Clinical Policy: Crisaborole (Eucrisa)

Reference Number: DE.PMN.110
Effective Date: 09.25
Last Review Date: 05.25
Line of Business: 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 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.

Eucrisa will be electronically approved after trial of a preferred topical steroid or immunomodulator

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 one preferred medium to very high potency topical corticosteroids of different molecular identities, 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;
5. Dose does not exceed 400 grams per 365 days.

Approval duration: 6 months

B. 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 PDL, the no coverage criteria policy: CP.PMN.255; or
b. For drugs NOT on the PDL, the non-formulary policy :CP.PMN.16 ; 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.PMN.53.

II. Continued Therapy

A. 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 currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 400 grams per 365 days.

Approval duration: 12 months

B. 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 PDL, the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the formulary PDL, the non-formulary policy: CP.PMN.16; 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.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 – CP.PMN.53 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 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, foam, lotion, ointment		
High Potency Topical Corticosteroids		
amcinonide 0.1% cream, ointment, lotion	Apply topically to the affected area(s) BID	Varies
betamethasone 0.05% (Diprolene® AF) cream (augmented formulation), ointment		
betamethasone valerate 0.1%, 0.12% (Luxiq®) ointment, foam		
clobetasol propionate 0.025% (Impoyz®) cream		
diflorasone 0.05% (Apexicon E®, Psorcon®) cream		
fluocinonide 0.05% cream, ointment, gel, solution		
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% (Cordran®, Nolix®) cream, lotion, ointment		
fluticasone propionate 0.005%, 0.05% cream, ointment		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
hydrocortisone valerate 0.2% cream		
mometasone furoate 0.1% cream, lotion, solution		
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 twice daily. 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.

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 2023. Available at: www.eucrisa.com. Accessed January 16, 2025.
2. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier. Updated periodically. Available at: http://www.clinicalkey.com/pharmacology. Accessed February 21, 2025.
3. 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.
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. 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 Jul;89(1):e1-e20.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.25	

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.