Clinical Policy Title:	crisaborole
Policy Number:	RxA.379
Drug(s) Applied:	Eucrisa®
Original Policy Date:	03/06/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Eucrisa® is a phosphodiesterase 4 inhibitor. It is indicated for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
crisaborole (Eucrisa®)	Mild-to-moderate atopic dermatitis	Apply a thin layer topically to the affected areas twice daily	N/A

Dosage Forms

- Ointment (2%): 60 g, 100 g

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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 one 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. Requested dose does not exceed 2 grams per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Atopic Dermatitis (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance 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 2 grams per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Very High Potency		
augmented betamethasone 0.05% 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		
diflorasone diacetate 0.05% cream, ointment		
High Potency		
augmented betamethasone 0.05% cream, lotion	Apply topically to the affected area(s) BID	Should not be used for longer than 3 consecutive months
diflorasone 0.05% cream		
fluocinonide acetonide 0.05% cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (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		

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
triamcinolone acetonide 0.025%, 0.1% (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.

APPENDIX D: General Information

Not Applicable

References

1. Eucrisa® Prescribing Information. New York: NY: Pfizer Labs, Division of Pfizer, Inc.; April 2020. Available at: www.eucrisa.com. Accessed February 1, 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 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.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	02/2020	03/06/2020
Policy was reviewed: • Eucrisa® 100 grams was added to Background	05/2020	05/21/2020

• QL of 2 grams per day was added to Initial Approval Criteria Continued Therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance or…”		
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Last Review Date was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Background was updated for minimum age from 2 years to 3 months. 5. APPENDIX B: Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance...." 6. Initial Approval criteria was updated for minimum age from 2 years to 3 months. 7. Initial Approval criteria Commercial and Medicaid approval duration were updated to 6 months. 8. Continued Approval criteria: Commercial and Medicaid approval duration were updated to 6 months. 9. Maxiflor®, Diprolene AF®, Florone®, Florone E®, Lidex®, Lidex E®, PSORCON E®, Aristocort®, Elocon® were removed from therapeutic alternatives table due to off market. 10. References were updated.	02/01/2021	03/09/2021

11. Updated dosing information to include route of administration: Apply a thin layer topically to the affected areas twice daily.		