STEP THERAPY POLICY

POLICY: Topical Products – Zoryve Foam Step Therapy Policy

- Zoryve® Foam (roflumilast 0.3% topical foam – Arcutis)

REVIEW DATE: 02/11/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Zoryve® foam, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for the treatment of **seborrheic dermatitis** in patients ≥ 9 years of age and for the treatment of **plaque psoriasis** of the scalp and body in patients ≥ 12 years of age.[1] Of note, Zoryve is also available as a 0.05% cream for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 years to 5 years of age; a 0.15% cream for the topical treatment of mild to moderate atopic dermatitis in adults and pediatric patients ≥ 6 years of age; and as a 0.3% cream for the topical treatment of plaque psoriasis, including intertriginous areas, in adults and pediatric patients ≥ 6 years of age.[2]

GUIDELINES

There are no formal treatment guidelines for the management of **seborrheic dermatitis**. The current standard of care for seborrheic dermatitis is to use multiple agents (usually an antifungal and/or anti-inflammatory). The American

Academy of Dermatology cite topical antifungal agents as typical first-line therapy.[3] Low potency topical corticosteroids may be considered as first-line or second-line therapy; however, use is limited to short durations due to the potential for adverse effects. Additionally, recommendations provided by the Clinical, Cosmetic, and Investigational Dermatology (CCID) [2022] non-preferentially recommend topical ciclopirox or topical ketoconazole for scalp and non-scalp seborrheic dermatitis; formulation is guided by patient preference.[4]

The mainstay of treatment of **plaque psoriasis** is topical therapy, including corticosteroids, vitamin D analogs, calcineurin inhibitors, keratolytics (e.g., tazarotene), and combination therapies (e.g., a corticosteroid with a vitamin D analog).[5] Joint guidelines from the American Academy of Dermatology (AAD) and the Medical Board of the National Psoriasis Foundation (NPF) [2021] have been published for the management of psoriasis with topical therapies.[6] Zoryve 0.3% foam is not addressed in the guidelines. Use of a topical corticosteroid for up to 4 weeks is recommended for plaque psoriasis not involving intertriginous areas (strength of recommendation, A). A topical vitamin D analog can be used long-term (up to 52 weeks) for the treatment of psoriasis [strength of recommendation, A]. Guidelines also address the use of topical calcineurin inhibitors, topical tazarotene, topical salicyclic acid, and phototherapy.

Policy Statement

This program has been developed to encourage the use of one Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: Topical Corticosteroids (medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid) [Brand and Generic Products] {See Table 1}

Table 1. Topical Corticosteroids (Groups 1, 2, 3, and 4).[7]

Generic Name	Strength	Formulations
Group 1: Super-High Potency		
Betamethasone dipropionate, augmented	0.05%	ointment, gel, lotion
Clobetasol propionate	0.05%	cream, foam, gel, lotion, ointment, shampoo, solution, spray
Fluocinonide	0.1%	cream
Flurandrenolide	4 mcg/cm^2	tape
Halobetasol propionate	0.05%	cream, foam, ointment, lotion
Group 2: High Potency		
Amcinonide	0.1%	ointment
Betamethasone dipropionate, augmented	0.05%	cream
Betamethasone dipropionate	0.05%	cream, ointment
Clobetasol propionate	0.025%	cream
Desoximetasone	0.25%	cream, ointment, spray
	0.05%	gel
Diflorasone diacetate	0.05%	cream (emollient), ointment
Fluocinonide	0.05%	cream, gel, ointment, solution
Halcinonide	0.1%	cream, ointment
Halobetasol propionate	0.01%	lotion
Group 3: Medium-High Potency		
Amcinonide	0.1%	cream, lotion
Betamethasone dipropionate	0.05%	cream (emollient)
Betamethasone valerate	0.1%	ointment
	0.12%	foam
Desoximetasone	0.05%	cream, ointment
Diflorasone diacetate	0.05%	cream
Fluocinonide-E	0.05%	cream (emollient)
Fluticasone propionate	0.005%	ointment
Mometasone furoate	0.1%	ointment
Triamcinolone acetonide	0.5%	cream, ointment
Group 4: Medium Potency		
Betamethasone dipropionate	0.05%	spray
Clocortolone pivalate	0.1%	cream
Fluocinolone acetonide	0.025%	ointment
Flurandrenolide	0.05%	ointment
Hydrocortisone valerate	0.2%	ointment
Mometasone furoate	0.1%	cream, lotion, solution
Triamcinolone acetonide	0.1%	cream, ointment
	0.05%	ointment
	0.2 mg per 2-second spray	aerosol spray

Step 2: Zoryve 0.3% foam

Topical Products – Zoryve Foam Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. Approve a Step 2 Product if patient meets ONE of the following (A, B, or C):
  A) Patient has tried one Step 1 Product; OR
  B) Patient is treating seborrheic dermatitis and meets ONE of the following (i, ii, iii, or iv):
    i. Patient has tried one prescription topical corticosteroid (brand or generic); OR
    ii. Patient has tried a combination product containing a topical corticosteroid; OR
    iii. Patient has tried one topical antifungal (brand or generic); OR
    Note: Topical antifungals include ketoconazole 2% cream/foam/shampoo, ciclopirox 0.77% cream/gel, or ciclopirox 1% shampoo.
    iv. Patient has tried a combination product containing a topical antifungal; OR
  C) Patient is treating plaque psoriasis and meets ONE of the following (i, ii, or iii):
    i. Patient has tried one topical vitamin D analog; OR
    Note: Topical vitamin D analogs include calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% foam, calcipotriene 0.005% ointment, calcipotriene 0.005% solution, calcitriol 3 mcg/g ointment (Vectical, generic), Sorilux.
    ii. Patient has tried one combination product containing a topical vitamin D analog and topical corticosteroid; OR
    Note: Topical products containing a vitamin D analog and a topical corticosteroid include calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension (Taclonex, generic), Enstilar, Wynzora.
    iii. Patient is treating plaque psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia.

REFERENCES

1. Zoryve® 0.3% topical foam [prescribing information]. Westlake Village, CA: Arcutis; May 2025.
2. Zoryve® cream [prescribing information.] Westlake, CA; Arcutis Biotherapeutics: October 2025.
3. Jackson JM, Alexis A, Zirwas M, et al. Unmet needs for patients with seborrheic dermatitis. *J Am Acad Dermatol*. 2024;90(3):597-604.
4. Dall'Oglio F, Nasca MR, Gerbino G, et al. An overview of the diagnosis and management of seborrheic dermatitis. *Clinical, Cosmetic and Investigational Dermatology.* 2022:15 1537–1548.
5. Griffiths CEM, Armstrong AW, Gudjonsson JE, Barker JNWN. Psoriasis. *Lancet*. 2021;397:1301-1315.
6. Elmets C, 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;84:432-470.

7. Facts and Comparisons® Online. Wolters Kluwer Health; 2021. Available at: https://fco.factsandcomparisons.com/lco/action/home. Accessed on February 5, 2026. Search terms: topical corticosteroids.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/14/2024
Annual Revision	No criteria changes.	02/19/2025
Selected Revision	**Step 1 products:** Changed to brand and generic medium, medium-high, high, and super high potency topical corticosteroids from topical generic steroids and topical generic antifungals. **Zoryve 0.3% Foam criteria:** For patients treating seborrheic dermatitis, exceptions were added if patient has tried one prescription topical corticosteroid (brand or generic) or if the patient has tried one topical antifungal. The exceptions that patient has tried a combination product containing a topical corticosteroid or a combination product containing a topical antifungal were specified for patients treating seborrheic dermatitis. For patients treating plaque psoriasis, exceptions were added if patient has tried a topical vitamin D analog or a combination topical vitamin D analog and corticosteroid, or if the patient is treating plaque psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia.	08/20/2025
Annual Revision	No criteria changes.	02/11/2026

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