# Clinical Policy: Roflumilast (Daliresp, Zoryve)

Reference Number: CP.PMN.46
Effective Date: 11.01.11
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

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

## FDA Approved Indication(s)

Daliresp is indicated as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

Zoryve is indicated:

- 0.3% cream: for the topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.
- 0.15% cream: for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.
- Foam: for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

Limitation(s) of use:

- Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.
- Daliresp 250 mcg is a starting dose for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

## 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 health plans affiliated with Centene Corporation® that roflumilast, Daliresp, and Zoryve are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Chronic Obstructive Pulmonary Disease** (must meet all)**:**

1. Request is for roflumilast tablet (Daliresp);
2. Diagnosis of COPD;
3. Age ≥ 18 years;
4. Current (within the past 30 days) forced expiratory volume in one second ($FEV_1$) < 50% predicted;

5. Member meets one of the following (a or b):
   a. Failure of triple inhaled therapy consisting of a combination of a long-acting beta$_2$-agonist (LABA), long-acting antimuscarinic antagonist (LAMA), and inhaled corticosteroid (ICS) at up to maximally indicated doses;
   b. Both i and ii:
      i. Failure of dual inhaled therapy consisting of a combination of a LABA and LAMA at up to maximally indicated doses;
      ii. Current (within the past 30 days) blood eosinophil count < 100 cells/uL;
6. Daliresp is prescribed concurrently with a long-acting bronchodilator (i.e., LABA or LAMA);
7. For brand Daliresp requests, member must use generic roflumilast, unless contraindicated or clinically significant adverse effects are experienced;
8. Dose does not exceed both of the following (a and b):
   a. 500 mcg per day;
   b. 1 tablet per day.

**Approval duration: 12 months**

**B. Plaque Psoriasis** (must meet all)**:**
1. Request is for roflumilast 0.3% cream (Zoryve);
2. Diagnosis of plaque psoriasis with body surface area involvement ≤ 20%;
3. Prescribed by or in consultation with a dermatologist or rheumatologist;
4. Age ≥ 6 years;
5. 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*
6. Request does not exceed 1 tube per month.

**Approval duration: 12 months**

**C. Seborrheic Dermatitis** (must meet all)**:**
1. Request is for roflumilast foam (Zoryve);
2. Diagnosis of seborrheic dermatitis with body surface area involvement ≤ 20%;
3. Prescribed by or in consultation with a dermatologist;
4. Age ≥ 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**

**D. Atopic Dermatitis** (must meet all)**:**
1. Request is for roflumilast 0.15% cream (Zoryve);
2. Diagnosis of atopic dermatitis;
3. Age ≥ 6 years;
4. Failure of both of the following (a and b), each tried for 2 weeks, unless clinically significant adverse effects are experienced or all are contraindicated:
   a. Two generic medium to very high potency topical corticosteroids of different molecular identities (*see Appendix B)*, unless involved areas include the face, neck, or intertriginous areas;
   b. Topical tacrolimus;
      **Prior authorization may be required for topical tacrolimus*
5. Dose does not exceed 1 tube per month.

**Approval duration: 12 months**

**E. Other diagnoses/indications** (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Chronic Obstructive Pulmonary Disease** (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is receiving benefit from the referenced states for the applicable product and regulation (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Request is for roflumilast tablet (Daliresp);
3. Member is responding positively to therapy;
4. For brand Daliresp requests, member must use generic roflumilast, unless contraindicated or clinically significant adverse effects are experienced;

5. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 500 mcg per day;
   b. 1 tablet per day.

**Approval duration: 12 months**

**B. Plaque Psoriasis** (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is receiving benefit from the referenced states for the applicable product and regulation (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Request is for roflumilast 0.3% cream (Zoryve);
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 1 tube per month.

**Approval duration: 12 months**

**C. Seborrheic Dermatitis** (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is receiving benefit from the referenced states for the applicable product and regulation (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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**

**D. Atopic Dermatitis** (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is receiving benefit from the referenced states for the applicable product and regulation (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Request is for roflumilast 0.15% cream (Zoryve);
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 1 tube per month.

**Approval duration: 12 months**

**E. Other diagnoses/indications** (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## 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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration
$FEV_1$: forced expiratory volume in one second
ICS: inhaled corticosteroid
LABA: long-acting $beta_2$-agonist
LAMA: long-acting antimuscarinic antagonist

*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 for all relevant lines of business and may require prior authorization.*

| COPD | | |
|---|---|---|
| **Drug Name** | **Dosing Regimen** | **Dose Limit/ Maximum Dose** |
| *ICS/LABA Combinations* | | |
| fluticasone/salmeterol (Advair Diskus®) | Refer to prescribing information | Refer to prescribing information |
| Breo Ellipta® (fluticasone/ vilanterol) | | |
| budesonide/formoterol (Symbicort®) | | |
| Dulera®* (mometasone/ formoterol) | Doses of 10 mcg formoterol/400 mcg mometasone and 10 mcg formoterol/ 200 mcg mometasone, each inhaled BID, have been studied | The optimal dose has not been established |

| COPD | | |
|---|---|---|
| **Drug Name** | **Dosing Regimen** | **Dose Limit/ Maximum Dose** |
| *LABA/LAMA Combinations* | | |
| Bevespi Aerosphere® (formoterol/glycopyrrolate) | Refer to prescribing information | Refer to prescribing information |
| Utibron Neohaler® (indacaterol/glycopyrrolate) | | |
| Anoro Ellipta® (vilanterol/umeclidinium) | | |
| Stiolto Respimat® (olodaterol/tiotropium) | | |
| *LAMAs* | | |
| Tudorza Pressair® (aclidinium bromide) | Refer to prescribing information | Refer to prescribing information |
| Seebri Neohaler® (glycopyrrolate) | | |
| Spiriva Respimat®/ HandiHaler® (tiotropium) | | |
| Incruse Ellipta (umeclidinium) | | |
| *LABAs* | | |
| Brovana® (arformoterol) | Refer to prescribing information | Refer to prescribing information |
| Arcapta Neohaler® (indacaterol) | | |
| Striverdi Respimat® (olodaterol) | | |
| Serevent Diskus® (salmeterol) | | |
| *ICS/LABA/LAMA Combinations* | | |
| Trelegy™ Ellipta® (fluticasone/umeclidinium/ vilanterol) | 1 inhalation by mouth QD | 1 inhalation/day |

| 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% | Apply topically to the affected area(s) BID | Should not be used for longer |

| PLAQUE PSORIASIS | | |
|---|---|---|
| **Drug Name** | **Dosing Regimen** | **Dose Limit/ Maximum Dose** |
| (Diprolene®, Alphatrex®) ointment, gel | | 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 | | |

| PLAQUE PSORIASIS | | |
|---|---|---|
| **Drug Name** | **Dosing Regimen** | **Dose Limit/ Maximum Dose** |
| 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 | | |
| luliconazole (Luzu®) 1% cream | | |
| oxiconazole (Oxistat®) 1% cream, lotion | | |

| SEBORRHEIC DERMATITIS | | |
|---|---|---|
| **Drug Name** | **Dosing Regimen** | **Dose Limit/ Maximum Dose** |
| sulconazole (Exelderm®) 1% cream, solution | | |
| **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 | | |

| ATOPIC DERMATITIS | | |
|---|---|---|
| **Drug Name** | **Dosing Regimen** | **Dose Limit/ Maximum Dose** |
| ***Very High Potency Topical Corticosteroids*** | | |
| augmented betamethasone 0.05% (Diprolene®) ointment, gel, lotion | Apply topically to the affected area(s) BID | Varies |
| clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution | | |
| diflorasone diacetate 0.05% (Apexicon E®) ointment | | |
| fluocinonide 0.1% (Vanos®) cream | | |
| halobetasol propionate 0.05% (Ultravate®) cream, ointment | | |
| ***High Potency Topical Corticosteroids*** | | |
| amcinonide 0.1% ointment, lotion | Apply topically to the affected area(s) BID | Varies |
| augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion | | |
| betamethasone valerate 0.1%, 0.12% (Luxiq®) ointment, foam | | |

| ATOPIC DERMATITIS | | |
|---|---|---|
| **Drug Name** | **Dosing Regimen** | **Dose Limit/ Maximum Dose** |
| clobetasol propionate 0.025% (Impoyz® ) cream | | |
| diflorasone 0.05% (Apexicon E®, Psorcon®) cream | | |
| fluocinonide acetonide 0.05% cream, ointment, gel, solution | | |
| fluticasone propionate 0.005% cream, ointment | | |
| halcinonide 0.1% cream, ointment, solution (Halog®) | | |
| halobetasol propionate 0.01% lotion (Bryhali®) | | |
| mometasone furoate 0.1% ointment | | |
| triamcinolone acetonide 0.5% (Triderm®) cream, ointment | | |
| ***Medium Potency Topical Corticosteroids*** | | |
| clocortolone pivalate 0.1% cream | Apply topically to the affected area(s) BID | Varies |
| desoximetasone 0.05%, 0.025% (Topicort®) cream, ointment, gel | | |
| fluocinolone acetonide 0.025% (Synalar®) cream, ointment | | |
| flurandrenolide 0.05% lotion, ointment (Cordran®) | | |
| hydrocortisone valerate 0.2% cream | | |
| mometasone 0.1% cream, ointment, lotion | | |
| triamcinolone acetonide 0.025%, 0.1% cream, ointment | | |
| ***Topical Calcineurin Inhibitors*** | | |
| tacrolimus (Protopic®) 0.03% or 0.1% ointment | Apply a thin layer to affected area BID. Age 2-15 years, use 0.03% ointment only. | Varies |

*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

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Daliresp | COPD | 500 mcg PO QD (starting treatment with 250 mcg QD for 4 weeks and increasing to 500 mcg QD thereafter may reduce the rate of discontinuation in some patients) | 500 mcg/day |
| Zoryve | Plaque psoriasis | Apply 0.3% cream to affected areas once daily | Once daily application |
| | Seborrheic dermatitis | Apply foam to affected areas once daily | Once daily application |
| | Atopic dermatitis | Apply 0.15% cream to affected areas once daily | Once daily application |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| Daliresp | Tablets: 250 mcg, 500 mcg |
| Zoryve | Cream (0.15%, 0.3%): 60 g tube<br>Foam (0.3%): 60 g can |

## VII. References

1. Daliresp Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals; March 2020. Available at: https://www.daliresp.com. Accessed May 8, 2024.
2. Zoryve Cream Prescribing Information. Westlake Village, CA: Arcutis Biotherapeutics, Inc; July 2024. Available at https://www.zoryvehcp.com. Accessed July 25, 2024.
3. Zoryve Foam Prescribing Information. Westlake Village, VA: Arcutis Biotherapeutics, Inc; December 2023. Available at: https://www.zoryvehcp.com. Accessed May 8, 2024.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 14, 2024.
*COPD*
5. Global Initiative for Chronic Obstructive Lung Disease (GOLD): Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2024 report). Available from: http://www.goldcopd.org. Accessed May 14, 2024.
*Psoriasis*
6. 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.
7. 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.
*Seborrheic Dermatitis*
8. Borda LJ and Wikramanayake TC. Seborrheic dermatitis and dandruff: A comprehensive review. J Clin Investig Dermatol. 2015 December; 3(2):1-22.
9. 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.

*Atopic Dermatitis*
10. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; 89(1): E1-E20.
11. Chu DK, Schneider L, Abrams E, 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. 2024; 132(3): 274-312.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 3Q 2020 annual review: no significant changes; references reviewed and updated. | 04.15.20 | 08.20 |
| 3Q 2021 annual review: no significant changes; added Commercial line of business; references reviewed and updated. | 03.17.21 | 08.21 |
| 3Q 2022 annual review: no significant changes; references reviewed and updated. | 03.30.22 | 08.22 |
| RT4: added criteria for newly FDA-approved dosage form (Zoryve cream) and indication of plaque psoriasis. | 08.08.22 | 11.22 |
| Template changes applied to other diagnoses/indications and continued therapy section. | 11.07.22 | |
| 3Q 2023 annual review: no significant changes; added HIM line of business; added redirection to generic roflumilast for brand Daliresp requests; references reviewed and updated. | 04.18.23 | 08.23 |
| RT4: updated age requirement from 12 to 6 years per updated pediatric extension on Zoryve label. | 10.17.23 | |
| RT4: added criteria for newly FDA-approved dosage form (Zoryve topical foam) and indication of seborrheic dermatitis. | 01.16.24 | 02.24 |
| 3Q 2024 annual review: no significant changes; revised policy/ criteria section to also include generic roflumilast; references reviewed and updated.<br>RT4: added criteria for newly FDA-approved dosage form (Zoryve 0.15% cream) and indication of atopic dermatitis; specified that only the 0.3% cream should be used for plaque psoriasis per updated FDA labeling. | 07.25.24 | 08.24 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.