Prior authorization, including a "Letter of Medical Necessity and Intent to Treat," and other documentation may be required by payers to cover a claim for a particular therapy. The following is educational guidance on the form and contents of a Letter of Medical Necessity, which is intended to reflect your judgment on the need for this therapy. Please carefully review the criteria and determine which, if any, apply to the particular case, and include in your letter only those you wish to indicate in support of the medical necessity. This is not intended to replace your assessment of the patient's medical condition and treatment. This is an educational service by Eton Pharmaceuticals, which makes no representations as to its accuracy or sufficiency.
The content of your Letter of Medical Necessity reflects exclusively your judgment and is your sole responsibility. Please note that some payers may have specific criteria and forms for prior authorization or to demonstrate medical necessity.
Please see Important Safety Information and accompanying full Prescribing Information.

ON OFFICE LETTERHEAD INCLUDING PROVIDER NAME, ADDRESS, PHONE, FAX

ALKINDI SPRINKLE® (hydrocortisone) oral granules

Letter of Medical Necessity and Intent to Treat

Date:

Payer Name:

Address:

Patient Name:
Patient Date of Birth:
Policy Number:
Group Number:

Subject: Intent to Treat with ALKINDI SPRINKLE® (hydrocortisone) oral granules for pediatric patient with adrenocortical insufficiency

To Whom It May Concern:

I am writing on behalf of my patient , who has been diagnosed with adrenocortical insufficiency. I am planning to treat with ALKINDI SPRINKLE® (hydrocortisone) granules for oral use. ALKINDI SPRINKLE® is indicated as replacement therapy in pediatric patients with adrenocortical insufficiency.

Adrenocortical Insufficiency:
Adrenocortical insufficiency is a rare endocrine disorder caused when part of the adrenal gland is not making enough cortisol, a vital hormone that regulates metabolism, maintains cardiovascular function, and helps the body respond to stress.

TREATMENT PLAN CRITERIA (Select any of the following that apply or write your own):

- ☐ My intended use of ALKINDI SPRINKLE® is to treat adrenal insufficiency with the appropriate dose regimen consistent with standard practice of medical care for children with adrenal insufficiency.
- ☐ The strength of hydrocortisone required for optimal dosing is not available in any other commercially available hydrocortisone formulation.
- ☐ Treatment requires accurate dosing to prevent complications from under- and overdosing.
- ☐ ALKINDI SPRINKLE® is available in strengths of 0.5 mg and 1 mg among other higher strengths as outlined in Section 2.1 of the approved Prescribing Information.
- ☐ The dosage strengths for ALKINDI SPRINKLE® allow for dose adjustments in increments of 0.5 mg, which in my view are needed in this case for appropriate treatment and dose titration.
- ☐ Clinical and lab monitoring per clinical practice guidelines is planned.
- ☐ There is no other equivalent FDA-approved option commercially available indicated specifically for treatment of adrenal insufficiency in children.
- ☐ Requiring failure on current or synthetic, long-acting glucocorticoid therapy would involve the risks of undertreatment (including life-threatening adrenal crisis and hyperandrogenism) and overtreatment (including poor growth, hypertension, and Cushing syndrome).
- ☐ The approach I have prescribed is consistent with the ***Endocrine Society Clinical Practice Guidelines. J Clin Endocrinol Metab.*** **2016;101:364-389**.

☐ To further support my treatment plan, the Prescribing Information for scored 5 mg Cortef, hydrocortisone tablets, USP indicates "*the lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.*" **FDA prescribing information, side effects and uses (https://dailymed.nlm.nih.gov).** Parent manipulation of 5 mg Cortef in my view is not optimal given the wide dosage variability, which has been reported when tablets are split or crushed to create smaller doses for children. **Madathilethu et al. *BMJ Paediatr Open.* 2018;2(1):e000198**.

☐

☐

☐

The diagnosis of adrenocortical insufficiency is established based on:

1.
2.
3.

Failure to approve ALKINDI SPRINKLE® may lead to:

1.
2.
3.

I have enclosed the following documents that support the need for ALKINDI SPRINKLE®(eg, lab reports; chart notes; and medical history, including previously used medications):

1.
2.
3.

I would appreciate your evaluation of this request and ask that you approve ALKINDI SPRINKLE® to enable, in my judgment, optimal medical care of . If you have any questions, feel free to contact me at

Thank you for your time and consideration,

, MD