

# Specialty Guideline Management Crenessity

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Crenessity	crinecerfont

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications<sup>1</sup>

Crenessity is 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).

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

### Initial requests

- Chart notes or medical record documentation confirming diagnosis of classic congenital adrenal hyperplasia (CAH) by any of the following:
  - Genetic test to confirm presence of pathogenic variants in CYP21A2

Reference number(s)
6766-A

- Lab tests confirming 21-hydroxylase deficiency [e.g., baseline morning serum 17-hydroxyprogesterone (17-OHP) measurement by liquid chromatography-tandem mass spectrometry (LC-MS/MS), cosyntropin (ACTH) stimulation test, adrenal steroid profile]
- Chart notes, medical record documentation, or claims history supporting current utilization of glucocorticoid therapy.

## Continuation requests

Chart notes or medical record documentation confirming the member has achieved or maintained a positive clinical response to treatment (e.g., reduction in glucocorticoid therapy).

## Prescriber Specialties

This medication must be prescribed by or in consultation with an endocrinologist.

## Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Diagnosis of any other known forms of congenital adrenal hyperplasia (CAH) (e.g., 11-beta-hydroxylase deficiency, 17-alpha-hydroxylase deficiency).
- History of bilateral adrenalectomy, hypopituitarism, or other condition requiring chronic glucocorticoid therapy.

## Coverage Criteria

### Classic congenital adrenal hyperplasia<sup>1-5</sup>

Authorization of 12 months may be granted for treatment of classic congenital adrenal hyperplasia (CAH) if all of the following criteria are met:

- Member is 4 years of age or older.
- The diagnosis is confirmed by any of the following:
  - Genetic test to confirm presence of pathogenic variants in CYP21A2
  - Lab tests confirming 21-hydroxylase deficiency [e.g., baseline morning serum 17-hydroxyprogesterone (17-OHP) measurement by liquid chromatography-tandem mass spectrometry (LC-MS/MS), cosyntropin (ACTH) stimulation test, adrenal steroid profile]

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- Member is currently receiving glucocorticoid therapy and will continue glucocorticoid therapy in combination with requested drug.

## Continuation of Therapy

Authorization of 12 months may be granted for the continued treatment in members requesting reauthorization for classic CAH when the member has achieved or maintained a positive clinical response (e.g., reduction in glucocorticoid therapy) while continuing glucocorticoid therapy in combination with the requested drug.

## References

1. Crenessity [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.
2. Speiser PW, Arlt W, Auchus RJ, et al. Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase Deficiency: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2018;103:4043-4088.
3. Sarafoglou K, Kim MS, Lodish M, et al. Phase 3 Trial of Crinecerfont in Pediatric Congenital Adrenal Hyperplasia. *N Engl J Med.* 2024;391:493-503.
4. Auchus RJ, Hamidi O, Pivonllo R, et al. Phase 3 Trial of Crinecerfont in Adult Congenital Adrenal Hyperplasia. *N Engl J Med.* 2024;391(6):604-514.
5. Merke DP, Auchus RJ. Congenital Adrenal Hyperplasia Due to 21-Hydroxylase Deficiency. *N Engl J Med.* 2020;383:1248-61.