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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Topical Products	**Original Policy Date:**	January 1, 2020
Subject:	Topical Antifungals and Antibiotics	**Page:**	1 of 6

Last Review Date: December 12, 2025

Topical Antifungals and Antibiotics

Description

Amzeeq 4% foam (minocycline)	Lotrisone* 1%/0.05% lotion (clotrimazole, betamethasone)
Bactroban 2% cream (mupirocin)	Metrocream 0.75% cream Rosadan 0.75% cream (metronidazole)
Bactroban 2% ointment (mupirocin)	Neo-Synalar* 0.5%/0.025% cream (neomycin, fluocinolone)
Ciclodan 0.77% cream Loprox 0.77% cream (ciclopirox)	Naftin 1% gel, cream (naftifine)
Ciclodan nail lacquer 8% topical solution Penlac nail lacquer 8% Topical Solution (ciclopirox)	Naftin 2% gel, cream (naftifine)
Cleocin T 1% solution (clindamycin)	Nizoral 2% cream (ketoconazole)
Clindamax 1% gel Cleocin T 1% gel Glindagel 1% gel (clindamycin)	Nydamax 0.75% gel Rosadan 0.75% gel (metronidazole)
Clindamax 1% lotion Cleocin T 1% lotion (clindamycin)	Nystatin 100,000 unit/g cream
Clotrimazole 1% cream	Nystatin 100,000 unit/g ointment
Corticosporin cream (neomycin 3.5mg/1g, polymyxin B 10,000IU/1g, hydrocortisone 0.5%)	Nystatin-Triamcinolone 100,000 unit/g-0.1% cream
Corticosporin ointment (neomycin 3.5mg/1g, polymyxin B 5,000IU/1g, bacitracin 400IU/1g, hydrocortisone 1%)	Nystatin-Triamcinolone 100,000 unit/g-0.1% ointment
Econazole Nitrate 1% cream	Ovace* (sodium sulfacetamide) 10% cream
Emgel 2%, Erygel* 2% gel (erythromycin)	Ovace* 10% and Ovace Plus* 9.8% (sodium sulfacetamide) foam

Erythromycin 2% solution	Ovace* and Ovace Plus Wash* (sodium sulfacetamide) 10% gel/cleansing gel
Evoclin 1% foam (clindamycin)	Ovace Plus Wash* (sodium sulfacetamide) 10% liquid
Gentamicin 0.1% cream	Ovace Plus* (sodium sulfacetamide) 9.8% lotion
Gentamicin 0.1% ointment	Ovace Plus* (sodium sulfacetamide) 10% shampoo
Ketoconazole 2% shampoo	Plexion NS (sodium sulfacetamide) 9.8% shampoo
Ketodan 2% foam Extina* 2% foam (ketoconazole)	Vusion topical ointment (miconazole 0.25%-zinc oxide 15%-white petrolatum 81.35%)
Loprox 0.77% gel (ciclopirox)	Xolegel* 2% gel (ketoconazole)
Loprox 0.77% suspension (ciclopirox)	Zilxi 1.5% foam (minocycline)
Lotrisone* 1%/0.05% cream (clotrimazole, betamethasone)	

Topical Antifungals and Antibiotics that do not have separate criteria

* Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

Background

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Pharmacy topical products have the potential for misuse. Misuse of these topical products is quite common and it is important to inform patients about the possible complications due to overuse of these drugs. The criteria was created in order to limit existing patients that have been taking doses above the FDA recommended limits and get them down to appropriate levels. This criteria is also intended to help prevent use of topical antifungals and antibiotics in topical foot baths.

Regulatory Status

Antifungal agents kill fungi or inhibit their growth. Antifungals that kill fungi are called fungicidal while those that inhibit their growth are called fungistatic. Topical antifungals are used for simple, localized fungal infections in patients with normal immune function.

Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

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Antibiotics, or antimicrobials, are medications that destroy or slow down the growth of bacteria. Bactericidal antibiotics kill the bacteria, while bacteriostatic antibiotics stop the bacteria from multiplying. Topical antibiotics are used for localized bacterial infections.

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

The topical products included in this policy may be considered **medically necessary** if the conditions indicated below are met.

The topical products included in this policy may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have **ALL** of the following:

1. FDA-approved indication supporting the use of topical product
2. Requested drug is **NOT** being used in a footbath

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Quantity

Drug	Quantity

Sodium sulfacetamide cleansing gel	355 units per 90 days
Sodium sulfacetamide shampoo Plexion NS shampoo	237 units per 90 days
Zilxi 1.5% foam	90 units per 90 days
Ketoconazole 2% shampoo	360 units per 90 days
All other products included in this policy	180 units per 90 days

Prior - Approval Limits

Quantity

Drug	Quantity
Sodium sulfacetamide cleansing gel	355 units per 90 days
Sodium sulfacetamide shampoo Plexion NS shampoo	237 units per 90 days
Zilxi 1.5% foam	90 units per 90 days
Ketoconazole 2% shampoo	360 units per 90 days
All other products included in this policy	180 units per 90 days*
Prior Authorization for more than one product at an individual quantity of 180 units per 90 days is allowed if being used to treat different indications.	

Drug with Approved Formulary Exception Only	Quantity
Erygel 2% gel	180 units per 90 days
Extina 2% foam	180 units per 90 days
Lotrisone 1%/0.05% cream, lotion	180 units per 90 days
Neo-Synalar cream	180 units per 90 days
Ovace cream, foam, gel, liquid, lotion	180 units per 90 days
Ovace cleansing gel	355 units per 90 days
Ovace shampoo	237 units per 90 days
Xolegel 2% gel	180 units per 90 days

Duration 6 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Pharmacy topical products have the potential for misuse. Misuse of these topical products is quite common and it is important to inform patients about the possible complications due to overuse of these drugs. The criteria was created in order to limit existing patients that have been taking doses above the FDA recommended limits down to appropriate levels.

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of the topical products included in this policy while maintaining optimal therapeutic outcomes.

Policy History

Date	Action
December 2019	Addition to PA
March 2020	Addition of Econazole Nitrate 1% cream to policy
April 2020	Addition of Vusion
June 2020	Annual review. Addition of Amzeeq, Evoclin, and Zilxi to policy per FEP
August 2020	Addition of Gentamicin 0.1% ointment
September 2020	Annual review
December 2020	Annual review. Addition of Ovace / Ovace Plus / Ovace Plus Wash. Changed Pre-PA for Zilxi from 180/90 to 90/90 per SME
January 2021	Removed Bactroban 2% nasal ointment from policy due to being discontinued. Extina requires formulary exception + PA
March 2021	Annual review. Addition of Aczone (dapsone) 5% and 7.5% gel to policy
April 2021	Increased the Quantity Limit of Ketoconazole 2% shampoo to 360 units per 90 days. Added statement indicating that PA is allowed for multiple products if being used to treat different indications. Changed criteria to allow for renewals and changed approval duration to 6 months for both initiation and renewal
June 2021	Annual review
September 2021	Annual review. Aczone removed from policy to its own criteria per MQA
November 2021	Addition of Plexion NS 9.8% shampoo to policy
December 2021	Annual review. Lotrisone (brand name only) requires formulary exception + PA

September 2022	Annual review
September 2023	Annual review
September 2024	Annual review
March 2025	Annual review
December 2025	Annual review. Per FEP, Erygel 2% gel and Neo-Synalar cream require FE

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.