UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2365-1
Program	Prior Authorization/Medical Necessity
Medication	Crenessity™(crinecerfont) oral capsule and oral suspension
P&T Approval Date	2/2025
Effective Date	4/1/2025

1. Background:

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 (CAH).

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Crenessity** will be approved based upon **all** of the following criteria:

   a. Diagnosis of *classic* congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency

   -AND-

   b. Diagnosis confirmed by **one** of the following:

      (1) Pretreatment serum 17-hydroxyprogesterone (17-OHP) level > 3,000 ng/dL
      (2) Cosyntropin stimulation 17OHP level > 10,000 ng/dL
      (3) Genetic variant in *CYP21A2* gene

   -AND-

   c. Patient is 4 years of age or older

   -AND-

   d. Chronic treatment with a supraphysiologic glucocorticoid (GC) regimen (e.g., dexamethasone, hydrocortisone, methylprednisolone, prednisone, prednisolone) defined as **one** of the following:

      (1) **Both** of the following:

         (a) Patient is 4 to 17 years old
         (b) Glucocorticoid dose > 12 mg/m^2/day in hydrocortisone dose equivalents

      -OR-

      (2) **Both** of the following:

(a) Patient is ≥ 18 years old
(b) Glucocorticoid dose > 13 mg/m^2/day in hydrocortisone dose equivalents

-AND-

e. Prescribed by an endocrinologist

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

1. **Crenessity** will be approved based on **<u>all</u>** of the following criteria:

   a. Documentation of positive clinical response to Crenessity therapy (e.g., reduction in total glucocorticoid daily dose, decreased androstenedione levels)

   -AND-

   b. Patient will continue to receive concomitant glucocorticoid replacement (e.g., dexamethasone, hydrocortisone, methylprednisolone, prednisone, prednisolone)

   -AND-

   c. Prescribed by an endocrinologist

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. Reference:

1. Crenessity [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.
2. 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.
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. New MI, Lorenzen F, Lerner AJ, et al. Genotyping steroid 21-hydroxylase deficiency: hormonal reference data. *J Clin Endocrinol Metab*. 1983;57(2):320-326.

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. *J Clin Endocrinol Metab*. 2018;103(11):4043-4088.

Program	Prior Authorization/Medical Necessity - Crenessity (crinecerfont)
Change Control	
2/2025	New program.