Alkindi® Sprinkle (hydrocortisone oral granules)

Policy # 00742
Original Effective Date: 04/12/2021
Current Effective Date: 04/01/2025

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 Alkindi®‡ Sprinkle (hydrocortisone oral granules) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Alkindi Sprinkle (hydrocortisone oral granules) will be considered when the following criteria are met:

- Patient has a diagnosis of adrenocortical insufficiency; AND
- Patient is LESS than 18 years of age; AND
- Patient is unable to achieve their dose of hydrocortisone by using generic hydrocortisone tablets, which are available in 5 mg, 10 mg, and 20 mg strengths.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Alkindi Sprinkle (hydrocortisone oral granules) when the patient is able to achieve their dose of hydrocortisone by using generic hydrocortisone tablets, which are available in 5 mg, 10 mg, and 20 mg strengths, 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 Alkindi Sprinkle (hydrocortisone oral granules) for non-FDA approved indications OR for patients 18 years of age or older to be **investigational.***

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Background/Overview

Alkindi Sprinkle is indicated as replacement therapy in pediatric patients with adrenocortical insufficiency. Alkindi Sprinkle requires individualized dosing, but the starting recommended dose is 8-10 mg/m^2. The dose should be rounded to the nearest 0.5 mg or 1 mg strength. The oral granules are available in 0.5 mg, 1 mg, 2 mg, and 5 mg strengths. The total dose should be divided by 3 and administered three times daily. Older patients can have their dose divided by 2 and given twice daily. Alkindi Sprinkle capsules are not intended to be swallowed and the granules should not be chewed or crushed. The capsules should be opened and the granules can be poured directly onto the patient's tongue, poured onto a spoon and placed in the patient's mouth, or sprinkled onto a spoonful of cold or room temperature soft food (such as yogurt or fruit puree). Immediately following administration, fluids such as water, milk, breastmilk, or formula, should be ingested to ensure all granules are swallowed. Of note, Alkindi Sprinkle was approved by the FDA based on pharmacokinetic data only.

Adrenal insufficiency is the impaired synthesis and release of adrenocortical hormones. Signs and symptoms of this condition vary depending on which hormone is deficient. In general, symptoms in children include fatigue and gastrointestinal complaints of nausea and vomiting. Treatment includes physiologic replacement of the steroids. The drug of choice is hydrocortisone. Hydrocortisone is available in generic tablet form in 5 mg, 10 mg, and 20 mg strengths. Generic hydrocortisone tablets offer a more economical option for therapy if therapy can be tailored with the available generic tablet strengths.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Alkindi Sprinkle is indicated as replacement therapy in pediatric patients with adrenocortical insufficiency.

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.

The intent of this policy is to ensure that this medication is being used for its FDA approved indication as well as within the appropriate age range. Generic hydrocortisone tablets in 5 mg, 10 mg, and 20 mg strengths have obviously been the mainstay of therapy for many years and offer a very economical option for therapy. However, if there is a dosage that can't be obtained with the available generic hydrocortisone tablets, Alkindi Sprinkle would be an option for therapy.

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References

1. Alkindi Sprinkle [package insert]. Eton Pharmaceuticals. Deer Park, Illinois. Updated October 2020.
2. Causes and Clinical Manifestations of Primary Adrenal Insufficiency in Children. UpToDate. Updated October 2019. Accessed February 2021.
3. Treatment of Adrenal Insufficiency in Children. UpToDate. Updated November 2019. Accessed February 2021.

Policy History

Original Effective Date: 04/12/2021
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03/04/2021	Medical Policy Committee review
03/10/2021	Medical Policy Implementation Committee approval. New policy.
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. No change to coverage.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. No change to coverage.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2025	Medical Policy Committee review
03/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2026

*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.

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.

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.