Clinical Policy: Roflumilast (Zoryve Foam only)

Reference Number: PA.CP.PMN.46
Effective Date: 09/2024
Last Review Date: 08/2025

Description
Roflumilast (Zoryve®) is a selective phosphodiesterase 4 inhibitor.

FDA Approved Indication(s)
Zoryve foam is indicated for the treatment of:

- seborrheic dermatitis in adult and pediatric patients 9 years of age and older;
- plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Zoryve foam is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Request is for roflumilast foam (Zoryve);
2. Diagnosis of plaque psoriasis;
3. Member has body surface area involvement ≤ 20% (≤ 25% if scalp is involved);
4. Prescribed by or in consultation with a dermatologist or rheumatologist;
5. Age ≥ 12 years;
6. Member meets one of the following (a or b):
   a. Failure of both of the following (i and ii) used concurrently, unless clinically significant adverse effects are experienced or all are contraindicated:
      i. Medium to ultra-high potency topical corticosteroid (*see Appendix B)*;
      ii. Calcipotriene, calcitriol, or tazarotene;
   b. For face or intertriginous areas (e.g., genitals, armpits, forearms, and groin): Failure of a topical calcineurin inhibitor* (*see Appendix B),* unless contraindicated or clinically adverse effects are experienced;
      **Prior authorization may be required for topical calcineurin inhibitors*
7. Request does not exceed 1 can per month.

Approval duration: 12 months

B. Seborrheic Dermatitis (must meet all)**:**

1. Request is for roflumilast foam (Zoryve);
2. Diagnosis of seborrheic dermatitis;
3. Member has body surface area involvement ≤ 20%;
4. Prescribed by or in consultation with a dermatologist;
5. Age ≥ 9 years;

6. Failure of both of the following (a and b), unless clinically significant adverse effects are experienced or all are contraindicated:
   a. Topical antifungal (*see Appendix B);*
   b. Topical corticosteroid (*see Appendix B);*
7. Request does not exceed 1 can per month.

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Plaque Psoriasis (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Request is for roflumilast foam (Zoryve);
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 1 can per month.

Approval duration: 12 months

B. Seborrheic Dermatitis (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Request is for roflumilast foam (Zoryve);
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 1 can per month.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

PLAQUE PSORIASIS		
Drug Name	**Dosing Regimen**	**Dose Limit/ Maximum Dose**
calcipotriene (Dovonex®) cream, ointment, solution	Apply topically to the affected area(s) BID	100 g/week
calcitriol (Vectical™) ointment	Apply topically to the affected area(s) BID	200 g/week
tazarotene (Tazorac®) gel, cream	Apply topically to the affected area(s) QHS	Once daily application
Ultra-High Potency Topical Corticosteroids		
augmented betamethasone dipropionate 0.05% (Diprolene®, Alphatrex®) ointment, gel	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
clobetasol propionate 0.05% (Temovate®, Temovate E®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Apexicon®) ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency Topical Corticosteroids		
augmented betamethasone dipropionate 0.05% (Diprolone®, Diprolene® AF) cream, lotion	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
betamethasone dipropionate 0.05% ointment		
desoximetasone (Topicort®) 0.25%, 0.05% cream, ointment, gel		
diflorasone 0.05% (Apexicon E®) cream		

fluocinonide acetonide 0.05% cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium/Medium to High Potency Topical Corticosteroids		
betamethasone dipropionate 0.05% cream	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
desoximetasone 0.05% (Topicort®) cream, ointment, gel		
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
fluticasone propionate 0.05% (Cutivate®) cream		
mometasone furoate 0.1% (Elocon®) cream, lotion, ointment		
triamcinolone acetonide 0.1%, 0.25%,0.5% (Aristocort®, Kenalog®) cream, ointment		
Combination Corticosteroid + (Vitamin D Analog or Retinoid)		
Enstilar® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) foam	Apply topically to affected areas QD for up to 4 weeks. Avoid use on face, groin, axillae, skin treatment site with atrophy present, or with occlusive dressing unless directed by a healthcare provider	60 g/4 days
Duobrii® (halobetasol propionate 0.01% and tazarotene 0.045%) lotion	Apply a thin layer of lotion once daily to affected areas until control is achieved	50 g/week
Topical Calcineurin Inhibitors		
tacrolimus (Protopic®) **(off-label)**	Apply twice daily to psoriatic lesions of the face and intertriginous areas	2 applications/day
pimecrolimus (Elidel®) **(off-label)**	Apply twice daily to affected intertriginous areas	2 applications/day
SEBORRHEIC DERMATITIS		
Drug Name	**Dosing Regimen**	**Dose Limit/ Maximum Dose**
Topical Antifungal		

ketoconazole (Nizoral® A-D, Extina®, Ketodan®, Xolegel™) 1-2% shampoo, 1-2% cream, foam, gel	Refer to prescribing information	Refer to prescribing information
ciclopirox 1-1.5% shampoo, 0.77% gel, 1% cream		
miconazole 2% solution		
clotrimazole (Lotrimin®) 1% cream, ointment, solution		
econazole (Ecoza®) 1% cream, foam		
Topical Corticosteroids		
betamethasone dipropionate 0.05% cream, gel, lotion, spray; betamethasone valerate 0.12% foam, 0.1% cream, lotion	Refer to prescribing information	Refer to prescribing information
clobetasol propionate (Temovate®, Temovate E®) 0.05% cream, ointment, gel, solution, shampoo		
desonide (Desowen®, Tridesilon®, Verdeso®) 0.05% cream, foam, gel, lotion, ointment		
hydrocortisone (NuZon®, NuCort®) 0.5-2.5% cream, ointment, lotion		
fluocinolone (Synalar®) 0.01% shampoo, lotion, cream		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): moderate to severe liver impairment (Child-Pugh B or C)
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Seborrheic dermatitis	Apply foam to affected areas once daily	Once daily application
Plaque psoriasis	Apply foam to affected areas once daily	Once daily application

VI. Product Availability

Foam 0.3%: 60 gm can

VII. References

1. Zoryve Foam Prescribing Information. Westlake Village, VA: Arcutis Biotherapeutics, Inc; May 2025. Available at: https://www.zoryvehcp.com. Accessed May 28, 2025.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2025. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 29, 2025.
3. 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):432-70.
4. Menter A, Cordoro KM, Davis DMR, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis in pediatric patients. J Am Acad Dermatol 2020;82(1):161-201.
5. Borda LJ and Wikramanayake TC. Seborrheic dermatitis and dandruff: A comprehensive review. J Clin Investig Dermatol. 2015 December; 3(2):1-22.
6. Dall'Oglio F, Nasca MR, Gerbino C and Micali G. An overview of the diagnosis and management of seborrheic dermatitis. Clinical, Cosmetic and Investigational Dermatology 2022:15 1537-1548.

Reviews, Revisions, and Approvals	Date
Policy created	08/2024
3Q 2025 annual review: RT4: added newly FDA-approved indication of plaque psoriasis for Zoryve foam; removed econazole, luliconazole, oxiconazole, and sulconazole from Appendix B as there is insufficient evidence for the use of these agents in seborrheic dermatitis; references reviewed and updated.	07/2025