 84 days
Oxistat® (oxiconazole nitrate 1% cream, generic)	<u>Indications:</u> • For the topical treatment of the following dermal infections: <b>tinea pedis, tinea cruris, and tinea corporis</b> due to <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , or <i>Epidermophyton floccosum</i> . • For the topical treatment of <b>tinea (pityriasis) versicolor</b> due to <i>Malassezia furfur</i> . <u>Dosing:</u> • For tinea pedis, apply to affected and immediately surrounding areas <b>QD to BID for 1 month</b> . • For tinea corporis, or tinea cruris, apply to affected and immediately surrounding areas <b>QD to BID for 2 weeks</b> . • For tinea (pityriasis) versicolor apply <b>QD for 2 weeks</b> . • If a patient shows no clinical improvement after the treatment period, the diagnosis should be reviewed.	30 gram tube 60 gram tube 90 gram tube	90 grams*	270 grams
Oxistat® (oxiconazole)	<u>Indication:</u> For the topical treatment of <b>tinea pedis, tinea cruris, and tinea corporis</b> due to <i>Trichophyton rubrum</i> ,	30 mL bottle	60 mL	180 mL

e nitrate 1% lotion)	<i>Trichophyton mentagrophytes</i> , or <i>Epidermophyton floccosum</i> . <u>Dosing:</u> • Apply to affected and immediately surrounding areas <b>QD to BID for 2 weeks</b> .	60 mL bottle		
Ertaczo® (sertaconazole nitrate 2% cream)	<u>Indication:</u> For the topical treatment of <b>interdigital tinea pedis</b> in immunocompetent adult and pediatric patients ≥ 12 years of age caused by <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , and <i>Epidermophyton floccosum</i> . <u>Dosing:</u> • Apply <b>BID for 4 weeks</b> . Apply a sufficient amount to cover both the affected areas between the toes and the immediately surrounding healthy skin. • Use for the full treatment time recommended by the physician, even though symptoms may have improved.	60 gram tube	60 grams	180 grams
Exelderm® (sulconazole nitrate 1% cream, authorized generic)	<u>Indication:</u> For the treatment of <b>tinea pedis (athlete's foot), tinea cruris</b> , and <b>tinea corporis</b> caused by <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , <i>Epidermophyton floccosum</i> , and <i>Microsporum canis</i> , and for the treatment of <b>tinea versicolor</b> . <u>Dosing:</u> • For tinea cruris, tinea corporis, and tinea versicolor, apply a small amount of cream to the affected and surrounding skin areas <b>QD or BID for 3 weeks</b> . • For tinea pedis, apply to the affected area and surrounding skin area <b>BID for 4 weeks</b> . • Early relief of symptoms is experienced by the majority of patients and clinical improvement may be seen fairly soon after treatment is begun. • If significant clinical improvement is not seen after 4 to 6 weeks of treatment, an alternate diagnosis should be considered.	60 gram tube	60 grams	180 grams

Brand (generic)	FDA-Approved Indication and Dosing	Availabil ity	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity Per 84 days
Exelderm® (sulconazole nitrate 1% solution, authorized generic)	<u>Indication:</u> For the treatment of <b>tinea cruris and tinea corporis</b> caused by <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , <i>Epidermophyton floccosum</i> , and <i>Microsporum canis</i> ; and for the treatment of <b>tinea versicolor</b> .	30 mL bottle	60 mL	180 mL

	<p>Effectiveness has not been proven in tinea pedis (athlete's foot).</p> <p><u>Dosing:</u></p> <ul style="list-style-type: none"> <li>• A small amount of solution should be gently massaged into the affected and surrounding skin areas <b>QD to BID for 3 weeks.</b></li> <li>• Symptomatic relief usually occurs within a few days and clinical improvement usually occurs within 1 week. To reduce the possibility of recurrence, treatment should be for 3 weeks.</li> <li>• If significant clinical improvement is not seen after 4 weeks of treatment, an alternate diagnosis should be considered</li> </ul>			
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\* The quantity limit is rounded up to accommodate the largest package size; 9% body surface area twice daily for 14 days is 63 units (mL, grams); QD – Once daily; BID – Twice daily.

**Topical Antifungals Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

#### **CRITERIA**

##### Mentax 1% cream

1. If a patient needs to treat greater than 9% body surface area or requires treatment for longer than 14 days, approve a one-time override of 60 grams per 28 days at retail or 180 grams per 84 days at home delivery if the patient has tinea (pityriasis) versicolor.

##### Ciclopirox olamine 0.77% cream (Loprox, generic) and Loprox cream kit

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 180 grams per 28 days at retail or 540 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, C, D, or E):
  - A) Patient has tinea pedis; OR
  - B) Patient has tinea cruris; OR
  - C) Patient has tinea corporis; OR
  - D) Patient has cutaneous candidiasis; OR
  - E) Patient has tinea (pityriasis) versicolor.

##### Ciclopirox 0.77% gel

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 200 grams per 28 days at retail or 600 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):
  - A) Patient has interdigital tinea pedis; OR
  - B) Patient has tinea corporis; OR

**C) Patient has seborrheic dermatitis of the scalp.**

Ciclopirox 1% shampoo (Loprox, generic)

No overrides recommended.

Ciclopirox 0.77% suspension (Loprox, generic) and Loprox suspension kit

- 1.** If the patient needs to treat than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 mL per 28 days at retail or 360 mL per 84 days at home delivery, if the patient meets ONE of the following (A, B, C, D, or E):
  - A)** Patient has tinea pedis; OR
  - B)** Patient has tinea cruris; OR
  - C)** Patient has tinea corporis; OR
  - D)** Patient has cutaneous candidiasis; OR
  - E)** Patient has tinea (pityriasis) versicolor.

Clotrimazole 1% solution

- 1.** If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 mL per 28 days at retail or 360 mL per 84 days at home delivery, if the patient meets ONE of the following (A or B):
  - A)** Patient has cutaneous candidiasis; OR
  - B)** Patient has tinea versicolor.

Clotrimazole 1% cream

- 1.** If the patient needs to treat greater than 7% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 90 grams per 28 days at retail or 180 grams per 84 days at home delivery, if the patient meets ONE of the following (A or B):
  - A)** Patient has cutaneous candidiasis; OR
  - B)** Patient has tinea versicolor.

Clotrimazole/betamethasone cream

- 1.** If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 180 grams per 28 days at retail or 540 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):
  - A)** Patient has tinea pedis; OR
  - B)** Patient has tinea cruris; OR
  - C)** Patient has tinea corporis.

Clotrimazole/betamethasone lotion

- 1.** If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 mL per 28 days at retail or 360 mL per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):
  - A)** Patient has tinea pedis; OR
  - B)** Patient has tinea cruris; OR

**C) Patient has tinea corporis.**

Econazole nitrate 1% cream

- 1.** If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 170 grams per 28 days at retail or 510 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, C, D, or E):
  - A)** Patient has tinea pedis; OR
  - B)** Patient has tinea cruris; OR
  - C)** Patient has tinea corporis; OR
  - D)** Patient has cutaneous candidiasis; OR
  - E)** Patient has tinea versicolor.

Ecoza 1% foam

- 1.** If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 140 grams per 28 days at retail or 420 grams per 84 days at home delivery, if the patient has interdigital tinea pedis.

Ketoconazole 2% cream

- 1.** If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, C, D, E, or F):
  - A)** Patient has tinea corporis; OR
  - B)** Patient has tinea cruris; OR
  - C)** Patient has tinea pedis; OR
  - D)** Patient has tinea (pityriasis) versicolor; OR
  - E)** Patient has cutaneous candidiasis; OR
  - F)** Patient has seborrheic dermatitis.

Ketoconazole 2% foam (Extina, generic)

- 1.** If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 200 grams per 28 days at retail or 600 grams per 84 days at home delivery, if the patient has seborrheic dermatitis.

Xolegel 2% gel

- 1.** If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 180 grams per 28 days at retail or 540 grams per 84 days at home delivery if the patient has seborrheic dermatitis.

Ketoconazole 2% shampoo

No overrides are recommended.

Luliconazole 1% cream (Luzu, generic)

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):

**A)** Patient has interdigital tinea pedis; OR

**B)** Patient has tinea cruris; OR

**C)** Patient has tinea corporis.

Miconazole nitrate/zinc oxide/white petrolatum 0.25%/15%/81.35% ointment, (Vusion, generic)

No overrides are recommended.

Note: The quantity limit supplies a quantity sufficient to treat for 7 days. Product labeling does not recommend use beyond 7 days.

Naftifine HCl 1% cream

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 180 grams per 28 days at home delivery or 540 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):

**A)** Patient has tinea pedis; OR

**B)** Patient has tinea cruris; OR

**C)** Patient has tinea corporis.

Naftifine HCl 2% cream

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):

**A)** Patient has interdigital tinea pedis; OR

**B)** Patient has tinea cruris; OR

**C)** Patient has tinea corporis.

Naftifine HCl 1% gel (Naftin, generic)

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 180 grams per 28 days at retail or 540 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):

**A)** Patient has tinea pedis; OR

**B)** Patient has tinea cruris; OR

**C)** Patient has tinea corporis.

Naftifine HCl 2% gel, (Naftin, generic)

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient has interdigital tinea pedis.

Nystatin 100,000 units/gram cream

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient is treating a cutaneous or mucocutaneous mycotic infection.

Nystatin 100 units/gram ointment

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery if the patient is treating a cutaneous or mucocutaneous mycotic infection.

Nystatin/triamcinolone acetonide 100,000 units per gram/0.1% cream

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient is treating cutaneous candidiasis.

Nystatin/triamcinolone acetonide 100,000 units per gram/0.1% ointment

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient is treating cutaneous candidiasis.

Oxiconazole nitrate 1% cream (Oxistat, generic)

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 180 grams per 28 days at retail or 540 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, C, or, D):
  - A) Patient has tinea pedis; OR
  - B) Patient has tinea cruris; OR
  - C) Patient has tinea corporis; OR
  - D) Patient has tinea (pityriasis) versicolor.

Oxistat 1% lotion

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 mL per 28 days at retail or 360 mL per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):
  - A) Patient has tinea pedis; OR
  - B) Patient has tinea cruris; OR
  - C) Patient has tinea corporis.

Ertaczo 2% cream

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient has interdigital tinea pedis.



#### Sulconazole nitrate 1% cream (Exelderm, generic)

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 grams per 28 days at retail or 360 grams per 84 days at home delivery, if the patient meets ONE of the following (A, B, C, or D):
  - A) Patient has tinea pedis; OR
  - B) Patient has tinea cruris; OR
  - C) Patient has tinea corporis; OR
  - D) Patient has tinea versicolor.

#### Sulconazole nitrate 1% solution, (Exelderm, generic)

1. If the patient needs to treat greater than 9% of their body surface area or requires treatment for longer than 14 days, approve a one-time override of 120 mL per 28 days at retail or 360 mL per 84 days at home delivery, if the patient meets ONE of the following (A, B, or C):
  - A) Patient has tinea cruris; OR
  - B) Patient has tinea corporis; OR
  - C) Patient has tinea versicolor.

#### **EXCLUSIONS**

1. No overrides are recommended for use in compounded formulations.

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## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/23/2023
Annual Revision	<p><b>Naftin 2% cream (naftifine hcl 2% cream, generic):</b> This product is only available as a generic, reference to the brand was removed.</p> <p><b>Vusion ointment (miconazole nitrate/zinc oxide/white petrolatum 0.25%/15%/81.35% ointment):</b> Generics were added.</p> <p><b>Clotrimazole 1% cream:</b> One time override quantities were updated to 90 grams per 28 days at retail and 180 grams per 84 days at home delivery if patient is treating great than 7% of their body surface area. Previously, the one-time override approved 45 grams at retail and 90 grams at home delivery.</p>	09/25/2024

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