**Sample Letter of Medical Necessity**

Payers vary in their requirements for determining medical necessity. See the following page for a sample letter that providers can reference when preparing the Letter of Medical Necessity on their office

letterhead. The letter of medical necessity should include the type of information that payers may require to establish required treatment, such as:

* The patient’s diagnosis, medical history, and current condition
* Information about prior treatments
* A summary of your clinical assessment and rationale for requesting coverage

The content herein is for informational purposes and for the healthcare provider’s convenience only. It is not intended as legal advice and is not a substitute for a provider’s independent professional judgment. This information is not a guarantee of coverage or payment (partial or full). Healthcare providers should always confirm coverage for individual patients with their insurance providers.

**Please see Important Safety Information on page 3 and full Prescribing Information.**

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| --- | --- |
| [Insurance Company] | Re: Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [Address Line 1] | Policy ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [Address Line 2] | Policy Group: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [Plan Fax Number] | Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

[Date]

Attn: [Medical/Pharmacy Director], [Department]

Dear [Medical/Pharmacy Director name]:

I am writing on behalf of [patient’s name], a [male/female] aged [patient’s age] years, to formally document the medical necessity for treatment with [CRENESSITY™ (crinecerfont) capsules/CRENESSITY™ (crinecerfont) oral solution] for a diagnosis of classic congenital adrenal hyperplasia (CAH). This letter provides information about the patient’s medical history, diagnosis, and treatment plan with CRENESSITY.

CRENESSITY is the only FDA-approved treatment indicated to improve androgen control and enable a reduced glucocorticoid dose in patients 4 years of age and older with classic CAH.

**Patient’s Medical History and Treatment Rationale:**

* Patient’s medical history, diagnosis, and current condition (eg, signs, symptoms, functioning): [Provide a brief statement about the patient’s diagnosis and medical history, including any underlying health issues, developmental concerns, lab values, risks/implications of delayed therapy, etc, that affect your treatment selection]
* Prior treatments and response to those treatments: [Provide a list of current and past medications, as well as reasons for not prescribing a medication (eg, contraindications, drug interactions, lack of efficacy) and a summary of patient experience for each medication, including clinical outcome, adverse drug reactions, and length and changes in therapy]
* [Summary as to why, based on your clinical judgment, your patient requires treatment with CRENESSITY]
* [Review the health plan’s medical policy criteria and point out the criteria that your patient meets. Explain why your patient should be excluded from any criteria that he or she does not meet]

In summary, based on my clinical opinion, CRENESSITY is medically necessary and reasonable for [patient’s name]’s medical condition. Please contact my office at [office phone number] if any additional information is required to ensure prompt approval for this course of treatment.

Sincerely,

[Physician’s name]

[Physician's NPI and specialty]

[List enclosures as appropriate, (eg, excerpt[s] from patient’s medical record, relevant treatment articles and guidelines, and product Prescribing Information)]

[Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**This page is for your reference only. Content on this page does not need to be sent to the insurance company.**

**INDICATION**

CRENESSITY is indicated to improve androgen control and enable a reduced glucocorticoid dose in patients 4 years of age and older with congenital adrenal hyperplasia (CAH)

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

CRENESSITY is contraindicated in patients with known allergy, hypersensitivity or significant intolerance to crinecerfont or any components of CRENESSITY.

**WARNINGS & PRECAUTIONS**

*Risk of Acute Adrenal Insufficiency or Adrenal Crisis with Inadequate Concomitant Glucocorticoid Therapy*. Acute adrenal insufficiency or adrenal crisis, which is potentially life-threatening, can occur in patients with underlying adrenal insufficiency who are on inadequate daily glucocorticoid doses especially in situations associated with increased cortisol need, such as acute intercurrent illness or other situations of increased stress. Do not discontinue glucocorticoids upon initiation of therapy with CRENESSITY. Patients should continue to stress dose with glucocorticoids in cases of illness.

*Increased Fertility and Unexpected Pregnancies*. In both men and women who have lower fertility due to CAH, fertility may be increased after beginning treatment with CRENESSITY, which can lead to unexpected pregnancies. Patients should be informed of the potential for increased fertility when starting treatment with CRENESSITY and to consider if a contraceptive measure is needed

**ADVERSE REACTIONS**

In adult patients, the most common adverse reactions (at least 5% for CRENESSITY and at least 2% greater than placebo) are fatigue, dizziness, and arthralgia. In pediatric patients, the most common adverse reactions (at least 5% for CRENESSITY and at least 2% greater than placebo) are headache, abdominal pain, and fatigue.

**DRUG INTERACTIONS**  
Consider increasing CRENESSITY dosage in patients on concomitant CYP3A4 inducers.

**LACTATION**

There are no data on the presence of CRENNESITY in human milk, the effects on the breastfed infant, or the effects on milk production. Available data in rats has shown the excretion of CRENESSITY in milk

**Please see full Prescribing Information.**