Clinical Policy: Crisaborole (Eucrisa)

Reference Number: CP.PMN.110
Effective Date: 06.01.17
Last Review Date: 05.21
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™) is a phosphodiesterase 4 inhibitor.

FDA Approved Indication(s)

Eucrisa is indicated for the topical treatment of mild to moderate atopic dermatitis in patients 2 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 health plans affiliated with Centene Corporation® 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 ≥ 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 ≥ 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
Very High Potency		
augmented betamethasone 0.05% (Diprolene® 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®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment		
High Potency		
augmented betamethasone 0.05% (Diprolene® 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®, Florone E®, Maxiflor®,Psorcon E®) cream		
fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium Potency		
desoximetasone 0.05% (Topicort ®) cream, ointment, gel	Apply topically to the affected area(s) BID	Should not be used for longer than 3 consecutive months
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
mometasone 0.1% (Elocon®) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment		
Topical Calcineurin Inhibitors		
Tacrolimus (Protopic®) 0.03% or 0.1% ointment	Apply a thin layer to affected area twice daily. 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® (generic) when the drug is available by brand name only and generic (Brand name®) 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

VII. References

1. Eucrisa Prescribing Information. New York: NY: Pfizer Labs, Division of Pfizer, Inc.; March 2020. Available at: www.eucrisa.com. Accessed January 22, 2021.
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
Policy created	02.17	05.17
Added medium to high potency topical corticosteroids to therapeutic alternatives	03.17	05.17
Converted to new template. Minor changes to verbiage and grammar.	07.17	11.17
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	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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

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.

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.