Clinical Policy: Cosyntropin (Cortrosyn)

Reference Number: LA.PHAR.203
Effective Date: 09.15.22
Last Review Date: 05.06.24 ~~06.02.23~~
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description
Cosyntropin (Cortrosyn®) is a synthetic subunit of adrenocorticotropic 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 Louisiana Healthcare Connections 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 ≤ 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 LA.PMN.255
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 LA.PMN.53

II. Continued Therapy

A. Presumed Adrenocortical Insufficiency

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

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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 LA.PMN.255
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: LA.PMN.53

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 LA.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ACTH: adrenocorticotropic 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

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 Accessed October 12, 2022.~~

~~2.~~1. Cortrosyn Prescribing Information. Rancho Cucamonga, CA. Amphastar Pharmaceuticals, Inc.; December 2021. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/016750Orig1s032lbl.pdf. Accessed October ~~12, 2022~~19, 2023.

~~3.~~2. Cosyntropin Drug Monograph. Clinical Pharmacology. Elsevier; 2022. Available at: https://www.clinicalkey.com/pharmacology/. Accessed October ~~12, 2022~~19, 2023.

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~~4.~~3. 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	LDH Approval Date
Converted corporate to local policy.	09.22	09.15.22
Template changes applied to other diagnoses/indications. Modified dosing limits for age 2 or less to 0.125 mg per prescribing information; removed inactive HCPCS code J0833; references reviewed and updated. Added verbiage this policy is for medical benefit only.	06.02.23	10.05.23
Annual review: no significant changes; references reviewed and updated.	05.06.24	

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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.

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

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.