Reference number(s)
6766-A

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 Indication

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

    - Lab tests confirming 21-hydroxylase deficiency [e.g., baseline morning serum 17-hyroxyprogesterone (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 and stable for at least 1 month.

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

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-hyroxyprogesterone (17-OHP) measurement by liquid chromatography-tandem mass spectrometry (LC-MS/MS), cosyntropin (ACTH) stimulation test, adrenal steroid profile]
- Member is currently receiving glucocorticoid therapy and stable for at least 1 month.

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).

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.