AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Zoryve (roflumilast) cream and foam	Page:	1 of 4
Effective Date:	2/13/2025	Last Review Date:	9/19/2024
Applies to:	☐Illinois ☒New Jersey ☒Maryland ☒Florida Kids ☒Pennsylvania Kids ☐Virginia		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Zoryve cream and foam under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Zoryve Cream
Plaque Psoriasis
Zoryve cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.

Atopic Dermatitis
Zoryve cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

Zoryve Foam
Zoryve foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

Applicable Drug List:

Zoryve (roflumilast) 0.3% cream
Zoryve (roflumilast) 0.15% cream
Zoryve (foflumilast) 0.3% foam

Policy/Guideline:

Criteria for Initial Approval:

Atopic Dermatitis
Authorization may be granted when the requested drug is being prescribed for the topical treatment of mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) CREAM 0.15%
- The patient is 6 years of age or older
- The patient has experienced an inadequate treatment response, intolerance, OR has a contraindication to a topical calcineurin inhibitor OR a medium or higher potency topical corticosteroid
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month
- Patient is unable to take Eucrisa for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication

Plaque Psoriasis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of plaque psoriasis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) cream 0.3%
- The patient is 6 years of age or older
- The patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response, intolerance OR has a contraindication to a topical steroid
    - The requested drug will be used on sensitive skin areas (e.g., face, genitals or skin folds)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

Seborrheic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of seborrheic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) foam
- The patient is 9 years of age or older
- The patient meets ONE of the following:
    - The patient is less than 16 years of age
    - The patient has experienced an inadequate treatment response, intolerance OR has a contraindication to a topical ketoconazole (i.e., 2% shampoo, 2% cream, 2% foam, 2% gel) OR a topical ciclopirox (i.e., 0.77% gel, 1% shampoo) product
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

Criteria for Continuation of Therapy

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) cream 0.15%
- The patient is 6 years of age or older
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)]
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

Plaque Psoriasis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of plaque psoriasis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) cream 0.3%
- The patient is 6 years of age or older
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, patient satisfaction, etc.)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

Seborrheic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of seborrheic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) foam
- The patient is 9 years of age or older
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, improvement from baseline, etc.)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

Approval Duration and Quantity Restrictions:

Initial Approval: 3 months

Renewal Approval: 12 months

Quantity Level Limit: 60 grams per 30 days; for body surface areas requiring more than 60gm per month: 120gm per 30 days

References:

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15. Clark GW, Pope SM, Jaboori KA. Diagnosis and Treatment of Seborrheic Dermatitis. *Am Fam Physician*. 2015;91(3):185-190. Available at: https://www.aafp.org/pubs/afp/issues/2015/0201/p185.html. Accessed: June 5, 2024.