Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Crenessity™ (crinecerfont) oral solution and tablets

Effective: June 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) – Approved Indications

Crenessity (crinecerfont) is a corticotropin-releasing factor type 1 receptor antagonist indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Crenessity oral solution or capsules for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of classic congenital adrenal hyperplasia as evidenced by a 21-hydroxylase deficiency confirmed by **one (1)** of the following:
    a. Elevated serum 17-hydroxyprogesterone level
    b. Genetic testing confirming presence of mutations in the 21-hydroxylase gene
    c. Positive newborn screen with confirmatory second-tier testing
    d. Cosyntropin stimulation test assessed by an endocrinologist

AND

2. Patient is at least 4 years of age or older

AND

3. Prescribed by endocrinologist or a physician who specializes in the treatment of adrenal hyperplasia

AND

4. Documentation of use as an adjunctive treatment with glucocorticoids

AND

5. Documentation of **one (1)** of the following:
    a. Patient requires a supraphysiologic glucocorticoid dose to control disease (defined as a total glucocorticoid dose greater than 12 mg/m^2/day in hydrocortisone dose equivalents for pediatrics, and a total glucocorticoid dose greater than 13 mg/m^2/day in hydrocortisone dose equivalents for adult patients)
    b. Patient has uncontrolled androgen levels despite maximally tolerated glucocorticoid dose

AND

6. If requesting oral solution, documentation of **one (1)** of the following:
    a. Patient weight is less than 55 kg
    b. Both of the following:
        i. Patient weight is greater than or equal to 55 kg
        ii. Patient has a swallowing disorder

Reauthorization Criteria

1. Documented diagnosis of classic congenital adrenal hyperplasia as evidenced by a 21-hydroxylase deficiency

AND

2. Patient is at least 4 years of age or older

AND

3. Prescribed by endocrinologist or a physician who specializes in the treatment of adrenal hyperplasia

AND

4. Documentation of use as an adjunctive treatment with glucocorticoids

AND

5. Documentation of a therapeutic response to Crenessity as evidenced by **one (1)** of the following:
    a. A reduction in daily glucocorticoid dose
    b. Improved androgen control

AND

6. For the oral solution, documentation of **one (1)** of the following:
    a. Patient weight is less than 55 kg
    b. Both of the following:
        i. Patient weight is greater than or equal to 55 kg
        ii. Patient has a swallowing disorder

Limitations

1. Initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals.
2. Patients new to the plan stable on Crenessity should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Crenessity (crinecerfont) [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc.; Dec 2024.
2. Auchus RJ, et al. Phase 3 trial of crinecerfont in adult congenital adrenal hyperplasia. N Engl J Med. 2024;391(6):504–514.
3. Fraga NR, et al. Congenital adrenal hyperplasia. Pediatr Rev. 2024;45(2):74–84.
4. Sarafoglou K, et al. Phase 3 trial of crinecerfont in pediatric congenital adrenal hyperplasia. N Engl J Med. 2024;391(6):493–503.
5. Speiser PW, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2019 Jan 1;104(1):39-40]. J Clin Endocrinol Metab. 2018;103(11):4043-4088.

Approval And Revision History

April 8, 2025: Reviewed by the Pharmacy & Therapeutics Committee.

- May 12, 2026: Administrative updates to clarify solution and remove CareLink from Medical Necessity Guideline template (effective 6/1/2026)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member

eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.