Clinical Policy: Cosyntropin (Cortrosyn)

Reference Number: PA.CP.PHAR.203
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for cosyntropin (Cortrosyn™).

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/dose;
   b. If > 2 years: 0.75 mg/dose.

Approval duration: 1 dose

B. Other diagnoses/indications: Refer to PA.CP.PMN.53 - Global Biopharm Policy

II. Continued Approval

A. Presumed Adrenocortical Insufficiency (must meet all):

B. Continuation of therapy will not be granted. Member must be evaluated against the initial approval criteria. **Other diagnoses/indications:** 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

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.

Formulations:
Cortrosyn (cosyntropin) for Injection 0.25 mg /mL
Cosyntropin for Injection 0.25 mg /mL

Cortrosyn and cosyntropin for injection are intended as a single dose injection and contain no antimicrobial preservative. Any unused portion should be discarded.

Appendices

Appendix A: Abbreviation Key

ACTH**:** adrenocorticotropic hormone

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	

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 30, 2017.
2. Cortrosyn Prescribing Information. Rancho Cucamonga, CA. Amphastar Pharmaceuticals, Inc.; September 2010. Available at http://www.cortrosyn.com. Accessed October 30, 2017.