



Drug Quantity Management – Per Days Topical Antifungals

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Product Identifier(s)

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INSTRUCTIONS FOR USE

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National Formulary Medical Necessity

Drugs Affected

Butenafine Product

- Mentax® (butenafine HCl 1% cream)

Ciclopirox Products

- Loprox® and Loprox® Cream Kit (ciclopirox olamine 0.77% cream, generic for 90 g tube only, not kit)
- ciclopirox 0.77% gel
- Loprox® (ciclopirox 1% shampoo, generic)
- Loprox® and Loprox® Suspension Kit (ciclopirox olamine 0.77% suspension, generic for 60 mL bottle only, not kit)

Clotrimazole Products

- clotrimazole 1% solution
- clotrimazole/betamethasone cream

- clotrimazole/betamethasone lotion

Econazole Products

- econazole nitrate 1% cream
- Ecoza[®] (econazole nitrate 1% foam)

Ketoconazole Products

- ketoconazole 2% cream
- Extina[®] (ketoconazole 2% foam, generic)
- Xolegel[®] (ketoconazole 2% gel)
- ketoconazole 2% shampoo

Luliconazole Product

- Luzu[®] (luliconazole 1% cream, generic)

Miconazole Product

- Vusion[®] (miconazole nitrate/zinc oxide/white petrolatum 0.25%/15%/81.35% ointment)

Naftifine Products

- naftifine hcl 1% cream
- Naftin[®] 2% cream (naftifine HCl 2% cream, generic) [Naftin 2% cream is obsolete as of 1/1/2021; generic 2% cream is available]
- Naftin[®] 1% gel (naftifine HCl 1% gel, generic)
- Naftin[®] 2% gel (naftifine HCl 2% gel)

Nystatin Products

- nystatin 100,000 units per gram cream
- nystatin 100,000 units per gram ointment
- nystatin/triamcinolone acetonide 100,000 units per gram/0.1% cream
- nystatin/triamcinolone acetonide 100,000 units per gram/0.1% ointment

Oxiconazole Products

- Oxistat[®] (oxiconazole nitrate 1% cream, generic)
- Oxistat[®] (oxiconazole nitrate 1% lotion)

Sertaconazole Product

- Ertaczo[®] (sertaconazole nitrate 2% cream)

Sulconazole Products

- Exelderm[®] (sulconazole nitrate 1% cream, generic)
- Exelderm[®] (sulconazole nitrate 1% solution, generic)

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 1 year in duration.

Drug Quantity Limits

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

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)	<p>Indication: For the topical treatment of tinea (pityriasis) versicolor due to <i>M. furfur</i> (formerly <i>P. orbiculare</i>).</p> <p>Dosing:</p> <ul style="list-style-type: none"> Apply a sufficient quantity to affected areas and immediately surrounding skin QD for 2 weeks. If an individual shows no clinical improvement after the treatment period, review the diagnosis/therapy. 	15 gram tube	30 grams	90 grams		
Loprox® cream and Loprox® cream kit (ciclopirox olamine 0.77% cream, generic for 90 g tube only, not kit)	<p>Indication: 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 floccosum</i>, and <i>Microsporum canis</i>; candidiasis (moniliasis) due to <i>Candida albicans</i>; and tinea (pityriasis) versicolor due to <i>Malassezia furfur</i>.</p> <p>Dosing:</p> <ul style="list-style-type: none"> Massage cream into the affected and surrounding skin areas BID. Individuals with tinea versicolor usually exhibit clinical and mycological clearing after 2 weeks of treatment. Clinical improvement usually occurs within 1 week of treatment. If an individual shows no clinical improvement after 4 weeks the diagnosis should be reviewed. 	30 gram tube			90 grams*	270 grams
ciclopirox 0.77% gel	<p>Indications:</p> <ul style="list-style-type: none"> For the topical treatment of superficial dermatophyte infections (interdigital tinea pedis and tinea corporis) due to <i>Trichophyton rubrum</i>, <i>Trichophyton mentagrophytes</i>, <i>Epidermophyton floccosum</i>. For the topical treatment of seborrheic dermatitis of the scalp. <p>Dosing:</p> <ul style="list-style-type: none"> Superficial dermatophyte infections: Massage into the affected areas and surrounding skin BID for 4 weeks. If an individual shows no clinical improvement after 4 weeks the diagnosis should be reviewed. Seborrheic dermatitis of the scalp: Apply to affected scalp areas BID for 4 weeks. Clinical improvement usually occurs within 1 week with continuing resolution of signs and symptoms through the 4th week of treatment. If an individual shows no clinical improvement after 4 weeks the diagnosis should be reviewed. 	30 gram	100 grams*	300 grams		
		45 gram				
		100 gram				
Loprox® (ciclopirox 1% shampoo, generic)	<p>Indication: For topical treatment of seborrheic dermatitis of the scalp in adults.</p> <p>Dosing:</p> <ul style="list-style-type: none"> Apply approximately 1 teaspoon (5 mL) to the scalp. Up to 2 teaspoons (10 mL) may be 	120 mL bottle	120 mL*	360 mL		

	<p>used for long hair. Treatment should be repeated twice per week for 4 weeks, with a minimum of 3 days between applications.</p> <ul style="list-style-type: none"> If no clinical improvement after 4 weeks the diagnosis should be reviewed. 			
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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
Loprox® 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)	<p>Indication: 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 floccosum</i>, and <i>Microsporum canis</i>; cutaneous candidiasis (moniliasis) due to <i>Candida albicans</i>; and tinea (pityriasis) versicolor due to <i>Malassezia furfur</i>.</p> <p>Dosing:</p> <ul style="list-style-type: none"> Gently massage into the affected and surrounding skin areas BID. Clinical improvement with relief of pruritus and other symptoms usually occurs within 1 week of treatment. If an individual shows no clinical improvement after 4 weeks of treatment, the diagnosis should be reviewed. Individuals with tinea versicolor usually exhibit clinical and mycological clearing after 2 weeks of treatment. 	30 mL bottle	60 mL	180 mL
		60 mL bottle		
clotrimazole 1% solution	<p>Indications:</p> <ul style="list-style-type: none"> For the topical treatment of candidiasis due to <i>Candida albicans</i> and tinea versicolor due to <i>Malassezia furfur</i>. 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 floccosum</i>, and <i>Microsporum canis</i>. <p>Dosing:</p> <ul style="list-style-type: none"> Apply sufficient quantity into the affected and surrounding skin areas BID. Clinical improvement, with relief of pruritus, usually occurs within 1 week of treatment. If the individual shows no clinical improvement after 4 weeks the diagnosis should be reviewed. 	10 mL bottle	60 mL	180 mL
		30 mL bottle		
clotrimazole 1% cream	<p>Indications:</p> <ul style="list-style-type: none"> For the topical treatment of candidiasis due to <i>Candida albicans</i> and tinea versicolor due to <i>Malassezia furfur</i>. 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>, 	15 gram tube	45 grams	135 grams
		30 gram tube		

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

econazole nitrate 1% cream	<u>Indications:</u> <ul style="list-style-type: none"> For the topical treatment of tinea pedis, tinea cruris, and tinea corporis 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>. For the treatment of cutaneous candidiasis. For the treatment of tinea versicolor. <u>Dosing:</u> <ul style="list-style-type: none"> For tinea pedis, tinea cruris, tinea corporis, and tinea versicolor apply a sufficient quantity QD. Tinea cruris should be treated for 2 weeks. Tinea pedis should be treated for 1 month. Individuals with tinea versicolor usually have clinical and mycological clearing after 2 weeks of treatment. For cutaneous candidiasis, apply a sufficient quantity BID for 2 weeks. If an individual shows no clinical improvement after the treatment period, the diagnosis should be reviewed. 	15 gram tube	85 grams	255 grams
		30 gram tube		
		85 gram tube		

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
Ecoza® (econazole nitrate 1% foam)	<u>Indication:</u> For the treatment of interdigital tinea pedis caused by <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , and <i>Epidermophyton floccosum</i> in individuals ≥ 12 years of age. <u>Dosing:</u> Apply to cover affected areas QD for 4 weeks .	70 gram canister	70 grams	210 grams
ketoconazole 2% cream	<u>Indications:</u> <ul style="list-style-type: none"> For the topical treatment of tinea corporis, tinea cruris, and tinea pedis caused by <i>Trichophyton rubrum</i>, <i>T. mentagrophytes</i> and <i>Epidermophyton floccosum</i> For the treatment of tinea (pityriasis) versicolor caused by <i>Malassezia furfur (Pityrosporum orbiculare)</i>. For the treatment of cutaneous candidiasis caused by <i>Candida spp.</i> For treatment of seborrheic dermatitis. <u>Dosing:</u> <ul style="list-style-type: none"> For cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis, and tinea (pityriasis) versicolor apply QD to cover the affected and immediate surrounding area. Candidal infections and tinea cruris and corporis should be treated for 2 weeks. Individuals with tinea versicolor usually require 2 weeks of treatment. Individuals with tinea pedis require 6 weeks of treatment. For seborrheic dermatitis apply to the affected area BID for 4 weeks or until clinical clearing. 	15 gram tube	60 grams	180 grams
		30 gram tube		
		60 gram tube		

	<ul style="list-style-type: none"> If an individual shows no clinical improvement after the treatment period, the diagnosis should be reviewed. 			
Extina® (ketoconazole 2% foam, generic)	<u>Indication:</u> For the topical treatment of seborrheic dermatitis in immunocompetent individuals ≥ 12 years of age. <u>Dosing:</u> <ul style="list-style-type: none"> Apply to the affected area(s) BID for 4 weeks. 	50 gram canister	100 grams	300 grams
		100 gram canister		
Xolegel® (ketoconazole 2% gel)	<u>Indication:</u> For the topical treatment of seborrheic dermatitis in immunocompetent adults and children ≥ 12 years of age. <u>Dosing:</u> <ul style="list-style-type: none"> Apply to the affected area QD for 2 weeks. 	45 gram tube	90 grams*	270 grams
ketoconazole 2% shampoo	<u>Indication:</u> For the treatment of tinea (pityriasis) versicolor 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"> Apply to the damp skin of the affected area and a wide margin surrounding this area. One application of the shampoo should be sufficient 	120 mL bottle	120 mL	360 mL

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
Luzu® (luliconazole 1% cream, generic)	<u>Indication:</u> For the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms <i>Trichophyton rubrum</i> and <i>Epidermophyton floccosum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> For interdigital tinea pedis, apply a thin layer of cream to the affected area and approximately 1 inch of the immediate surrounding area(s) QD for 2 weeks. For tinea cruris or tinea corporis, apply to the affected area and approximately 1 inch of the immediate surrounding area(s) QD for 1 week. 	60 gram tube	60 grams	180 grams
Vusion® (micinazole nitrate/zinc oxide/white petrolatum 0.25%/15%/8 1.35% ointment)	<u>Indication:</u> For the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast), in immunocompetent pediatric individuals ≥ 4 weeks. <u>Dosing:</u> <ul style="list-style-type: none"> Apply a thin layer of ointment to the diaper area with each diaper change for 7 days. Continue treatment for the full 7 days, even if there is improvement. Do not use for > 7 days. 	50 gram tube	100 grams*	300 grams

naftifine HCl 1% cream	<u>Indication:</u> For the topical treatment of tinea pedis, tinea cruris, and tinea corporis 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"> Apply a sufficient quantity of to the affected and surrounding skin areas QD. If no clinical improvement is seen after 4 weeks the individual should be re-evaluated. 	60 gram tube	90 grams*	270 grams
		90 gram tube		
Naftin® 2% cream (naftifine HCl 2% cream, generic) [Naftin 2% cream is obsolete 1/31/2021]	<u>Indication:</u> For the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism <i>Trichophyton rubrum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> Apply a thin layer QD to the affected areas plus a ½ inch margin of healthy surrounding skin for 2 weeks. 	45 gram tube	60 grams	180 grams
		60 gram tube		
Naftin® 1% gel (naftifine HCl 1% gel, generic)	<u>Indication:</u> For the topical treatment of tinea pedis, tinea cruris, and tinea corporis 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"> Apply a sufficient quantity of to the affected and surrounding skin areas BID. If no clinical improvement is seen after 4 weeks of treatment the individual should be re-evaluated. 	40 gram tube	90 grams*	270 grams
		60 gram tube		
		90 gram tube		

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
Naftin® 2% gel (naftifine HCl 2% gel)	<u>Indication:</u> For the treatment of interdigital tinea pedis 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"> Apply QD to the affected areas plus an approximate ½ inch margin of healthy surrounding skin for 2 weeks. 	45 gram tube	60 grams	180 grams
		60 gram tube		
nystatin 100,000 units per gram cream	<u>Indication:</u> For the treatment of cutaneous or mucocutaneous mycotic infections caused by <i>Candida albicans</i> and other susceptible <i>Candida</i> species. <u>Dosing:</u> <ul style="list-style-type: none"> Apply liberally to affected areas BID or as indicated until healing is complete. 	15 gram tube	60 grams	180 grams
		30 gram tube		
nystatin 100,000 units per gram ointment	<u>Indication:</u> For the treatment of cutaneous or mucocutaneous mycotic infections caused by <i>Candida albicans</i> and other susceptible <i>Candida</i> species. <u>Dosing:</u> <ul style="list-style-type: none"> Apply liberally to affected areas BID or as indicated until healing is complete. 	15 gram tube	60 grams	180 grams
		30 gram tube		

nystatin/triamcinolone acetonide 100,000 units per gram/0.1% cream	<u>Indication:</u> For the treatment of cutaneous candidiasis . <u>Dosing:</u> <ul style="list-style-type: none"> Apply to the affected areas BID. Discontinue if symptoms persist after 25 days of therapy. 	15 gram tube	60 grams	180 grams
		30 gram tube		
		60 gram tube		
nystatin/triamcinolone acetonide 100,000 units per gram/0.1% ointment	<u>Indication:</u> For the treatment of cutaneous candidiasis . <u>Dosing:</u> <ul style="list-style-type: none"> Apply to the affected areas BID. Discontinue if symptoms persist after 25 days of therapy. 	15 gram tube	60 grams	180 grams
		30 gram tube		
		60 gram tube		
Oxistat® (oxiconazole nitrate 1% cream, generic)	<u>Indications:</u> <ul style="list-style-type: none"> 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>, or <i>Epidermophyton floccosum</i>. For the topical treatment of tinea (pityriasis) versicolor due to <i>Malassezia furfur</i>. <u>Dosing:</u> <ul style="list-style-type: none"> For tinea pedis, apply to affected and immediately surrounding areas QD to BID for 1 month. For tinea corporis, or tinea cruris, apply to affected and immediately surrounding areas QD to BID for 2 weeks. For tinea (pityriasis) versicolor apply QD for 2 weeks. Tinea corporis, tinea cruris, and tinea (pityriasis) versicolor should be treated for 2 weeks. If an individual shows no clinical improvement after the treatment period, the diagnosis should be reviewed. 	30 gram tube	90 grams*	270 grams
		60 gram tube		
		90 gram tube		

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
Oxistat® (oxiconazole nitrate 1% lotion)	<u>Indication:</u> For the topical treatment tinea pedis, tinea cruris, and tinea corporis due to <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , or <i>Epidermophyton floccosum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> Apply to affected and immediately surrounding areas QD to BID for 2 weeks. 	30 mL bottle	60 mL	180 mL
		60 mL bottle		
Ertaczo® (sertaconazole nitrate 2% cream)	<u>Indication:</u> For the topical treatment of interdigital tinea pedis in immunocompetent adult and pediatric individuals ≥ 12 years of age caused by <i>Trichophyton rubrum</i> , <i>Trichophyton mentagrophytes</i> , and <i>Epidermophyton floccosum</i> . <u>Dosing:</u> <ul style="list-style-type: none"> Apply BID for 4 weeks. Apply a sufficient amount to cover both the affected areas 	60 gram tube	60 grams	180 grams

	<p>between the toes and the immediately surrounding healthy skin.</p> <ul style="list-style-type: none"> Use for the full treatment time recommended by the physician, even though symptoms may have improved. 			
Exelderm® (sulconazole nitrate 1% cream, generic)	<p>Indication: For the treatment of tinea pedis (athlete's foot), tinea cruris, and tinea corporis caused by <i>Trichophyton rubrum</i>, <i>Trichophyton mentagrophytes</i>, <i>Epidermophyton floccosum</i>, and <i>Microsporum canis</i>, and for the treatment of tinea versicolor.</p> <p>Dosing:</p> <ul style="list-style-type: none"> For tinea cruris, tinea corporis, and tinea versicolor, apply a small amount of cream to the affected and surrounding skin areas QD or BID for 3 weeks. For tinea pedis, apply to the affected area and surrounding skin area BID for 4 weeks. Early relief of symptoms is experienced by the majority of individuals 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
Exelderm® (sulconazole nitrate 1% solution, generic)	<p>Indication: For the treatment of tinea cruris and tinea corporis caused by <i>Trichophyton rubrum</i>, <i>Trichophyton mentagrophytes</i>, <i>Epidermophyton floccosum</i>, and <i>Microsporum canis</i>; and for the treatment of tinea versicolor. Effectiveness has not been proven in tinea pedis (athlete's foot).</p> <p>Dosing:</p> <ul style="list-style-type: none"> A small amount of solution should be gently massaged into the affected and surrounding skin areas QD to BID for 3 weeks. 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 weeks. If significant clinical improvement is not seen after 4 weeks of treatment, an alternate diagnosis should be considered. 	30 mL bottle	60 mL	180 mL

* 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.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Mentax 1% cream

- If an individual 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 individual has tinea (pityriasis) versicolor.

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

- If the individual 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 individual meets ONE of the following criteria (A, B, C, D, or E):

- A. Individual has tinea pedis; OR
- B. Individual has tinea cruris; OR
- C. Individual has tinea corporis; OR
- D. Individual has candidiasis; OR
- E. Individual has tinea versicolor.

Ciclopirox 0.77% gel

1. If the individual 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 individual meets ONE of the following (A, B, or C):
 - A. Individual has interdigital tinea pedis; OR
 - B. Individual has tinea corporis; OR
 - C. Individual 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 individual 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 individual meets ONE of the following (A, B, C, D, or E):
 - A. Individual has tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis; OR
 - D. Individual has cutaneous candidiasis; OR
 - E. Individual has tinea (pityriasis versicolor).

Clotrimazole 1% solution

1. If the individual 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 individual meets ONE of the following (A or B):
 - A. Individual has candidiasis; OR
 - B. Individual has tinea versicolor.

Clotrimazole 1% cream

1. If the individual 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 45 grams per 28 days at retail or 135 grams per 84 days at home delivery, if the individual meets ONE of the following (A or B):
 - A) Individual has candidiasis; OR
 - B) Individual has tinea versicolor.

Clotrimazole/betamethasone cream

1. If the individual 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 individual meets ONE of the following (A, B, or C):
 - A. Individual has tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis.

Clotrimazole/betamethasone lotion

1. If the individual 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 individual meets ONE of the following (A, B, or C):
 - A. Individual has tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis.

Econazole nitrate 1% cream

1. If the individual 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 individual meets ONE of the following (A, B, C, D, or E):
 - A. Individual has tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis; OR
 - D. Individual has cutaneous candidiasis; OR
 - E. Individual has tinea versicolor.

Ecoza 1% foam

1. If the individual 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 individual has interdigital tinea pedis.

Ketoconazole 2% cream

1. If the individual 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 individual meets ONE of the following (A, B, C, D, E, or F):
 - A. Individual has tinea corporis; OR
 - B. Individual 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 individual 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 individual has seborrheic dermatitis.

Xolegel 2% gel

1. If the individual 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 individual has seborrheic dermatitis.

Ketoconazole 2% shampoo

No overrides are recommended.

Luliconazole 1% cream (Luzu, generic)

1. If the individual 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 individual meets ONE of the following (A, B, or C):
 - A. Individual has interdigital tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis.

Vusion ointment

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 individual 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 individual meets ONE of the following (A, B, or C):

- A. Individual has tinea pedis; OR
- B. Individual has tinea cruris; OR
- C. Individual has tinea corporis.

Naftifine HCl 2% cream, (Naftin, generic)

1. If the individual 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 individual meets ONE of the following (A, B, or C):
 - A. Individual has interdigital tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis.

Naftifine HCl 1% gel (Naftin, generic)

1. If the individual 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 individual meets ONE of the following (A, B, or C):
 - A. Individual has tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis.

Naftifine HCl 2% gel, (Naftin, generic)

1. If the individual 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 individual has interdigital tinea pedis.

Nystatin 100,000 units/gram cream

1. If the individual 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 individual is treating a cutaneous or mucocutaneous mycotic infection

Nystatin 100 units/gram ointment

1. If the individual 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 individual is treating a cutaneous or mucocutaneous mycotic infection.

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

1. If the individual 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 individual is treating cutaneous candidiasis.

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

1. If the individual 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 individual is treating cutaneous candidiasis.

Oxiconazole nitrate 1% cream (Oxistat, generic)

1. If the individual 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 individual meets ONE of the following (A, B, C, or, D):
 - A. Individual has tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis; OR
 - D. Individual has tinea (pityriasis) versicolor.

Oxistat 1% lotion

1. If the individual 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 individual meets ONE of the following (A, B, or C):
 - A. Individual has tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis.

Ertaczo 2% cream

1. If the individual 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 individual has interdigital tinea pedis.

Sulconazole nitrate 1% cream (Exelderm, generic)

1. If the individual 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 individual meets ONE of the following (A, B, C, or D):
 - A. Individual has tinea pedis; OR
 - B. Individual has tinea cruris; OR
 - C. Individual has tinea corporis; OR
 - D. Individual has tinea versicolor.

Sulconazole nitrate 1% solution, (Exelderm, generic)

1. If the individual 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 individual meets ONE of the following (A, B, or C):
 - A. Individual has tinea cruris; OR
 - B. Individual has tinea corporis; OR
 - C. Individual has tinea versicolor.

Conditions Not Covered

Any other exception is considered not medically necessary, including the following:

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

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 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 products is outlined in the Drug Quantity Limits table. 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 infections.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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Revision History

Type of Revision	Summary of Changes	Approval Date
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<p>Annual Revision</p>	<p>Product changes were made as follows:</p> <p>Clotrimazole 1% cream: This product was removed from the policy, it is only available over the counter.</p> <p>Lotrisone (clotrimazole/betamethasone cream, generic): This product is only available as a generic, reference to the brand was removed.</p> <p>Nizoral (ketoconazole 2% shampoo, generic): This product is only available as a generic, reference to the brand was removed.</p> <p>Naftin 1% cream (naftifine hcl 1% cream, generic): This product is only available as a generic, reference to the brand was removed.</p> <p>Exelderm cream (sulconazole nitrate 1% cream): Generics were added.</p> <p>Exelderm solution (sulconazole nitrate 1% solution): Generics were added.</p> <p>Policy was updated to include the existing quantity limits when the product is obtained via retail or home delivery.</p> <p>The following quantity limits were changed to reflect the intent of the policy to cover 9% body surface area twice daily for 14 days (some quantities are rounded up to accommodate availability of the product):</p> <p>Ciclopirox 0.77% gel: Quantity limits were updated to 100 grams per 28 days at retail and 300 grams per 84 days at home delivery (previously 45 grams and 135 grams, respectively).</p> <p>Clotrimazole 1% solution: Quantity limits were updated to 60 mL per 28 days at retail and 180 mL per 84 days at home delivery (previously 30 mL and 180 mL, respectively).</p> <p>Clotrimazole/betamethasone cream: Quantity limits were updated to 90 grams per 28 days at retail and 270 grams per 84 days at home delivery (previously 45 grams and 135 grams, respectively).</p> <p>Xolegel: Quantity limits were updated to 90 grams per 28 days at retail and 270 grams per 84 days at home delivery (previously 45 grams and 135 grams, respectively).</p> <p>Vusion: Quantity limits were updated to 100 grams per 28 days at retail and 300 grams per 84 days at home delivery (previously 50 grams and 150 grams, respectively).</p> <p>Naftifine hcl 1% cream: Quantity limits were updated to 90 grams per 28 days at retail and 270 grams per 84 days at home delivery (previously 60 grams and 180 grams, respectively).</p> <p>Naftin 1% gel (generic): Quantity limits were updated to 90 grams per 28 days at retail and 270 grams per 84 days at home delivery (previously 60 grams and 180 grams, respectively).</p> <p>Nystatin 100,000 units/gram cream: Quantity limits were updated to 60 grams per 28 days at retail and 180 grams per 84 days at home delivery (previously 30 grams and 90 grams, respectively).</p> <p>Nystatin 100,000 units/gram ointment: Quantity limits were updated to 60 grams per 28 days at retail and 180 grams per 84 days at home delivery (previously 30 grams and 90 grams, respectively).</p> <p>Oxistat 1% cream (generic): Quantity limits were updated to 90 grams per 28 days at retail and 270 grams per 84 days at home delivery (previously 60 grams and 180 grams, respectively).</p> <p>Override criteria were updated as follows (note that previously non-FDA-approved indications were excluded from approval, criteria has been updated to reflect this intent):</p> <p>Mentax: One-time override quantities were updated to 60 grams per 28 days at retail and 180 grams per 84 days at home delivery if the patient has tinea (pityriasis) versicolor. Previously the one-time override approved 30 grams.</p> <p>Loprox cream (generic) and Loprox cream kit: One-time override quantities were updated to 180 grams per 28 days at retail and 540 grams per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea cruris, tinea corporis, candidiasis, or tinea versicolor. Previously the one-time override approved 90 grams.</p>	<p>8/24/2022</p>
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	<p>Ciclopirox 0.77% gel: One-time override quantities were updated to 200 grams per 28 days at retail and 600 grams per 84 days at home delivery if the patient has one of the following: interdigital tinea pedis, tinea corporis, or seborrheic dermatitis of the scalp. Previously the one-time override approved 45 grams</p> <p>Loprox suspension (generic) and Loprox suspension kit: One-time override quantities were updated to 120 mL per 28 days at retail and 360 mL per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea cruris, tinea corporis, cutaneous candidiasis, or tinea (pityriasis) versicolor. Previously the one-time override approved 60 mL.</p> <p>Clotrimazole 1% solution: One-time override quantities were updated to 120 mL per 28 days at retail and 360 mL per 84 days at home delivery if the patient has one of the following: candidiasis or tinea versicolor. Previously the one-time override approved 30 mL.</p> <p>Clotrimazole/betamethasone cream: One-time override quantities were updated to 180 grams per 28 days at retail and 540 grams per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea cruris, or tinea corporis. Previously the one-time override approved 45 grams.</p> <p>Clotrimazole/betamethasone lotion: One-time override quantities were updated to 120 mL per 28 days at retail and 360 mL per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea cruris, or tinea corporis. Previously the one-time override approved 60 mL.</p> <p>Econazole nitrate 1% cream: One-time override quantities were updated to 170 grams per 28 days at retail and 510 grams per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea cruris, tinea corporis, cutaneous candidiasis, or tinea versicolor. Previously the one-time override approved 85 grams.</p> <p>Ecoza: One-time override quantities were updated to 140 grams per 28 days at retail and 420 grams per 84 days at home delivery if the patient has interdigital tinea pedis. Previously the one-time override approved 70 grams.</p> <p>Ketoconazole 2% cream: One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has one of the following: tinea corporis, tinea cruris, tinea pedis, tinea (pityriasis) versicolor, cutaneous candidiasis, or seborrheic dermatitis. Previously the one-time override approved 60 grams.</p> <p>Extina (generic): One-time override quantities were updated to 200 grams per 28 days at retail and 600 grams per 84 days at home delivery if the patient has seborrheic dermatitis. Previously the one-time override approved 100 grams.</p> <p>Xolegel: One-time override quantities were updated to 180 grams per 28 days at retail and 540 grams per 84 days at home delivery if the patient has seborrheic dermatitis. Previously the one-time override approved 45 grams.</p> <p>Luzu (generic): One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has one of the following: interdigital tinea pedis, tinea corporis, or tinea cruris. Previously the one-time override approved 60 grams.</p> <p>Naftifine hcl 1% cream: One-time override quantities were updated to 180 grams per 28 days at retail and 540 grams per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea corporis, or tinea cruris. Previously the one-time override approved 60 grams.</p> <p>Naftin 2% cream (generic): One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has one of the following: interdigital tinea pedis, tinea corporis, or tinea cruris. Previously the one-time override approved 60 grams.</p> <p>Naftin 1% gel (generic): One-time override quantities were updated to 180 grams per 28 days at retail and 540 grams per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea corporis, or tinea cruris. Previously the one-time override approved 60 grams.</p> <p>Naftin 2% gel (generic): One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has interdigital tinea pedis. Previously the one-time override approved 60 grams.</p>	
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	<p>Nystatin 100,000 units/gram cream: One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has a cutaneous or mucocutaneous mycotic infection. Previously the one-time override approved 30 grams.</p> <p>Nystatin 100,000 units/gram ointment: One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has a cutaneous or mucocutaneous mycotic infection. Previously the one-time override approved 30 grams.</p> <p>Nystatin/triamcinolone acetonide 100,000 units per gram/0.1% creamOne-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has a cutaneous candidiasis. Previously the one-time override approved 60 grams.</p> <p>Nystatin/triamcinolone acetonide 100,000 units per gram/0.1% ointment: One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has a cutaneous candidiasis. Previously the one-time override approved 60 grams.</p> <p>Oxistat cream (generic): One-time override quantities were updated to 180 grams per 28 days at retail and 540 grams per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea cruris, tinea corporis, or tinea (pityriasis) versicolor. Previously the one-time override approved 60 grams.</p> <p>Oxistat lotion: One-time override quantities were updated to 120 mL per 28 days at retail and 360 mL per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea cruris, or tinea corporis. Previously the one-time override approved 60 mL.</p> <p>Ertaczo: One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has interdigital tinea pedis. Previously the one-time override approved 60 grams.</p> <p>Exelderm cream (generic): One-time override quantities were updated to 120 grams per 28 days at retail and 360 grams per 84 days at home delivery if the patient has one of the following: tinea pedis, tinea cruris, tinea corporis, or tinea versicolor. Previously the one-time override approved 60 grams.</p> <p>Exelderm solution (generic): One-time override quantities were updated to 120 mL per 28 days at retail and 360 mL per 84 days at home delivery if the patient has one of the following: tinea cruris, tinea corporis, or tinea versicolor. Previously the one-time override approved 60 mL.</p>	
Selected Revision	<p>Clotrimazole 1% cream (prescription): Quantity limits were re-added to reflect the currently operational rule. The limit was updated to include the existing quantity limits when the product is obtained via retail or home delivery. A statement was added to note that the limit for clotrimazole 1% cream allows for treatment of up to 7% of the patient's body surface area twice daily for 14 days.</p>	11/09/2022

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