BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

# 5.30.095

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| **Section:** | Prescription Drugs | **Effective Date:** | July 1, 2025 |
| **Subsection:** | Endocrine and Metabolic Drugs | **Original Policy Date:** | March 21, 2025 |
| **Subject:** | Crenessity | **Page:** | 1 of 4 |

***Last Review Date:*** June 12, 2025

# Crenessity

## Description

### Crenessity (crinecerfont)

**Background**
Crenessity (crinecerfont) is a selective corticotropin-releasing factor (CRF) type 1 receptor antagonist. Crenessity blocks the binding of CRF to CRF type 1 receptors in the pituitary but not CRF type 2 receptors. Crenessity binding to CRF type 1 receptors inhibits adrenocorticotropic hormone (ACTH) secretion from the pituitary, thereby reducing ACTH-mediated adrenal androgen production (1).

**Regulatory Status**
FDA-approved indication: 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) (1).

Crenessity has warnings for hypersensitivity reactions and risk of acute adrenal insufficiency or adrenal crisis with inadequate concomitant glucocorticoid therapy (1).

Patients receiving Crenessity should continue glucocorticoid replacement therapy for the adrenal insufficiency associated with congenital adrenal hyperplasia. Androstenedione levels can be assessed beginning four weeks after Crenessity initiation to inform reduction in glucocorticoid dosage as clinically indicated. Glucocorticoid dosage should not be reduced below what is required for replacement therapy (1).

The safety and effectiveness of Crenessity in pediatric patients less than 4 years of age have

not been established (1).

**Related policies**

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Crenessity may be considered **medically necessary** if the conditions indicated below are met.

Crenessity may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 4 years of age or older

**Diagnosis**

Patient must have the following:

Classic congenital adrenal hyperplasia (CAH)

**AND ALL** of the following:

1. Diagnosis has been confirmed by **ONE** of the following:
   i. Genetic test confirming the presence of pathogenic variants in CYP21A2
   ii. 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]
2. Patient has been stable on glucocorticoid therapy for at least 1 month
3. Patient will continue glucocorticoid replacement therapy for adrenal insufficiency associated with CAH

## Prior – Approval *Renewal* Requirements

**Age** 4 years of age or older

**Diagnosis**

Patient must have the following:

Classic congenital adrenal hyperplasia (CAH)

**AND ALL** of the following:

1. Patient has achieved or maintained a positive clinical response to therapy (e.g., reduction in glucocorticoid therapy)
2. Patient will continue glucocorticoid replacement therapy for adrenal insufficiency associated with CAH

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Quantity** 400 mg per day

**Duration** 12 months

### Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Crenessity is a corticotropin-releasing factor type 1 receptor antagonist that is indicated as adjunctive treatment to glucocorticoid replacement to control androgens in patients with classic congenital adrenal hyperplasia (CAH). The safety and effectiveness of Crenessity in pediatric patients less than 4 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Crenessity while maintaining optimal therapeutic outcomes.

**References**

1. Crenessity [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.

## Policy History

| Date | Action |
|---|---|
| March 2025 | Addition to PA |
| June 2025 | Annual review |

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.**