

# 5.90.40

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	January 1, 2020
<b>Subject:</b>	Topical Antifungals and Antibiotics	<b>Page:</b>	1 of 5

**Last Review Date:** March 12, 2021

## Topical Antifungals and Antibiotics

### Description

Aczone 5% gel (dapsone)	Loprox 0.77% suspension (ciclopirox)
Aczone 7.5% gel (dapsone)	Lotrisone 1%/0.05% cream (clotrimazole, betamethasone)
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

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Econazole Nitrate 1% cream	Ovace* (sodium sulfacetamide) 10% cream
Emgel 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	Vusion topical ointment (miconazole 0.25%-zinc oxide 15%-white petrolatum 81.35%)
Ketodan 2% foam Extina* 2% foam (ketoconazole)	Xolegel* 2% gel (ketoconazole)
Loprox 0.77% gel (ciclopirox)	Zilxi 1.5% foam (minocycline)**

## 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.

\*\*This medication is currently pending tier determination and may not be available at this time

### 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

FDA approved indication:

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.

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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** in patients with a FDA-approved indication supporting the use of topical product and if the conditions indicated below are met.

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

## Prior-Approval Requirements

### Diagnosis

Patient must have the following:

FDA-approved indication supporting the use of topical product

### Prior – Approval *Renewal* Requirements

None

### Policy Guidelines

## Pre - PA Allowance

### Quantity

Drug	Quantity
Sodium sulfacetamide cleansing gel	355 units per 90 days

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Sodium sulfacetamide shampoo	237 units per 90 days
Zilxi 1.5% foam	90 units per 90 days
All other products included in this policy	180 units per 90 days

## Prior - Approval Limits

Pre-PA allows for the FDA recommended maximum dosage

<b>Drug with approved formulary exception only</b>	<b>Quantity</b>
Extina 2% foam	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**      3 months

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## Prior-Approval *Renewal* Limits

None

### 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.

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## 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 (dapson) 5% and 7.5% gel to policy

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.**