Clinical Policy: Cosyntropin (Cortrosyn)

Reference Number: PA.CP.PHAR.203
Effective Date: 01/2018
Last Review Date: 01/2023

Coding Implications
Revision Log

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
It is the policy of PA Health & Wellness that cosyntropin and Cortrosyn are **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Presumed Adrenocortical Insufficiency (must meet all):

1. Prescribed for the 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 of Cortrosyn does not exceed one of the following (a or b):
   a. If ≤ 2 years: 0.125 mg per dose (1 vial);
   b. If > 2 years: 0.75 mg per dose (3 vials);

Approval duration: 1 dose

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Presumed Adrenocortical Insufficiency:

1. Re-authorization is not permitted. Member must be evaluated against the initial approval criteria.

Approval duration: Not applicable

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. 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): history of previous adverse reaction to Cortrosyn, synthetic ACTH, or to any of the excipients.
- Boxed warning(s): none reported

IV. 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

V. Product Availability
Vial for injection: 0.25 mg

VI. 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. 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.
3. Cosyntropin Drug Monograph. Clinical Pharmacology. Tampa, FL: Gold Standard Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com. Accessed September 20, 2021.
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 (Cortrosyn), 0.25 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Modified max dose criteria from 0.125 mg to 0.25 mg for age ≤ 2 years since 0.125 is not a true max per labeling, plus partial vials cannot be dispensed so a dose of 0.125 is unenforceable post-approval. References reviewed and updated.	02/2018	

Reviews, Revisions, and Approvals	Date	Approval Date
1Q 2019 annual review: references reviewed and updated	01/2019	
1Q 2020 annual review: references reviewed and updated.	01/2020	
1Q 2021 annual review: references reviewed and updated.	01/2021	
1Q 2022 annual review: added generic redirection for Cortrosyn requests; references reviewed and updated	01/2022	
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.	01/2023	