

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3143-4
Program	Step Therapy
Medication	ketoconazole foam (generic Extina®), Ketodan® (ketoconazole) foam
P&T Approval Date	8/2020, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Ketoconazole foam (generic Extina) and Ketodan are indicated for the treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older. The safety and efficacy of ketoconazole foam and Ketodan for treatment of fungal infections has not been established.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try ciclopirox or ketoconazole shampoo prior to receiving coverage for ketoconazole foam (generic Extina) or Ketodan.

2. Coverage Criteria^a:

<p>A. Ketoconazole foam (generic Extina) or Ketodan will be approved based on the following criterion:</p> <ol style="list-style-type: none"> 1. Patient has a history of failure, contraindication, or intolerance to one of the following: <ol style="list-style-type: none"> a. ciclopirox (generic ciclopirox gel, generic Loprox) b. ketoconazole shampoo (generic Nizoral) <p style="text-align: center;">Authorization will be issued for 1 month</p> <p>^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>
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3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may apply.

4. References:

1. Ketoconazole Foam [package insert]. Allegan, MI: Padagis; September 2022.
2. Ketodan [package insert]. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc.; September 2021.
3. Del Rosso, James Q. Adult Seborrheic Dermatitis: A Status Report on Practical Topical Management. J Clin Aesthet Dermatol. 2011;4(5):32–38.

Program	Step Therapy – Extina
Change Control	
Date	Change
8/2020	New program.
2/2022	Annual review. No changes.
2/2023	Annual review. No changes.
2/2024	Annual review. Updated references. Updated to clarify the generic products and removed brand Extina due to product discontinuation.