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Subsection:	Topical Products	Original Policy Date:	February 3, 2017
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Last Review Date: March 12, 2021

Eucrisa

Description

Eucrisa (crisaborole)

Background

Eucrisa is indicated for topical treatment of mild to moderate atopic dermatitis. Atopic dermatitis, a chronic inflammatory skin disease, is often referred to as "eczema," which is a general term for the several types of inflammation of the skin. Atopic dermatitis is the most common of the many types of eczema and onset typically begins in childhood and can last through adulthood. The cause of atopic dermatitis is a combination of genetic, immune and environmental factors. Eucrisa (crisaborole) is a phosphodiesterase 4 (PDE-4) inhibitor. PDE-4 inhibition results in increased intracellular cyclic adenosine monophosphate (cAMP) levels. The specific mechanism(s) by which crisaborole exerts its therapeutic action for the treatment of atopic dermatitis is not well defined (1).

Regulatory Status

FDA-approved indication: Eucrisa is a phosphodiesterase 4 inhibitor indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older (1).

Topical corticosteroids are used in the management of atopic dermatitis in both adults and children and are the mainstay of anti-inflammatory therapy. Topical calcineurin inhibitors (TCI) are a second class of anti-inflammatory therapy. They are naturally produced by *Streptomyces* bacteria and inhibit calcineurin dependent T-cell activation, blocking the production of pro-

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inflammatory cytokines and mediators of the AD inflammatory reaction. They have also been demonstrated to affect mast cell activation, and tacrolimus decreases both the number and costimulatory ability of epidermal dendritic cells. Topical calcineurin inhibitors are only approved for use in patients 2 years of age and older (2).

The safety and effectiveness of Eucrisa have been established in pediatric patients age 3 months and older for topical treatment of mild to moderate atopic dermatitis (1).

Related policies

Topical Anti-Inflammatories

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Eucrisa may be considered **medically necessary** in patients 3 months of age or older with mild to moderate atopic dermatitis and if the conditions indicated below are met.

Eucrisa may be considered **investigational** for patients less than 3 months of age and for all other indications.

Prior-Approval Requirements

Age 3 months of age or older

Diagnosis

Patient must have the following:

1. Mild to moderate atopic dermatitis (eczema)
 - a. 18 years of age or older
 - i. Inadequate treatment response, intolerance or contraindication to **ONE** medication in **EACH** of the following categories:
 - 1) Topical calcineurin inhibitor (see Appendix I)
 - 2) **High** potency topical corticosteroid (see Appendix II)
 - b. 2 to 17 years of age

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- i. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 - 1) Topical calcineurin inhibitor (see Appendix I)
 - 2) A topical corticosteroid (see Appendix II)
- c. 3 months to less than 2 years of age
 - i. Inadequate treatment response, intolerance, or contraindication to a topical corticosteroid (see Appendix II)

AND the following:

- a. Documented baseline evaluation of the condition using **ONE** of the following scoring tools:
 - i. Investigator's Static Global Assessment (ISGA) score
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - ii. Eczema Area and Severity Index (EASI)
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - iii. Patient-Oriented Eczema Measure (POEM)
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - iv. Scoring Atopic Dermatitis (SCORAD) index
(e.g., <https://dermnetnz.org/topics/scorad/>)

Prior – Approval *Renewal* Requirements

Age 3 months of age or older

Diagnosis

Patient must have the following:

- 1. Atopic dermatitis (eczema)
 - a. Documented improvement using **ONE** of the following scores:
 - i. ISGA – decrease from baseline by at least 2 points
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - ii. EASI – decrease from baseline by at least 75%
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - iii. POEM – decrease from baseline by at least 3 points
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - iv. SCORAD – decrease from baseline by at least 50%

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(e.g., <https://dermnetnz.org/topics/scorad/>)

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity 60g 4 tubes **OR**
 100g 4 tubes
Duration 4 months

Prior – Approval *Renewal* Limits

Quantity 60g 3 tubes per 90 days **OR**
 100g 3 tubes per 90 days
Duration 12 months

Rationale

Summary

Eucrisa (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older. Eucrisa is a phosphodiesterase 4 (PDE-4) inhibitor. The most common adverse reaction occurring in $\geq 1\%$ in subjects is application site pain. Hypersensitivity reactions, including contact urticaria, have occurred in patients treated with Eucrisa. The safety and effectiveness of Eucrisa have been established in pediatric patients age 3 months and older for topical treatment of mild to moderate atopic dermatitis (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Eucrisa while maintaining optimal therapeutic outcomes.

References

1. Eucrisa [package insert]. New York, NY: Pfizer Inc.; April 2020.
2. Eichenfield L, Tom W, etc. Guidelines of care for the management of atopic dermatitis. Journal of American Academy of Dermatology. July 2014. Volume 71:1 pg. 116-132.

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Policy History

Date	Action
February 2017	Addition to PA
April 2017	Change of the tried and failed of Elidel and Protopic to just one Topical calcineurin inhibitor Addition of EASI, POEM and SCORAD scoring tools to criteria for evaluation
June 2017	Annual review
September 2017	Annual review
May 2018	Addition of url links for scoring tools
June 2018	Annual editorial review
September 2019	Annual review and reference update
April 2020	Lowered age requirement to 3 months of age or older and revised t/f steroid requirement for pediatric patients. Scoring tool links updated
June 2020	Annual editorial review and reference update. SCORAD tool link updated
September 2020	Revised requirement for patients age 3 months to less than 2 years of age so they no longer have to fail a topical calcineurin inhibitor
December 2020	Annual editorial review. ISGA tool link updated. Revised PA quantities and durations to 4 tubes for 4 months for initiation and 3 tubes per 90 days for 12 months for continuation
March 2021	Annual editorial review. Investigator's Static Global Assessment link updated.

Keywords

This policy was approved by the FEP[®] Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

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Relative Potency of Topical Calcineurin Inhibitors			
	Drug	Dosage Form	Strength
I.	Medium potency		
	Tacrolimus	Ointment	0.1%
II.	Low potency		
	Tacrolimus	Ointment	0.03%
	Pimecrolimus	Cream	1%

APPENDIX II

Relative Potency of Selected Topical Corticosteroid Products			
	Drug	Dosage Form	Strength
I.	Very high potency		
	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment	0.05%
	Diflorasone diacetate	Ointment	0.05%
	Halobetasol propionate	Cream, Ointment	0.05%
II.	High potency		
	Amcinonide	Cream, Lotion, Ointment	0.1%
	Augmented betamethasone dipropionate	Cream, Lotion	0.05%
	Betamethasone	Cream, Ointment	0.05%
	Betamethasone valerate	Ointment	0.1%
	Desoximetasone	Cream, Ointment	0.25%
		Gel	0.05%
	Diflorasone diacetate	Cream, Ointment (emollient base)	0.05%
	Fluocinonide	Cream, Ointment, Gel	0.05%
	Halcinonide	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment	0.5%	
III.	Medium potency		

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	Betamethasone	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Clocortolone pivalate	Cream	0.1%
	Desoximetasone	Cream	0.05%
	Fluocinolone acetonide	Cream, Ointment	0.025%
	Flurandrenolide	Cream, Ointment, Lotion	0.05%
		Tape	4 mcg/cm ²
	Fluticasone propionate	Cream	0.05%
		Ointment	0.005%
III.	Hydrocortisone butyrate	Ointment, Solution	0.1%
	Hydrocortisone valerate	Cream, Ointment	0.2%
	Mometasone furoate	Cream, Ointment, Lotion	0.1%
	Prednicarbate	Cream, Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
		Cream, Ointment, Lotion	0.1%
IV.	<i>Low potency</i>		
	Alclometasone dipropionate	Cream, Ointment	0.05%
	Desonide	Cream	0.05%
	Fluocinolone acetonide	Cream, Solution	0.01%
	Hydrocortisone	Lotion	0.25%
		Cream, Ointment, Lotion, Aerosol	0.5%
		Cream, Ointment, Lotion, Solution	1%
		Cream, Ointment, Lotion	2.5%
	Hydrocortisone acetate	Cream, Ointment	0.5%
		Cream, Ointment	1%