

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1395-5
Program	Prior Authorization/Notification
Medication	Zoryve® (roflumilast)
P&T Approval Date	9/2022, 9/2023, 11/2023, 2/2024, 12/2024
Effective Date	3/1/2025

1. Background:

Zoryve (roflumilast) 0.3% cream is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Zoryve (roflumilast) foam is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older. Zoryve (roflumilast) 0.15% cream is indicated for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

2. Coverage Criteria^a:

<p>A. <u>Plaque Psoriasis</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Zoryve 0.3% cream will be approved based upon the following criterion:</p> <p style="padding-left: 40px;">(1) Diagnosis of plaque psoriasis</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Zoryve 0.3% cream will be approved based upon the following criterion:</p> <p style="padding-left: 40px;">(1) Documentation of positive clinical response to therapy</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p> <p>B. <u>Seborrheic Dermatitis</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Zoryve foam will be approved based upon the following criterion:</p> <p style="padding-left: 40px;">(1) Diagnosis of seborrheic dermatitis</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p>

<p>a. Zoryve foam will be approved based upon the following criterion:</p> <p>(1) Documentation of positive clinical response to therapy</p> <p>Authorization will be issued for 12 months.</p> <p>C. Atopic Dermatitis</p> <p>1. <u>Initial Authorization</u></p> <p>a. Zoryve 0.15% cream will be approved based upon the following criterion:</p> <p>(1) Diagnosis of mild to moderate atopic dermatitis</p> <p>Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Zoryve 0.15% cream will be approved based upon the following criterion:</p> <p>(1) Documentation of positive clinical response to therapy</p> <p>Authorization will be issued for 12 months.</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, Medical Necessity, and/or Step Therapy may be in place.

4. References:

1. Zoryve cream [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2024.
2. Zoryve foam [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; December 2023.

Program	Prior Authorization/Notification – Zoryve (tapinarof)
Change Control	
9/2022	New program.
9/2023	Annual review with no change to clinical criteria.

11/2023	Updated background to include patients 6 years of age and older. Updated reference.
2/2024	Added criteria for Zoryve foam for seborrheic dermatitis. Updated background and reference.
12/2024	Added criteria for Zoryve 0.15% cream for atopic dermatitis. Updated plaque psoriasis criteria to specify 0.3% cream. Updated all authorizations to 12 months. Updated background and reference.