

Atopic Dermatitis Agents – Topical Phosphodiesterase 4 (PDE4) Inhibitors

Medical policy no. 90.23.00

Effective Date: April 1, 2020

Related medical policies:

- **90.78.40 Atopic Dermatitis Agents – Topical Immunosuppressive**
- **90.27.30 Atopic Dermatitis Agents – Monoclonal Antibodies**

Note: New-to-market drugs are non-preferred and subject to this class/category prior authorization (PA) criteria. Non-preferred agents in this class/category, require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed.

Background:

Atopic dermatitis (AD) is a chronic, non-contagious, inflammatory disease of the skin resulting from a combination of genetic and environmental factors. Often referred to as “eczema,” it is characterized by extremely dry, itchy skin on the insides of the elbows, behind the knees, and on the face, hands, and feet.

The American Academy of Dermatology guidelines for the care and management of atopic dermatitis recommend the use of topical corticosteroids in patients who have failed to respond to good skin care and regular use of emollients alone. The guidelines recommend using topical calcineurin inhibitors in the following situations: patients’ refractory to topical corticosteroids, use in sensitive areas (e.g. face, axilla, anogenital region, and skin folds), patients with steroid induced-atrophy, and in patients who require long-term treatment.

Crisaborole (Eucrisa™) is a topical treatment for atopic dermatitis in patients 2 years of age and older. Phosphodiesterase 4 (PDE4) inhibitors are topical drugs that allow cyclic adenosine monophosphate (cAMP) to remain intact in order to decrease the proinflammatory response (e.g., cytokine release) associated with atopic dermatitis.

Medical necessity

Drug	Medical Necessity
crisaborole (Eucrisa™)	Crisaborole may be considered medically necessary when used for: <ul style="list-style-type: none"> • topical treatment of atopic dermatitis in patients 2 years of age and older

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
<p>Atopic dermatitis</p> <p><u>Preferred drugs:</u></p> <ul style="list-style-type: none"> • crisaborole (Eucrisa™) 	<p>Crisaborole may be covered when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Must be 2 years of age or older; AND 2. Have a diagnosis of atopic dermatitis with documentation of baseline evaluation of the disease, including severity of symptoms. 3. History of failure (unable to achieve or maintain remission of low or mild disease) to daily use of ALL (a and b) of the following: <ol style="list-style-type: none"> a. Trial of at least TWO topical corticosteroids (medium or higher potency) for daily treatment of minimum 14-days each in previous 6 months, unless contraindicated to all preferred topical corticosteroids <ol style="list-style-type: none"> i. Contraindications include: <ol style="list-style-type: none"> 1. Treatment of sensitive areas (face, anogenital, skin folds); 2. Steroid induced atrophy; 3. Long-term uninterrupted use; AND b. Trial of at least ONE topical calcineurin inhibitors (i.e., pimecrolimus, tacrolimus) for at least 28-days, unless contraindicated; <p>If ALL criteria are met, the request may be approved for 6 months</p>
	<p>Criteria (Reauthorization)</p>
	<p>Crisaborole may be reauthorized when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Clinical documentation of disease stability or improvement from baseline. 2. If ALL criteria are met, the request may be approved for 12 months

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
crisaborole (Eucrisa™)	#1 (60g) tube per 30-day

References

1. Eucrisa Prescribing Information. Anacor Pharmaceuticals. Palo Alto, CA. October 2017.
2. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014 Feb;70(2):338-51.
3. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014 Jul;71(1):116-32.

4. Sidbury R, Davis DM, Cohen DE, Cordoro KM, Berger TG, Bergman JN, et al. Guidelines of care for the management of atopic dermatitis: section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.
5. Sidbury R, Tom WL, Bergman JN, Cooper KD, Silverman RA, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: Section 4. Prevention of disease flares and use of adjunctive therapies and approaches. J Am Acad Dermatol. 2014 Dec;71(6):1218-33. Comparison of representative topical corticosteroid preparations. UpToDate. Available at: <https://www.uptodate.com/home> Accessed December 2017.

History

Date	Action and Summary of Changes
10/11/2019	Clarification on reauthorization criteria 1.
09/24/2019	General formatting updates
08/21/2019	Updated documentation of baseline evaluation requirement
04/18/2018	New Policy