

**Clinical Policy: Roflumilast (Zoryve Foam only)**

Reference Number: PA.CP.PMN.46

Effective Date: 09/2024

Last Review Date: 08/2024

**Description**

Roflumilast (Zoryve<sup>®</sup>) 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.

**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<sup>®</sup> that Zoryve foam is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

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

1. Request is for roflumilast foam (Zoryve);
2. Diagnosis of seborrheic dermatitis with body surface area involvement  $\leq 20\%$ ;
3. Prescribed by or in consultation with a dermatologist;
4. Age  $\geq 9$  years;
5. 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*);
6. Request does not exceed 1 can per month.

**Approval duration: 12 months**

**B. 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. 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**

**B. 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.*

<b>SEBORRHEIC DERMATITIS</b>		
<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
<b>Topical Antifungal</b>		
ketoconazole (Nizoral <sup>®</sup> A-D, Extina <sup>®</sup> , Ketodan <sup>®</sup> , Xolegel <sup>™</sup> ) 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 <sup>®</sup> ) 1% cream, ointment, solution		
econazole (Ecoza <sup>®</sup> ) 1% cream, foam		
luliconazole (Luzu <sup>®</sup> ) 1% cream		
oxiconazole (Oxistat <sup>®</sup> ) 1% cream, lotion		
sulconazole (Exelderm <sup>®</sup> ) 1% cream, solution		
<b>Topical Corticosteroids</b>		
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

<b>SEBORRHEIC DERMATITIS</b>		
<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
clobetasol propionate (Temovate <sup>®</sup> , Temovate E <sup>®</sup> ) 0.05% cream, ointment, gel, solution, shampoo		
desonide (Desowen <sup>®</sup> , Tridesilon <sup>®</sup> , Verdeso <sup>®</sup> ) 0.05% cream, foam, gel, lotion, ointment		
hydrocortisone (NuZon <sup>®</sup> , NuCort <sup>®</sup> ) 0.5-2.5% cream, ointment, lotion		
fluocinolone (Synalar <sup>®</sup> ) 0.01% shampoo, lotion, cream		

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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**

<b>Indication</b>	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
Seborrheic dermatitis	Apply foam to affected areas once daily	Once daily application

**VI. Product Availability**

Foam 0.3%: 60 gm

**VII. References**

1. Zoryve Foam Prescribing Information. Westlake Village, VA: Arcutis Biotherapeutics, Inc; December 2023. Available at: <https://www.zoryvehcp.com>. Accessed May 8, 2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed May 14, 2024.
3. Borda LJ and Wikramanayake TC. Seborrheic dermatitis and dandruff: A comprehensive review. J Clin Investig Dermatol. 2015 December; 3(2):1-22.
4. 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.

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>
Policy created	08/2024