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5.90.041

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	January 1, 2020
Subject:	Antifungal and Antibiotic Powders	**Page:**	1 of 4

Last Review Date: March 7, 2025

Antifungal and Antibiotic Powders

Description

Antifungals: Econazole Powder, Ketoconazole Powder, Nyamyc (nystatin) Powder, Nystop (nystatin) Powder

Antibiotics: Mupirocin Powder, Tobramycin Powder, Vancomycin Powder

Background
Pharmacy compounding is an ancient practice in which pharmacists combine, mix, or alter ingredients to create unique medications that meet specific needs of individual patients. Some examples of the need for compounding products would include the following: the dosage formulation must be changed to allow a person with dysphagia (trouble swallowing) to have a liquid formulation of a commercially available tablet only product; or to obtain the exact strength needed of the active ingredient, to avoid ingredients that a particular patient has an allergy to, or simply to add flavoring to medication to make it more palatable.

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 powder products have the potential for misuse. Misuse of these powder products is quite common, and it is important to inform patients about the possible complications due to overuse of these drugs.

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.

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.

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.

Antifungal and antibiotic products included in this policy may be considered **medically necessary** if the conditions indicated below are met.

Antifungal and antibiotic products included in this policy may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

FDA-approved indication supporting the requested medication's use

AND ALL of the following for medications being compounded:

1. The requested dosage form is FDA-approved
2. The requested product is **NOT** for use in foot baths
3. The requested dose/strength does **NOT** exceed the maximum FDA-approved dose/strength for the requested ingredient
4. The requested dose is **NOT** commercially available

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Nystatin Powder **only**: 90 grams per 90 days

No Pre-PA for all other powders

Prior - Approval Limits

Duration 12 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 powder products have the potential for misuse. Misuse of these powder products is quite common, and it is important to inform patients about the possible complications due to overuse of these drugs.

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

Policy History

Date	Action
December 2019	Addition to PA

March 2020	Revised requirement to “FDA-approved indication supporting the requested medication’s use” and additional requirements only apply to medications being compounded
June 2020	Annual review
March 2021	Annual review
March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.90.041
March 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.