Eucrisa™ (crisaborole)

Policy # 00552
Original Effective Date: 04/19/2017
Current Effective Date: 12/11/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Eucrisa™‡ (crisaborole) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Eucrisa (crisaborole) will be considered when ALL of the following criteria are met:

- Patient has a diagnosis of mild to moderate atopic dermatitis (eczema); AND
- Patient has tried and failed (e.g., intolerance or inadequate response) ONE prescription generic topical corticosteroid product unless there is clinical evidence or patient history that suggests the use of ONE prescription generic topical corticosteroid will be ineffective or cause an adverse reaction to the patient (e.g., atopic dermatitis lesions in sensitive areas such as the face or genital areas); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has tried and failed (e.g., intolerance or inadequate response) generic tacrolimus ointment OR generic pimecrolimus ointment unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Eucrisa (crisaborole) when the patient has NOT tried and failed ONE prescription generic topical corticosteroid product AND either generic tacrolimus ointment or generic pimecrolimus ointment to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Eucrisa (crisaborole) when used for any non-FDA approved indication to be **investigational.***

Background/Overview

Eucrisa is a phosphodiesterase 4 inhibitor indicated for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older. It is available in a 2% ointment and should be applied twice daily to affected areas. Once clinical effect is achieved a once daily application can be considered. There are various other treatment options for atopic dermatitis, including first line agents such as topical corticosteroids (many of which are in generic form), and immunomodulating agents, such as generic tacrolimus and generic pimecrolimus. The availability of generic products in this treatment category lends itself to be a more economical option for the treatment of atopic dermatitis versus the branded products available on the market. To note, there are no head to head studies with Eucrisa versus the other products in this treatment category to suggest superiority.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Eucrisa is indicated for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration

approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Eucrisa was studied in two multicenter, randomized, double-blind, parallel-group, vehicle-controlled trials with a 5% to 95% treatable body surface area. Subjects in both trials were randomized 2:1 to receive Eucrisa or vehicle applied twice daily for 28 days. The primary efficacy endpoint was the proportion of subjects at day 29, who achieved success, defined as an ISGA (Investigator's Static Global Assessment) score of 0 or 1 with a 2 grade or greater improvement from baseline. In trial 1, 32.8% of Eucrisa patients met the endpoint vs. 25.4% of vehicle patients. In trial 2, 31.4% of Eucrisa patients met the endpoint vs. 18% of vehicle patients.

One randomized, double-blind, vehicle-controlled trial assessed the efficacy and safety of Eucrisa once daily over 52 weeks in pediatric (3 months to less than 18 years of age) and adult subjects with mild to moderate atopic dermatitis, who achieved success on Eucrisa twice daily during open-label treatment of up to 8 weeks.

A total of 497 subjects 3 months of age and older with a 2% to 90% treatable BSA, entered into an open-label period to receive Eucrisa twice daily for up to 8 weeks. Of the 497, a total of 254 subjects 3 months of age and older, who achieved both ISGA success (score of clear [0] or almost clear [1] with a ≥2 grade improvement from baseline) and EASI50 response (at least 50% improvement from baseline in EASI scores) were randomized 1:1 into a double-blind period to receive Eucrisa once daily or vehicle for 52 weeks or until they developed a flare. At the beginning of the double-blind period, 59% of the subjects had an ISGA of almost clear (1) and 41% had an ISGA of clear (0). About 27% of patients maintained an IGSA of clear or almost clear compared to 18% of patients in the vehicle group.

To reiterate, the availability of generic products in this treatment category lends itself to be a more economical option for the treatment of atopic dermatitis versus the branded products available on the market. To note, there are no head to head studies with Eucrisa versus the other products in this treatment category to suggest superiority.

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References

1. Eucrisa [package insert]. Anacor Pharmaceuticals. Palo Alto, California. Updated April 2023.
2. Eucrisa Drug Evaluation. Express Scripts.

Policy History

Original Effective Date: 04/19/2017
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04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. New policy.
04/05/2018	Medical Policy Committee review
04/18/2018	Medical Policy Implementation Committee approval. No change to coverage.
04/04/2019	Medical Policy Committee review
04/24/2019	Medical Policy Implementation Committee approval. No change to coverage.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. No change to coverage.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Added generic pimecrolimus ointment as an option for use prior to Eucrisa. Updated the age in the background information (from 2 years to 3 months).
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. No change to coverage.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. No change to coverage.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Updated background and rationale sections to reflect updated dosing information of once daily dosing.

Next Scheduled Review Date: 11/2024

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.