

## **Clinical Policy: Crisaborole (Eucrisa)**

Reference Number: CP.PMN.110

Effective Date: 06.01.17

Last Review Date: 05.22

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Crisaborole (Eucrisa<sup>™</sup>) is a phosphodiesterase 4 inhibitor.

### **FDA Approved Indication(s)**

Eucrisa is indicated for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months 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 health plans affiliated with Centene Corporation<sup>®</sup> that Eucrisa is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Atopic Dermatitis (must meet all):**

1. Diagnosis of atopic dermatitis;
2. Age  $\geq$  3 months;
3. Failure of a 2-week trial of two generic medium-to-very high potency topical corticosteroids, unless contraindicated (e.g., areas involving the face, neck or intertriginous areas) or clinically significant adverse effects are experienced;
4. For age  $\geq$  2 years: Failure of a 2-week trial of topical tacrolimus, unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization may be required for topical tacrolimus*
5. Dose does not exceed 60 grams (1 tube) per 30 days.

##### **Approval duration:**

**Medicaid/HIM** – 6 months

**Commercial** – Length of Benefit

##### **B. Other diagnoses/indications**

1. 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): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Atopic Dermatitis (must meet all):

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 grams (1 tube) per 30 days.

#### Approval duration:

**Medicaid/HIM** – 12 months

**Commercial** – Length of Benefit

### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Centene Corporation and documentation supports positive response to therapy.

**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): 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*

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

| Drug Name   | Dosing Regimen   | Dose Limit/Maximum Dose  |
|---|--|--|
| <b><i>Very High Potency</i></b>   |  |  |
| augmented betamethasone 0.05% (Diprolene <sup>®</sup> AF) ointment, gel   | Apply topically to the affected area(s) BID  | Should not be used for longer than 3 consecutive weeks               |
| clobetasol propionate 0.05% (Temovate <sup>®</sup> ) cream, ointment, gel, solution                                       |  |  |
| diflorasone diacetate 0.05% (Maxiflor <sup>®</sup> , Psorcon E <sup>®</sup> ) cream, ointment                             |  |  |
| <b><i>High Potency</i></b>  |  |  |
| augmented betamethasone 0.05% (Diprolene <sup>®</sup> AF) cream, lotion   | Apply topically to the affected area(s) BID  | Should not be used for longer than 3 consecutive months              |
| diflorasone 0.05% (Florone <sup>®</sup> , Florone E <sup>®</sup> , Maxiflor <sup>®</sup> , Psorcon E <sup>®</sup> ) cream |  |  |
| fluocinonide acetone 0.05% (Lidex <sup>®</sup> , Lidex E <sup>®</sup> ) cream, ointment, gel, solution                    |  |  |
| triamcinolone acetone 0.5% (Aristocort <sup>®</sup> , Kenalog <sup>®</sup> ) cream, ointment                              |  |  |
| <b><i>Medium Potency</i></b>  |  |  |
| desoximetasone 0.05% (Topicort <sup>®</sup> ) cream, ointment, gel  | Apply topically to the affected area(s) BID  | Should not be used for longer than 3 consecutive months              |
| fluocinolone acetone 0.025% (Synalar <sup>®</sup> ) cream, ointment   |  |  |
| mometasone 0.1% (Elocon <sup>®</sup> ) cream, ointment, lotion  |  |  |
| triamcinolone acetone 0.025%, 0.1% (Aristocort <sup>®</sup> , Kenalog <sup>®</sup> ) cream, ointment                      |  |  |
| <b><i>Topical Calcineurin Inhibitors</i></b>  |  |  |
| Tacrolimus (Protopic <sup>®</sup> ) 0.03% or 0.1% ointment  | Apply a thin layer to affected area twice daily.<br>Age 2-15 years, use 0.03% ointment only. | Limit use to affected areas. Discontinue when symptoms have cleared. |

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.

*Appendix C: Contraindications/Boxed warnings*

- Contraindication(s): hypersensitivity to crisaborole or any component of the formulation
- Boxed warning(s): none reported

**V. Dosage and Administration**

| Indication                         | Dosing Regimen                          | Maximum Dose |
|------------------------------------|---|--------------|
| Mild-to-moderate atopic dermatitis | Apply to the affected areas twice daily | N/A          |

**VI. Product Availability**

Ointment (2%): 60 g, 100 g

**VII. References**

1. Eucrisa Prescribing Information. New York: NY: Pfizer Labs, Division of Pfizer, Inc.; April 2020. Available at: [www.eucrisa.com](http://www.eucrisa.com). Accessed February 6, 2022.
2. Paller AS, Tom WL, Lebwohl MG, et al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. *J Am Acad Dermatol*. 2016;75:3:494-503.
3. Eichenfield F, Tom WL, Chamlin SL et al. Guidelines of Care for the Management of Atopic Dermatitis. *J Am Acad Dermatol*. 2014; 70(2): 338–351.
4. Wong JTY, Tsuyuki RT, Cresswell-Melville A, et al. Guidelines for the management of atopic dermatitis (eczema) for pharmacists. *Can Pharm J (Ott)*. 2017;150(5):285-297.
5. Ference JD and Last AR. Choosing topical corticosteroids. *American Family Physician Journal*. 2009; 79(2):135-140.

| Reviews, Revisions, and Approvals   | Date     | P&T Approval Date |
|---|----------|-------------------|
| 2Q 2018 annual review: added maximum quantity per month; policies combined for Medicaid and Commercial lines of business; references reviewed and updated.    | 02.08.18 | 05.18             |
| Added topical tacrolimus trial requirement per financial consideration guided by an SDC Chair.  | 08.02.18 |                   |
| 2Q 2019 annual review: HIM line of business added; added contraindications; references reviewed and updated.  | 02.08.19 | 05.19             |
| 2Q 2020 annual review: updated for pediatric age extension; no significant changes; references reviewed and updated.  | 04.23.20 | 05.20             |
| Added age qualifier of ≥ 2 years for redirection to topical tacrolimus  | 05.28.20 |                   |
| 2Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated. | 01.22.21 | 05.21             |
| 2Q 2022 annual review: no significant changes; references reviewed and updated.   | 02.06.22 | 05.22             |

**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.

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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.

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