ALASKA MEDICAID
Prior Authorization Criteria

Crenessity™ (crinecerfont)

FDA INDICATIONS AND USAGE[1]

Crenessity™ 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).

APPROVAL CRITERIA[1,2,3,4]

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with an endocrinologist **AND**;
3. Patient has the diagnosis of classic 21-hydroxlyase deficiency CAH has been medically confirmed by one of the following
    a. Elevated 17-hydroxyprgesterone (17-OHP) level
    b. Confirmed mutation in the CYP21A2 gene consistent with CAH
    c. Positive newborn screening with confirmatory second-tier testing
    d. Cosyntropin stimulation test **AND**;
4. Patient is currently receiving glucocorticoid treatment for CAH **AND**;
5. Crenessity™ will be prescribed in combination with glucocorticoid treatment

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient will not receive glucocorticoids at or above the physiological replacement dose

CAUTIONS[1]

- Glucocorticoid dose should be maintained at or above the dose necessary for endogenous cortisol replacement while taking Crenessity. Patients below this level are at increased risk of acute adrenal insufficiency or adrenal crisis.
- Dose adjustment may be required in patients taking together with a moderate or strong CYP3A4 inducer

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to one year if:
- Provider submits evidence as part of the request which demonstrates a positive response to therapy as indicated by one or more of the following
    - Reduction in glucocorticoid daily dose
    - Reduction in serum androstenedione

QUANTITY LIMIT

- 34 day supply at FDA approved dose

REFERENCES / FOOTNOTES:

1. Crenessity (crinecerfont) [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc; December 2024
2. Sarafoglou K, Kim MS, Lodish M, Felner EI, Martinerie L, Nokoff NJ, Clemente M, Fechner PY, Vogiatzi MG, Speiser PW, Auchus RJ, Rosales GBG, Roberts E, Jeha GS, Farber RH, Chan JL; CAHtalyst Pediatric Trial Investigators. Phase 3 Trial of Crinecerfont in Pediatric Congenital Adrenal Hyperplasia. N Engl J Med. 2024 Aug 8;391(6):493-503.
3. Auchus RJ, Hamidi O, Pivonello R, Bancos I, Russo G, Witchel SF, Isidori AM, Rodien P, Srirangalingam U, Kiefer FW, Falhammar H, Merke DP, Reisch N, Sarafoglou K, Cutler GB Jr, Sturgeon J, Roberts E, Lin VH, Chan JL, Farber RH; CAHtalyst Adult Trial Investigators. Phase 3 Trial of Crinecerfont in Adult Congenital Adrenal Hyperplasia. N Engl J Med. 2024 Aug 8;391(6):504-514.
4. ClinicalTrials.gov. Global safety and efficacy registration study of crinecerfont for congenital adrenal hyperplasia (CAHtalyst). Available at: https://www.clinicaltrials.gov/study/NCT04490915.