NEUROCRINE™ Access Support

Crenessity® (crinecerfont)

Streamlining Access

Navigating the CRENESSITY Approval Landscape

Prior authorizations (PAs) are often required for specialty medications like CRENESSITY. We understand that navigating insurance requirements can be challenging, so Neurocrine Access Support works with you and your office to help streamline the process.

With this support, **~9 out of 10 patients receive approval through their insurance. Of those who received an approval, 8 out of 10 received approval within 30 days.**[1]

Support for PAs, Denials, and Reauthorizations

Neurocrine Access Support provides hands-on assistance throughout the process.

A dedicated Care Coordinator helps with benefit verification and PA support, so your office can move patients forward with fewer delays.

Need live support? Call your dedicated Care Coordinator.

1-855-CRNSITY (276-7489)
8 AM to 8 PM ET, Monday through Friday

At any point in the treatment journey, Neurocrine Regional Patient Access Managers (RPAMs) can help with more complex coverage or reauthorization situations.

See the following pages for guidance on working through the insurance approval landscape:

PAGE 2 Navigating PAs

PAGE 3 Understanding Denials and Preparing Appeals

PAGE 4 Planning for Reauthorizations

Scan or click here to visit the Neurocrine Access Support website for useful access resources, including sample templates for Letters of Medical Necessity and Appeal, and more information about the program.

INDICATION

CRENESSITY (crinecerfont) 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).

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

CRENESSITY is contraindicated in patients with hypersensitivity to crinecerfont or any excipients of CRENESSITY.

Please see Important Safety Information throughout and full Prescribing Information.

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Navigating PAs

Key Information to Include in a PA Request for CRENESSITY

Many insurers have a specific PA form that needs to be completed. PA criteria for CRENESSITY vary by plan. Your Care Coordinator will help review PA forms or plan policy documents to offer clarity on what information is needed for your patient.

Being familiar with criteria that are typically required to access CRENESSITY can help streamline this process.

Common criteria include:

- **Patient Age:** Proof (ie, patient date of birth) that patients are within the label-indicated age range
- **Diagnostic Criteria:** Diagnosis of classic CAH as demonstrated by criteria such as an elevated 17-OHP level, a confirmed CYP21A2 genotype, a positive NBS with confirmatory second-tier testing, or cosyntropin stimulation testing
  - Plans may require evidence of just one or of multiple criteria
- **Treatment With GCs:** Record of treatment history and intention to continue concomitant GC therapy
  - Some plans also have specific dose threshold requirements
- **Laboratory Values:** Evidence of elevated androgen (ie, A4) levels
  - Some plans may also have specific A4 threshold requirements
- **Prescriber Details:** Requirement that CRENESSITY be prescribed by or in consultation with an endocrinologist
- **Dose Requirements:** Plans may outline other requirements such as those related to pediatric weight-based dosing or demonstrated need (eg, dysphagia) for the approval of the oral suspension dosage form

If your patient does not meet a specified threshold, you have the option to submit a Letter of Medical Necessity. Neurocrine Access Support can help.

Developing a Letter of Medical Necessity

If you feel that your patient may benefit from CRENESSITY but does not meet specific insurance criteria (eg, GC dose or A4 level thresholds), you have the option to submit a Letter of Medical Necessity. You can also submit a letter to strengthen your PA request with additional clinical details. It may be useful to include information such as:

- Your patient's treatment history and a summary of their experience with each
- The rationale for your patient's need for CRENESSITY, based on your clinical judgment
- Enclosures such as relevant patient medical records, treatment guidelines, published articles, etc.

17-OHP=17-hydroxyprogesterone; A4=androstenedione; CAH=congenital adrenal hyperplasia; CYP=cytochrome P; GC, glucocorticoid; NBS=newborn screening.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions. A hypersensitivity reaction, including throat tightness, angioedema, and generalized rash, occurred in a subject after 3 days of treatment with CRENESSITY. If a clinically significant hypersensitivity reaction occurs, initiate appropriate therapy and discontinue CRENESSITY.

Please see Important Safety Information throughout and full Prescribing Information.

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Understanding Denials and Preparing Appeals

An Insurance Denial Does Not Automatically Mean That Your Patient Cannot Get CRENESSITY

You have the option to appeal the plan's decision. Your Care Coordinator can work with your office help navigate the appeal process, including clarifying:

- The plan's process for appealing a denial
- Plan deadlines for appeal submissions
- Other plan-specific considerations to keep in mind

To streamline the appeal process and get assistance with a timely submission, **send your Care Coordinator the denial letter from your patient's plan** as soon as possible.

Common Reasons for Denials

- Incomplete information (eg, missing patient details, lab tests, diagnostic criteria)
- GC dosing lower than plan threshold

What to Include in an Appeal

During the appeal process, it can be helpful to keep the following general points in mind:

- Address the plan's specific reason for denial
- Include information that was missing from your original PA request (even if it was not called out in the denial letter)
- Any new clinical information that may have emerged since the time of your PA request
- Including a Letter of Appeal can further explain your rationale for prescribing CRENESSITY and support your appeal

You also have the option to request that the plan conduct an expedited review. Work with your Neurocrine Access Support team to understand what information you may need to provide for this kind of a request.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Risk of Acute Adrenal Insufficiency or Adrenal Crisis with Inadequate Concomitant Glucocorticoid Therapy. Acute adrenal insufficiency or adrenal crisis, which is potentially life-threatening, can occur in patients with underlying adrenal insufficiency who are on inadequate daily glucocorticoid doses, especially in situations associated with increased cortisol need, such as acute intercurrent illness, serious trauma, or surgical procedures. Continue glucocorticoids upon initiation of and during treatment with CRENESSITY. Do not reduce the glucocorticoid dose below the dose required for cortisol replacement. Patients should continue to use stress dosing of glucocorticoids in cases of increased cortisol need.

Please see Important Safety Information throughout and full Prescribing Information.

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Planning for Reauthorizations

Prepare in Advance to Help Ensure That You Will Be Ready for Submissions

Reauthorizations are a standard requirement for specialty therapies like CRENESSITY. Approval durations vary by plan (eg, 6 or 12 months).

Neurocrine Access Support will contact you before the PA expiration date to help prepare for reauthorization. They will help you identify plan-specific requirements, track timelines, and assist you throughout the submission process.

Providing recent labs often helps support reauthorizations, so it's important to plan ahead.

Key Information to Include in a Reauthorization

Required documentation typically includes evidence of clinical benefit, such as some or all of the following:

- Reduction or change in GC dose
- Reduction or control of A4 levels
- Signs of improvement with comorbidities associated with classic CAH and/or treatment with GCs

Neurocrine Access Support Is Here to Help You and Your Office Navigate CRENESSITY Approval

- Our team can help with PAs, appeals, and reauthorizations, including helping you develop Letters of Medical Necessity and Appeal
- Care Coordinators and RPAMs are available to help you understand specific plan requirements
- Maintain records of your submissions and plan determinations and share them with Neurocrine Access Support, so we can help support your future submission requests

Our commitment is simple and unwavering: to ensure every patient who needs CRENESSITY can start and continue on treatment.

Reference: 1. Historical average analyzed as of May 2026.

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

In adult patients, the most common adverse reactions (at least 4% for CRENESSITY and greater than placebo) are fatigue, headache, dizziness, arthralgia, back pain, decreased appetite, and myalgia.

In pediatric patients, the most common adverse reactions (at least 4% for CRENESSITY and greater than placebo) are headache, abdominal pain, fatigue, nasal congestion, and epistaxis.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at **www.fda.gov/medwatch** or call **1-800-FDA-1088**.

Dosage Form and Strengths:
CRENESSITY is available in 50 mg and 100 mg capsules, and as an oral solution of 50 mg/mL.

Please see full Prescribing Information.

CP-CFT-US-1162 08/2026

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