Clinical Policy: Cosyntropin (Cortrosyn)

Reference Number: ERX.SPA.183
Effective Date: 01.11.17
Last Review Date: 02.18 Revision Log

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

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
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Cortrosyn is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Presumed Adrenal Insufficiency (must meet all)**:**

1. Prescribed for diagnostic testing of adrenocortical insufficiency;
2. Dose does not exceed one of the following (a or b):
   a. If age ≤ 2 years: 0.25 mg/dose (1 vial);
   b. If age > 2 years: 0.75 mg/dose (3 vials).

Approval duration: 1 dose

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Presumed Adrenal Insufficiency

1. Continuation of therapy will not be granted. Member must meet the initial approval criteria.

Approval duration: N/A

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
N/A

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
For diagnosis 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. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	12.16	01.17
4Q17 Annual Review Converted to new template. 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 PI, plus partial vials cannot be dispensed so a dose of 0.125 cannot be enforced post-approval. Added continuation criteria to clarify that continuation of therapy will not be granted and member must meet the initial approval criteria.	09.21.17	11.17
1Q18 annual review: No significant changes. References reviewed and updated.	10.30.17	02.18

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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