MEDICAL MUTUAL®

Drug Policy

Policy:	Crenessity™ (crinecerfont) capsules, solution, for oral use	Annual Review Date: 11/20/2025 Last Revised Date: 11/20/2025

OVERVIEW

Crenessity, a corticotropin-releasing factor type 1 receptor antagonist, is indicated for the treatment of classic congenital adrenal hyperplasia (CAH) as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients ≥ 4 years of age.[1]

POLICY STATEMENT

This policy involves the use of Crenessity. Prior authorization is recommended for pharmacy benefit coverage of Crenessity. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Crenessity as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Crenessity be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Crenessity is recommended in those who meet the following criteria:

1. **Classic Congenital Adrenal Hyperplasia (CAH).** Approve for the duration noted if the patient meets ONE of the following (A and B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 4 years of age; AND
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** The medication will be taken in combination with a systemic glucocorticoid; AND
         Note: Examples of glucocorticoids include hydrocortisone, prednisone, prednisolone, or dexamethasone.
       - **b)** Patients has a diagnosis of 21-hydroxylase deficiency CAH confirmed by ONE of the following* [(1), (2), (3), or (4)]:
         - **(1)** Elevated 17-hydroxyprogesterone level > 3,000 ng/dL; OR
         - **(2)** Confirmed cytochrome (CYP)21A2 genotype; OR
         - **(3)** Positive newborn screening with confirmatory second-tier testing; OR

(4) Diagnostic results after cosyntropin stimulation of 17OHP level > 10,000 ng/dL; AND

iii. The medication is prescribed by or in consultation with an endocrinologist, urologist, or a physician who specializes in the treatment of adrenal hyperplasia; AND

iv. If the request is for Crenessity oral suspension, one of the following applies (a or b):

a) Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following [(1), (2), or (3)]:

(1) Age; OR

(2) Oral-motor difficulties; OR

(3) Dysphagia; OR

b) Patient utilizes a feeding tube for medication administration.

B) Patient is Currently Receiving Crenessity. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient is experiencing a positive clinical response to Crenessity*; AND
Note: Examples of responses to Crenessity therapy are reduced androstenedione levels, decreased 17-hydroxyprogesterone levels, or reduction in glucocorticoid dose from baseline (i.e., prior to Crenessity therapy) or improved or stabilized clinical signs/symptoms of classic Congenital Adrenal Hyperplasia (e.g., decrease in body mass index standard deviation scores, improved insulin resistance, reduction of hirsutism, or improvement in androstenedione-to-testosterone ratio).

ii. Patient will continue to receive concomitant glucocorticoid replacement; AND

iii. The medication is prescribed by or in consultation with an endocrinologist, urologist, or a physician who specializes in the treatment of adrenal hyperplasia.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Crenessity has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Crenessity™ capsules and oral solution [prescribing information]. San Diago, CA: Neurocrine Biosciences, December 2024.
2. Fraga NR, Minaeian N, Kim MS. Congenital adrenal hyperplasia. *Pediatr Rev*. 2024;45(2):74-84.
3. Auchus RJ, Hamidi O, Pivonello R, et al. Phase 3 trial of crinecerfont in adult congenital adrenal hyperplasia. *N Engl J Med*. 2024;391(6):504-514.
4. Sarafoglou K, Kim MS, Lodish M, et al. Phase 3 trial of crinecerfont in pediatric congenital adrenal hyperplasia. *N Engl J Med*. 2024;391(6):493-503.