Reference number(s)
5538-E

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit
Zoryve

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Zoryve	roflumilast	cream
Zoryve	roflumilast	foam

Indications

FDA-approved Indications

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

Seborrheic Dermatitis

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

Plaque Psoriasis

Zoryve topical foam, 0.3%, is indicated for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

Initial Step Therapy with Quantity Limit

Include Prescription (Rx) and Over-the-counter (OTC) products unless otherwise stated.

Initial Step Therapy For Zoryve (roflumilast) Cream 0.3%

If the patient has filled a prescription for at least a 30-day supply of a topical steroid within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Initial Step Therapy For Zoryve (roflumilast) Cream 0.15%:

If the patient has filled a prescription for at least a one day supply of a topical calcineurin inhibitor OR a medium or higher potency topical corticosteroid within the past 180 days (see Table 1) under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Initial Step Therapy For Zoryve (roflumilast) Foam

If the patient has filled a prescription for at least a 30-day supply of 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 OR a topical steroid within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

Initial Limit Criteria

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Zoryve (roflumilast) 0.15%, 0.3% Cream	60 grams / 25 days	180 grams / 75 days
Zoryve (roflumilast) 0.3% Foam	60 grams / 25 days	180 grams / 75 days

Table 1: Examples of Topical Corticosteroids for Treatment of a Atopic Dermatitis[7,8,11]

Potency	Examples
Medium Potency	• betamethasone dipropionate lotion, spray 0.05% • betamethasone valerate cream/lotion 0.1%/foam 0.12% • clocortolone pivalate cream 0.1% • desonide lotion, ointment 0.05% • desoximetasone cream 0.05% • fluocinolone acetonide cream/ointment/kit 0.025% • flurandrenolide cream/lotion 0.05% • fluticasone propionate cream/lotion 0.05%/ointment 0.005% • hydrocortisone valerate cream/ointment 0.2% • mometasone furoate cream/solution 0.1% • prednicarbate cream/ointment 0.1% • triamcinolone acetonide cream/kit/lotion/ointment 0.1% • triamcinolone acetonide cream/lotion/ointment 0.025%
High Potency	• amcinonide cream/ointment/lotion 0.1% • betamethasone dipropionate cream/ointment 0.05% • betamethasone dipropionate augmented cream/lotion 0.05%

Potency	Examples
	• betamethasone valerate ointment 0.1% • desoximetasone cream/ointment/spray 0.25%/gel/ointment 0.05% • diflorasone diacetate cream 0.05%fluocinonide cream/emulsified cream/ointment/gel/solution 0.05% • halcinonide cream/solution 0.1% • mometasone furoate ointment 0.1% • triamcinolone acetonide aerosol solution 0.147 mg/g • triamcinolone acetonide cream/ointment 0.5%
Very High Potency	• betamethasone dipropionate augmented ointment/gel 0.05% • clobetasol propionate cream/foam/gel/lotion/ointment/shampoo/solution/spray 0.05%/cream 0.025% • diflorasone diacetate ointment 0.05% • fluocinonide cream 0.1% • flurandrenolide tape 4 mcg/cm2 • halobetasol propionate cream/kit/lotion/ointment 0.05%

Coverage Criteria

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 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.

Plaque Psoriasis

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

- The request is for Zoryve (roflumilast) CREAM 0.3% and the patient meets ALL of the following criteria:
    - 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 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.
- The request is for Zoryve (roflumilast) FOAM and the patient meets ALL of the following criteria:
    - The patient is 12 years of age or older.
    - The requested drug will be used on the scalp or body.
    - The patient meets ONE of the following:
        - The patient has experienced an inadequate treatment response, intolerance, or 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 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.

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 ONE of the following criteria is met:

- The request is for Zoryve (roflumilast) CREAM 0.3% and the patient meets ALL of the following criteria:
    - 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.
- The request is for Zoryve (roflumilast) FOAM and the patient meets ALL of the following criteria:
    - The patient is 12 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.

Quantity Limits Apply

60 grams per 25 days or 180 grams per 75 days

For body surface areas requiring more than 60 grams per month: 120 grams per 25 days or 360 grams per 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 5538-E: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

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16. Clark GW, Pope SM, Jaboori KA. Diagnosis and Treatment of Seborrheic Dermatitis. Am Fam Physician. 2015;91(3):185-190.