Clinical Guideline



Oscar Clinical Guideline: Eucrisa (crisaborole) (PG023, Ver. 6)

Eucrisa (crisaborole)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Atopic dermatitis (AD), commonly known as eczema, is a chronic, inflammatory skin disorder primarily characterized by intense itchiness and recurrent eczematous lesions. Its pathology involves a combination of skin barrier dysfunction, immune dysregulation, and environmental and genetic factors. AD is often associated with other atopic disorders such as asthma and allergic rhinitis.

AD presents differently across age groups, with acute, subacute, and chronic stages. In infants and toddlers, it typically affects the face, scalp, and extensor surfaces of the extremities, while in older children and adults, it tends to localize to the flexural areas. It is a relapsing disease, with flares commonly triggered by irritants, allergens, infections, and stress.

Standard treatment of AD involves a combination of skin care practices, trigger avoidance, and pharmacologic interventions. The cornerstone of AD management includes regular use of moisturizers to enhance the skin barrier and reduce dryness and pruritus. Mild to moderate AD is typically managed with topical medications, which may include corticosteroids and calcineurin inhibitors such as tacrolimus.

More severe cases may necessitate systemic treatments such as systemic corticosteroids, immunosuppressants, or newer biologic therapies.

Eucrisa (crisaborole) is a non-steroidal, anti-inflammatory phosphodiesterase-4 inhibitor for topical use. It has been approved for the treatment of mild to moderate atopic dermatitis in patients aged 3 months and older. Crisaborole works by reducing inflammation and increasing hydration in the skin. Its primary advantage is its safety profile, which is notably devoid of the adverse effects commonly associated with prolonged use of topical corticosteroids, such as skin atrophy. The most common side effect is skin irritation at the application site, including symptoms such as pain, burning, or stinging.

Definitions

"Atopic Dermatitis" is a chronic, pruritic, inflammatory skin disease that often includes clinical features of skin dryness, erythema, oozing and crusting, and lichenification.

"**Pruritus**" refers to itchiness, a common and distressing symptom of atopic dermatitis that can significantly affect quality of life.

"Erythema" refers to the redness of the skin caused by increased blood flow in the superficial capillaries. In atopic dermatitis, erythema is a sign of inflammation.

"Lichenification" refers to skin thickening with accentuation of skin markings, often a consequence of chronic scratching or rubbing in conditions like atopic dermatitis.

"**Exudation**" is the oozing of fluid, usually serous fluid, which can occur in acute phases of atopic dermatitis when vesicles or blisters rupture.

"Topical Corticosteroids" are medications applied directly to the skin to reduce inflammation and irritation. They are a mainstay of treatment for atopic dermatitis but can have side effects with prolonged use, such as skin thinning.

"Calcineurin Inhibitors" are immunomodulating drugs used topically in the management of atopic dermatitis, such as tacrolimus and pimecrolimus. They suppress the activity of the immune system and decrease inflammation, but are generally used when topical corticosteroids are ineffective or contraindicated.

"Biologics" are a newer class of drugs derived from living organisms that target specific parts of the immune system. They are used for moderate to severe atopic dermatitis when topical treatments aren't effective.

"Xerosis" refers to abnormally dry skin, a characteristic feature of atopic dermatitis. Regular use of moisturizers is recommended to combat xerosis in AD management.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Eucrisa (crisaborole)** medically necessary when **ALL** of the following criteria are met:

- 1. The member has a diagnosis of mild to moderate atopic dermatitis; AND
- 2. The member meets **ONE** of the following:
 - a. is unable to use, or has tried and failed **BOTH** of the following:
 - i. a topical corticosteroid; and
 - ii. a topical calcineurin inhibitor (such as tacrolimus); or
 - b. requires treatment in an affected area that is considered sensitive (such as the face, axillae, or groin) **AND** the member is unable to use, or has tried and failed a topical calcineurin inhibitor (such as tacrolimus).

If the above prior authorization criteria are met, Eucrisa (crisaborole) will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization of Eucrisa (crisaborole) for a period of 12 months will be granted if the member demonstrates a positive clinical response to therapy, as evidenced by **ANY** of the following:

- 1. Reduction in body surface area involvement of atopic dermatitis lesions; OR
- 2. Decrease in pruritus severity; OR
- 3. Improvement in signs and symptoms of atopic dermatitis, such as erythema, exudation, excoriation, induration/papulation, and lichenification.

Experimental or Investigational / Not Medically Necessary

Eucrisa (crisaborole) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

- AAAAI/ACAAI JTF Atopic Dermatitis Guideline Panel; Chu DK, Schneider L, Asiniwasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE- and Institute of Medicine-based recommendations. Ann Allergy Asthma Immunol. 2024 Mar;132(3):274-312. doi: 10.1016/j.anai.2023.11.009. Epub 2023 Dec 18. PMID: 38108679.
- 2. Ahmed, A., et al. "Magnitude of Benefit for Topical Crisaborole in the Treatment of Atopic Dermatitis in Children and Adults Does Not Look Promising: A Critical Appraisal." British Journal of Dermatology, vol. 178, 2018, pp. 659.
- 3. Bieber, T. "Atopic Dermatitis: An Expanding Therapeutic Pipeline for a Complex Disease." Nature Reviews Drug Discovery, vol. 20, 2021, pp. 1-20.
- 4. Drucker, A. M., et al. "Systemic Immunomodulatory Treatments for Patients with Atopic Dermatitis: A Systematic Review and Network Meta-Analysis." JAMA Dermatology, Apr. 2020, https://doi.org/10.1001/jamadermatol.2020.0435.
- 5. Eichenfield, L. F., et al. "Guidelines of Care for the Management of Atopic Dermatitis: Section 2. Management and Treatment of Atopic Dermatitis with Topical Therapies." Journal of the American Academy of Dermatology, vol. 71, 2014, pp. 116.
- 6. Eichenfield, L. F., et al. "Long-Term Safety of Crisaborole Ointment 2% in Children and Adults with Mild to Moderate Atopic Dermatitis." Journal of the American Academy of Dermatology, vol. 77, 2017, pp. 641.
- 7. Eucrisa Ointment 2% (crisaborole) [prescribing information]. New York, NY: Pfizer Labs; April 2023.
- 8. Fishbein, A. B. "Management of Atopic Dermatitis in Children Younger Than Two Years of Age by Community Pediatricians: A Survey and Chart Review." The Journal of Pediatrics, vol. 221, 2020, pp. 138-144.
- 9. Frazier, W., and Bhardwaj, N. "Atopic Dermatitis: Diagnosis and Treatment." American Family Physician, vol. 101, no. 10, 2020, pp. 590-598.
- 10. Hanna, S., et al. "What Is the Risk of Harm Associated With Topical Calcineurin Inhibitors?" Journal of Cutaneous Medicine and Surgery, first published September 3, 2019, https://doi.org/10.1177/1203475419857688.
- 11. Hong, C., et al. "Evidence Review of Topical Calcineurin Inhibitors for the Treatment of Adult Atopic Dermatitis." Journal of Cutaneous Medicine and Surgery, https://doi.org/10.1177/1203475419857669.
- 12. Johnson, B. B., et al. "Treatment-Resistant Atopic Dermatitis: Challenges and Solutions." Clinical, Cosmetic and Investigational Dermatology, vol. 12, 2019, pp. 181.
- 13. Kolb, L., and Ferrer-Bruker, S. J. "Atopic Dermatitis." StatPearls, updated 2021, StatPearls Publishing, 2022, https://www.ncbi.nlm.nih.gov/books/NBK448071/.
- 14. Luger, T., et al. "Unmet Medical Needs in the Treatment of Atopic Dermatitis in Infants: An Expert Consensus on Safety and Efficacy of Pimecrolimus." Pediatric Allergy and Immunology, vol. 32, no. 3, 2021, pp. 414-424.
- 15. Schlessinger, J., et al. "Safety, Effectiveness, and Pharmacokinetics of Crisaborole in Infants Aged 3 to <24 Months with Mild-to-Moderate Atopic Dermatitis: A Phase IV Open-Label Study (CrisADe CARE 1)." American Journal of Clinical Dermatology, vol. 21, 2020, pp. 275.
- 16. Seger, E. W., et al. "Relative Efficacy of Systemic Treatments for Atopic Dermatitis." Journal of the American Academy of Dermatology, vol. 80, 2019, pp. 411.

Clinical Guideline Revision / History Information

Original Date: 08/06/2020

Reviewed/Revised: 06/24/2021, 12/01/2021, 06/23/2022, 06/29/2023, 06/27/2024