

## Clinical Policy: Cosyntropin (Cortrosyn)

Reference Number: CP.PHAR.203

Effective Date: 04.01.16

Last Review Date: 02.23

Line of Business: HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Cosyntropin (Cortrosyn<sup>®</sup>) is a synthetic subunit of adrenocorticotrophic hormone (ACTH).

### FDA Approved Indication(s)

Cortrosyn is indicated for use as a diagnostic agent in the screening of patients presumed to have adrenocortical insufficiency.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Cortrosyn is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Presumed Adrenocortical Insufficiency (must meet all):

1. Prescribed for diagnostic testing of adrenocortical insufficiency;
2. If Cortrosyn is requested, member must use generic cosyntropin, unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed one of the following (a or b):
  - a. If age  $\leq$  2 years: 0.125 mg per dose (1 vial);
  - b. If age  $>$  2 years: 0.75 mg per dose (3 vials).

**Approval duration: 1 dose**

##### B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

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of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

**II. Continued Therapy****A. Presumed Adrenocortical Insufficiency**

1. Re-authorization is not permitted. Members must meet the initial approval criteria.  
**Approval duration: Not applicable**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information***Appendix A: Abbreviation/Acronym Key*

ACTH: adrenocorticotrophic hormone

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): hypersensitivity to Cosyntropin injection, synthetic ACTH, or to any of the excipients.
- Boxed warning(s): none reported

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**V. Dosage and Administration**

| Indication                                  | Dosing Regimen  | Maximum Dose |
|---|---|--------------|
| Diagnostic testing of adrenal insufficiency | 0.25-0.75 mg IV or IM; in pediatric patients ≤ 2 years, 0.125 mg will often suffice | 0.75 mg/dose |

**VI. Product Availability**

Vial for injection: 0.25 mg

**VII. References**

1. Cosyntropin Prescribing Information. Princeton, NJ: Sandoz Inc. May 2018. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/022028s005lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022028s005lbl.pdf) Accessed October 12, 2022.
2. Cortrosyn Prescribing Information. Rancho Cucamonga, CA. Amphastar Pharmaceuticals, Inc.; December 2021. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/016750Orig1s032lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/016750Orig1s032lbl.pdf). Accessed October 12, 2022.
3. Cosyntropin Drug Monograph. Clinical Pharmacology. Elsevier; 2022. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed October 12, 2022.
4. Bornstein, S, Allolio B, Arlt, Wiebke, et al. Diagnosis and Treatment of Primary Adrenal Insufficiency: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology and Metabolism. Feb 2016; 101(2): 364-389.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description                     |
|-------------|---------------------------------|
| J0834       | Injection, cosyntropin, 0.25 mg |

| Reviews, Revisions, and Approvals  | Date     | P&T Approval Date |
|--|----------|-------------------|
| 1Q 2019 annual review: no significant changes; references reviewed and updated   | 10.12.18 | 02.19             |
| 1Q 2020 annual review: no significant changes; references reviewed and updated; added HIM line of business                       | 11.04.19 | 02.20             |
| 1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated. | 11.03.20 | 02.21             |
| 1Q 2022 annual review: added generic redirection for Cortrosyn requests; references reviewed and updated                         | 09.20.21 | 02.22             |
| Template changes applied to other diagnoses/indications.   | 10.03.22 |                   |

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| Reviews, Revisions, and Approvals  | Date     | P&T Approval Date |
|--|----------|-------------------|
| 1Q 2023 annual review: no significant changes; modified dosing limits for age 2 or less to 0.125 mg per prescribing information; removed inactive HCPCS code J0833; references reviewed and updated. | 10.13.22 | 02.23             |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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