UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2287-5
Program	Prior Authorization/Medical Necessity
Medication	Zoryve® (roflumilast)
P&T Approval Date	9/2022, 2/2023, 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]:

A. Plaque Psoriasis

1. **Initial Authorization**

a. **Zoryve 0.3% cream** will be approved based on **all** of the following criteria:

(1) Diagnosis of plaque psoriasis

-AND-

(2) Minimum duration of a 4-week trial and failure, contraindication, or intolerance to **one** of the following topical therapies:

(a) Corticosteroids (e.g., betamethasone, clobetasol, desonide)
(b) Vitamin D analogs (e.g., calcitriol, calcipotriene)
(c) Tazarotene
(d) Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
(e) Anthralin
(f) Coal tar

-AND-

(3) Patient is not receiving **Zoryve 0.3% cream** in combination with a Targeted Immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Zoryve 0.3% cream** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to therapy

-AND-

(2) Patient is not receiving **Zoryve 0.3% cream** in combination with a Targeted Immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

B. Seborrheic Dermatitis

1. **Initial Authorization**

a. **Zoryve foam** will be approved based upon the following criterion:

(1) Diagnosis of seborrheic dermatitis

-AND-

(2) Minimum duration of a 4-week trial and failure, contraindication, or intolerance to at least **one** of the following therapies:

(a) Topical corticosteroids (e.g., betamethasone, hydrocortisone)
(b) Topical, shampoo, or systemic antifungals (e.g., ketoconazole, ciclopirox, itraconazole)
(c) Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

-AND-

(3) Patient is not receiving **Zoryve foam** in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Zoryve foam** will be approved based upon the following criterion:

(1) Documentation of positive clinical response to therapy

-AND-

(2) Patient is not receiving **Zoryve foam** in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Authorization will be issued for 12 months.

C. Atopic Dermatitis

1. **Initial Authorization**

a. **Zoryve 0.15% cream** will be approved based on **all** of the following criteria:

(1) Diagnosis of mild to moderate atopic dermatitis

-AND-

(2) History of failure, contraindication, or intolerance to **two** of the following therapeutic classes of topical therapies:

(a) **One** of the following:
- For mild atopic dermatitis: a topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)
- For moderate atopic dermatitis: a topical corticosteroid of at least a medium- to high-potency (e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

(b) One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]*
(c) Eucrisa (crisaborole)*

-AND-

(3) Patient is **not** receiving **Zoryve 0.15% cream** in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Zoryve 0.15% cream** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to therapy

-AND-

(2) Patient is **not** receiving **Zoryve 0.15% cream** in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

[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.
* Elidel, Protopic/tacrolimus ointment, and Eucrisa require prior authorization.

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 be in place.

4. References:

1. Zoryve cream [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2023.
2. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
3. Zoryve foam [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; December 2023.

Program	Prior Authorization/Medical Necessity - Zoryve (tapinarof)
Change Control	
9/2022	New program.
2/2023	Revised trial and failure requirement from either two topical therapies or calcipotriene and betamethasone dipropionate to a trial and failure of one topical therapy.
11/2023	Updated not to be used in combination to Targeted Immunomodulators. Simplified reauthorization criteria to only require positive clinical response and not used in combination with other treatment medications. 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. Removed prescriber requirements. Updated background and reference.