Clinical Policy: Cosyntropin (Cortrosyn)

Reference Number: PA.CP.PHAR.203
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

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

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 health plans affiliated with Pennsylvania Health and 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. Used for the diagnostic testing of adrenocortical insufficiency;
2. Prescribed dose of Cortrosyn does not exceed one of the following (a or b):
   a. If ≤ 2 years: 0.25 mg per dose;
   b. If > 2 years: 0.75 mg per dose.

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 Pennsylvania Health and 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

Background
Description/Mechanism of Action:
Cortrosyn (cosyntropin) exhibits the full corticosteroidogenic activity of natural adrenocorticotropic hormone (ACTH). The pharmacologic profile of Cortrosyn is similar to that of purified natural ACTH. It has been established that 0.25 mg of Cortrosyn will stimulate the adrenal cortex maximally and to the same extent as 25 units of natural ACTH. The extra-adrenal

effects which natural ACTH and cosyntropin have in common include increased melanotropic activity, increased growth hormone secretion, and an adipokinetic effect.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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
- 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

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
J0833	Injection, cosyntropin, not otherwise specified, 0.25 mg
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.	02/18	
1Q 2019 annual review: references reviewed and updated	01/19	

References

1. Cosyntropin Prescribing Information. Rockford, IL: Mylan Institutional, LLC; January 2013. Available at http://www.mylan.com/en/products/product-catalog/product-profile-page?id=CFF5A292-052C-4646-A4FA-84904388960D. Accessed October 12, 2018.
2. Cortrosyn Prescribing Information. Rancho Cucamonga, CA. Amphastar Pharmaceuticals, Inc.; September 2010. Available at http://www.cortrosyn.com. Accessed October 12, 2018.