Clinical Policy: Crisaborole (Eucrisa)

Reference Number: PA.CP.PMN.110
Effective Date: 4.17.19
Last Review Date: 04.19

Revision Log

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 PA Health & Wellness 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 ≥ 2 years;
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. 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): PA.CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

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: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   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): PA.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 policy – PA.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
- 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.; December 2018. Available at: www.eucrisa.com. Accessed February 8, 2019.
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 Dematitis. J Am Acad Dermatol. 2014 February; 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). May 2017;150(5):285-297.
5. Ference JD and Last AR. Choosing topical corticosteroids. American Family Physician Journal. January 2009; 79(2):135-140.

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