Clinical Policy: Cosyntropin (Cortrosyn)

Reference Number: PA.CP.PHAR.203
Effective Date: 01/2018
Last Review Date: 01/2025

Description
Cosyntropin (Cortrosyn®) is a synthetic subunit of adrenocorticotropic hormone (ACTH).

FDA Approved Indication(s)
Cortrosyn is indicated, in combination with other diagnostic tests, for use as a diagnostic agent in the screening adrenocortical insufficiency in adult and pediatric patients.

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 (1 vial);
   b. If ≥ 2 years: 0.25 mg (1 vial).

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.PHARM.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 cosyntropin or any excipients of Cortosyn.
- Boxed warning(s): none reported

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Diagnostic testing of adrenal insufficiency	Single dose administered by IV or IM injection Adults: 0.25 mg Pediatric patients < 2 years: 0.125 mg Pediatric patients 2 to 17 years: 0.25 mg	See dosing regimen

V. Product Availability

Vial for injection: 0.25 mg

VI. References

1. Cortrosyn Prescribing Information. Rancho Cucamonga, CA. Amphastar Pharmaceuticals, Inc.; December 2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/016750s033lbl.pdf.Accessed October 22, 2024.
2. Cosyntropin Drug Monograph. Clinical Pharmacology. Tampa, FL: Gold Standard Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com. Accessed October 19, 2023.
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
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
1Q 2019 annual review: references reviewed and updated	01/2019

Reviews, Revisions, and Approvals	Date
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
1Q 2024 annual review: no significant changes; references reviewed and updated.	01/2024
1Q 2025 annual review: updated maximum dosing in those age 2 years and older to 0.25 mg as a single-dose per updated prescribing information; references reviewed and updated.	01/2025