CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Crenessity (crinecerfont)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Crenessity is a corticotropin-releasing factor type 1 (CRF1) receptor antagonist initially approved by the FDA in 2024. It is indicated as adjunctive treatment for glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).
Congenital Adrenal Hyperplasia (CAH) is an autosomal recessive disorder most commonly caused by 21-hydroxylase deficiency. This enzyme deficiency leads to impaired cortisol and aldosterone production, resulting in adrenal insufficiency, androgen excess, and, in severe cases, life-threatening salt-wasting crises. The condition typically presents in the newborn period, either through newborn screening detecting elevated 17-hydroxyprogesterone levels or by the presence of atypical genitalia in females. Diagnosis is confirmed through hormonal assays, cosyntropin stimulation testing, and genetic analysis of CYP21A2 mutations. Long-term management requires glucocorticoid replacement therapy to prevent adrenal insufficiency and control excess androgen production.

Crenessity (crinecerfont) will be considered for coverage when the following criteria are met:

Classic Congenital Adrenal Hyperplasia (CAH)

For **initial** authorization:

1. Member is at least 4 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has a diagnosis of classic CAH due to 21-hydroxylase deficiency confirmed by at least one of the following:
   a) Elevated 17-hydroxyprogeserone (17OHP) level with or without cosyntropin stim test (e.g., >1,000 ng/dL or >30 nmol/L)
   b) CYP21A2 mutations through genetic testing,; AND
4. Member requires a supraphysiologic glucocorticoid dose (i.e., >12 mg/m^2/day hydrocortisone equivalents for pediatrics or >13 mg/m^2/day for adults); AND
5. Member will continue glucocorticoid replacement.
6. **Dosage allowed/Quantity limit:**
   a) Adults (≥18 years): 100 mg orally twice daily
   b) Pediatric (4-17 years): weight-based dosing as follows:

Weight Range	Dose (twice daily)
10 kg to < 20 kg	25 mg
20 kg to < 55 kg	50 mg
≥ 55 kg	100 mg

   c) Quantity limit: 60 capsules per 30 days or 4 bottles per 30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document ability to reduce glucocorticoid dose and/or androstenedione (A4) levels.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Crenessity (crinecerfont) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/19/2025	New policy for Crenessity created.

References:

1. Crenessity. [Package insert]. Neurocrine Biosciences, Inc;2024.
2. Sarafogolu 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. doi:10.1056/NEFMoa2404655
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. doi:10.1056/NEJMoa2404656
4. Uslar T, Olmos R, Martínez-Aguayo A, Baudrand R. Clinical Update on Congenital Adrenal Hyperplasia: Recommendations from a Multidisciplinary Adrenal Program. *J Clin Med*. 2023;12(9):3128. Published 2023 Apr 26. doi:10.3390/jcm12093128
5. Speiser PW, Arlt W, Auchus RJ, 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. doi: 10.1210/jc.2018-02371.]. *J Clin Endocrinol Metab*. 2018;103(11):4043-4088. doi:10.1210/jc.2018-01865

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