Effective date: 12/1/2022
Last Reviewed: 9/2022, 6/2023, 3/2024, 9/2024, 11/2025 Scope: Medicaid

ZORYVE (roflumilast) cream and foam

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Zoryve Cream 0.3%

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

Zoryve Cream 0.15%

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

Zoryve Cream 0.05%

Zoryve cream, 0.05%, is indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

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.

Zoryve 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.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Plaque Psoriasis (PsO)

Requests for Zoryve Cream 0.3%

Initial authorization of 12 months may be granted for members when the following criteria are met:

1. Documentation that the member is 6 years of age or older diagnosed with plaque psoriasis
2. BSA affected is between 2-20%. Documentation of BSA affected is provided.
3. Zoryve is prescribed by, or in consultation with, a specialist in dermatology, allergy/immunology or rheumatology.
4. Documentation that the member experienced an inadequate treatment response to at least a 2-4 consecutive week trial within the last 12 months of a high or ultra-high potency topical corticosteroid (e.g., augmented betamethasone, clobetasol). Contraindications, adverse effects and/or intolerance must be documented.

5. Documentation that the member experienced an inadequate treatment response or intolerance from two of the following therapies in combination with a topical corticosteroid within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
    a. Topical calcineurin inhibitors (e.g., tacrolimus ointment, pimecrolimus cream)
    b. Topical vitamin D analogs (e.g., calcipotriene 0.005% ointment, cream, solution)
    c. Topical retinoid (e.g., tazarotene cream 0.1%)
    d. Phototherapy
    e. Oral systemic non-biologic drugs (e.g., methotrexate or cyclosporine)
6. Zoryve will not be used concomitantly with Vtama (tapinoraf) cream, any biologic DMARD (e.g., adalimumab, infliximab) or any targeted synthetic DMARD (e.g., apremilast).

Requests for Zoryve Foam
Initial authorization of 12 months may be granted for members when the following criteria are met:

1. Documentation that the member is 12 years of age or older diagnosed with plaque psoriasis
2. Documentation that BSA affected is ≤25%, with ≥10% affecting scalp and ≤20% affecting non-scalp areas.
3. Zoryve is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
4. Documentation that the member experienced an inadequate treatment response to at least a 2-4 consecutive week trial within the last 12 months of a high or ultra-high potency topical corticosteroid (e.g., augmented betamethasone, clobetasol). Contraindications, adverse effects and/or intolerance must be documented.
5. Documentation that the member experienced an inadequate treatment response or intolerance from one of the following therapies in combination with a topical corticosteroid within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
    a. Topical calcineurin inhibitors (e.g., tacrolimus ointment, pimecrolimus cream)
    b. Topical vitamin D analogs (e.g., calcipotriene 0.005% ointment, cream, solution)
    c. Topical retinoid (e.g., tazarotene cream 0.1%)
    d. Phototherapy
    e. Oral systemic non-biologic drugs (e.g., methotrexate or cyclosporine)
6. Zoryve will not be used concomitantly with Vtama (tapinoraf) cream, any biologic DMARD (e.g., adalimumab, infliximab) or any targeted synthetic DMARD (e.g., apremilast).

B. Atopic Dermatitis (AD)
Initial authorization of 12 months may be granted for members when the following criteria are met:

1. Documentation that the member is 2 years of age or older.
2. Zoryve is prescribed by, or in consultation with, a specialist in dermatology or allergy/immunology.
3. Documentation that the member has a diagnosis of mild to moderate AD with affected body surface area (BSA) of 3% to 20%. Documentation of BSA affected is provided.
4. Documentation that the member experienced an inadequate treatment response or intolerance to at least one medium to super-high potency topical corticosteroid for at least 2 consecutive weeks. Contraindications, adverse effects and/or intolerance must be documented.
5. Documentation that the member experienced an inadequate treatment response or intolerance to one of the following 3 formulary topical drugs: tacrolimus ointment for 6 consecutive weeks, pimecrolimus cream for 6 consecutive weeks or Eucrisa (crisaborole) ointment for 4 consecutive weeks. Contraindications, adverse effects and/or intolerance must be documented.

6. Zoryve will not be used concomitantly with Eucrisa (crisaborole) ointment, Opzelura (ruxolitinib) cream, Vtama (tapinoraf) cream, Anzupgo (delgocitinib) cream, any therapeutic biologics, or JAK inhibitors.

C. Seborrheic Dermatitis

Initial authorization of 12 months may be granted for members when the following criteria are met:

1. Documentation that the member is 9 years of age or older, diagnosed with seborrheic dermatitis
2. Zoryve is prescribed by, or in consultation with, a specialist in dermatology.
3. Member meets one of the following:
    a. For members 9-15 years of age, member experienced an inadequate treatment response or intolerance from two of the following therapies within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
        i. Topical ketoconazole (i.e., 2% shampoo, 2% cream)
        ii. Topical corticosteroids (e.g., fluocinolone 0.01% solution, betamethasone valerate 0.1% cream, desonide 0.05% cream or ointment)
        iii. Topical calcineurin inhibitors (e.g., tacrolimus ointment, pimecrolimus cream).
    b. For members 16 years of age and older, member meets both of the following:
        i. Member experienced an inadequate treatment response or intolerance from response to at least a 4 week trial within the last 12 months of topical ketoconazole (i.e., 2% shampoo, 2% cream). Contraindications, adverse effects and/or intolerance must be documented.
        ii. Member experienced an inadequate treatment response or intolerance from two of the following therapies within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
            a. Ciclopirox 1% shampoo or 0.77% cream
            b. Topical corticosteroids (e.g., fluocinolone 0.01% solution, betamethasone valerate 0.1% cream, desonide 0.05% cream or ointment)
            c. Topical calcineurin inhibitors (e.g., tacrolimus ointment, pimecrolimus cream)
4. Zoryve will not be used concomitantly with Vtama (tapinoraf) cream, any biologic DMARD (e.g., adalimumab, infliximab) or any targeted synthetic DMARD (e.g., apremilast).

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members who are using the requested medication for plaque psoriasis, atopic dermatitis, and seborrheic dermatitis when the following criteria are met:

1. Documentation that the member achieves or maintains a positive clinical response as evidenced by improvement in signs and symptoms of the condition when any of the following is met:
    a. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, swelling, lichenification, burning, cracking, pain, clear or almost clear skin)
    b. Reduction in body surface area (BSA) affected from baseline
2. Zoryve will not be used concomitantly with Vtama (tapinoraf) cream, Eucrisa (crisaborole) ointment, Opzelura (ruxolitinib) cream, Anzupgo (delgocitinib) cream, any therapeutic biologic (e.g., adalimumab, infliximab), or any targeted synthetic DMARD (e.g., apremilast, JAK inhibitors).

IV. QUANITY LIMIT

Zoryve 0.05% cream, 0.15% cream, 0.3% cream, and 0.3% foam have a quantity limit of 60 grams per 30 days.

V. REFERENCES

1. Zoryve Cream [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2025.
2. Zoryve Foam [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; May 2025.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/04/2024).
4. Elmets CA, Korman NJ, Prater EF, 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(2):432-470.
5. Menter A, Cordoro K, Davis D, et al. Guidelines of Care for the Management and Treatment of Psoriasis in Pediatric Patients. *J Am Acad Dermatol*. 2020;82(1):161-201.
6. Dall'Oglio F, Nasca MR, Gerbino C, et al. An Overview of the Diagnosis and Management of Seborrheic Dermatitis. August 6, 2022. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9365318/. Accessed March 4, 2024.
7. Desai S, McCormick E, Friedman A, An Up-to-Date Approach to the Management of Seborrheic Dermatitis. December 20223. 21 (12). Available at: https://jddonline.com/articles/an-up-to-date-approach-to-the-management-of-seborrheic-dermatitis-S1545961622P1373X/. Accessed March 4, 2024.
8. 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: March 4, 2024.
9. Eichenfield, Lawrence F. et al. Guidelines of care for the management of atopic dermatitis. Journal of the American Academy of Dermatology, Volume 71, Issue 1, 116 – 132.
10. Chu, Derek K. et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE– and Institute of Medicine–based recommendations. Annals of Allergy, Asthma & Immunology, Volume 132, Issue 3, 274 – 312.