Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 10, 2024 March 18, 2025

Zoryve® (roflumilast)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

0.3% CREAM:

- Patient must be ≥ 6 years of age.
- Patient must have a documented diagnosis of plaque psoriasis, including intertriginous areas, with 2% to 20% involvement of body surface area (BSA).
- Patient has had an inadequate response, intolerance, or contraindication to a minimum 4-week trial duration on at least 1 of the following *(clinical documentation demonstrating prior treatment failures must be provided)*:
  - Preferred topical corticosteroids; **OR**
  - Calcipotriene.
- Medication is prescribed by, or in consultation with a dermatologist.
- Prescriber attests that the patient does not have moderate to severe liver impairment (Child-Pugh B or C).

0.15% CREAM:

- Patient must be ≥ 6 years of age.
- Patient must have a documented diagnosis of mild to moderate atopic dermatitis.
- Patient has had an inadequate response, intolerance, or contraindication to a minimum 4-week trial duration on at least 1 of the following *(clinical documentation demonstrating prior treatment failures must be provided)*:
  - Preferred topical corticosteroids; **OR**
  - Preferred topical calcineurin inhibitor (e.g. pimecrolimus, tacrolimus)
- Medication is prescribed by, or in consultation with a dermatologist.
- Prescriber attests that the patient does not have moderate to severe liver impairment (Child-Pugh B or C).

0.3% FOAM:

- Patient must be ≥ 9 years of age.
- Patient must have a documented diagnosis of seborrheic dermatitis.
- Patient has had an inadequate response, intolerance, or contraindication to a minimum 4-week trial duration on at least 1 of the following *(clinical documentation demonstrating prior treatment failures must be provided)*:
  - Topical antifungals (e.g., ciclopirox, ketoconazole, etc.); **OR**
  - Preferred topical corticosteroids.
- Medication is prescribed by, or in consultation with a dermatologist.

- Prescriber attests that the patient does not have moderate to severe liver impairment (Child-Pugh B or C).

Note: *The propellants in Zoryve® foam are flammable. Patients should be advised to avoid fire, flame, and smoking during and immediately following application.*

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of improved clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a 0.15% cream, 0.3% cream, and 0.3% foam