

5.90.040

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| Section: | Prescription Drugs | Effective Date: | April 1, 2025 |
| Subsection: | Topical Products | Original Policy Date: | January 1, 2020 |
| Subject: | Topical Antifungals and Antibiotics | Page: | 1 of 6 |

Last Review Date: March 7, 2025

Topical Antifungals and Antibiotics

Description

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|--|---|
| 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% gel (erythromycin) | Ovace* 10% and Ovace Plus* 9.8% (sodium sulfacetamide) foam |

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|---|---|
| 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 |
|------|----------|
|------|----------|

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|--|-----------------------|
| Sodium sulfacetamide cleansing gel | 355 units per 90 days |
| Sodium sulfacetamide shampoo | 237 units per 90 days |
| Plexion NS shampoo | |
| 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 | 237 units per 90 days |
| Plexion NS shampoo | |
| 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* |
| <i>*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.</i> | |

| <u>Drug with Approved Formulary Exception Only</u> | Quantity |
|--|-----------------------|
| Extina 2% foam | 180 units per 90 days |
| Lotrisone 1%/0.05% cream, lotion | 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

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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 (dapson) 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 |

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| | |
|----------------|---------------|
| September 2023 | Annual review |
| September 2024 | Annual review |
| March 2025 | Annual review |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.