Clinical Policy: CRISABOROLE (EUCRISA)
Reference Number: IL.PMN.110
Effective Date: 08.01.20
Last Review Date: 2.27.23
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 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. Member meets one of the following (a or b):
    a. Failure of one topical corticosteroids within last one year, unless contraindicated or clinically significant adverse effects are experienced;
    b. Failure of one topical calcineurin inhibitor within last one year (e.g., tacrolimus 0.03% ointment, tacrolimus 0.1% ointment, pimecrolimus 1% cream, Elidel 1% cream, Protopic 0.03% ointment, or Protopic 0.1% ointment), unless contraindicated or clinically significant adverse effects are experienced;
    **Prior authorization may be required*

3. Dose does not exceed 60 grams (1 tube) per 30 days and 300 grams per year;

Approval duration:
Medicaid– 6 months

B. Other diagnoses/indications

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 (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or

b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: 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.PMN.53 for Medicaid.

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. Dose does not exceed 60 grams (1 tube) per 30 days and 300 grams per year;

Approval duration:
Medicaid– 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 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.PHAR.21 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		
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution	Apply topically to the affected area(s) BID	Should not be used for longer than 3 consecutive weeks
diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment		
High Potency		
diflorasone 0.05% (Florone®, Florone E®, Maxiflor®,Psorcon E®) cream	Apply topically to the affected area(s) BID	Should not be used for longer than 3 consecutive months
fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium Potency		
fluocinolone acetonide 0.025% (Synalar®) cream, ointment	Apply topically to the affected area(s) BID	Should not be used for longer than 3 consecutive months
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, 100 g

VII. References

1. Eucrisa Prescribing Information. New York: NY: Pfizer Labs, Division of Pfizer, Inc.; March 2020. Available at: www.eucrisa.com. Accessed February 27, 2023.
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	
Policy created, adapted from CP.PMN.110 **CRISABOROLE**	07.15.20	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
(EUCRISA) for migration to HFS PDL		
2Q2021 annual review: no significant change; updated tablet *Appendix B: Therapeutic Alternatives;* reviewed and updated references	6.23.21	
Per HFS Criteria 2021: removed age restriction. Per HFS criteria, only restriction requiring failure on one topical corticosteroid or one topical calcineurin inhibitor.	9.28.21	
4Q2021 review- Per HFS criteria, added quantanty limit of 30 days supply and 300g per year; removed medium to high potency from the trial of topical corticosteroids; look back period of 1 year for TCS and TCI;	12.9.21	
Annual review: Template changes applied to other diagnoses/indications and continued therapy section; product availability updated; references reviewed and updated	2.27.23	

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.