Clinical Policy Title:	cosyntropin
Policy Number:	RxA.76
Drug(s) Applied:	Cortrosyn®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Cosyntropin (Cortrosyn®) is a synthetic subunit of adrenocorticotropic hormone. It is indicated for use as a diagnostic agent in the screening of patients presumed to have adrenocortical insufficiency.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
cosyntropin (Cortrosyn®)	Diagnostic testing of adrenal insufficiency	Adults: 0.25-0.75 mg IV or IM; Pediatrics <2 years: 0.125 mg IV or IM	0.75 mg/dose

Dosage Forms

- Vial of sterile lyophilized powder for injection: 0.25 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Presumed Adrenocortical 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 per dose (1 vial);
   b. If age > 2 years: 0.75 mg per dose (3 vials).

Approval Duration
Commercial: 1 dose
Medicaid: 1 dose

II. Continued Therapy Approval

A. Presumed Adrenocortical Insufficiency (must meet all):

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval Duration
Commercial: Not applicable

Medicaid: Not applicable

III. Appendices

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.

APPENDIX D: General Information

- Cosyntropin exhibits the full corticosteroidogenic activity of natural ACTH. Various studies have shown that the biologic activity of ACTH resides in the N-terminal portion of the molecule and that the 1-20 amino acid residue is the minimal sequence retaining full activity. Partial or complete loss of activity is noted with progressive shortening of the chain beyond 20 amino acid residues.

References

1. Cosyntropin Prescribing Information. Princeton, NJ: Sandoz Inc. June 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022028s005lbl.pdf. Accessed February 03, 2021.
2. Cortrosyn Prescribing Information. Rancho Cucamonga, CA. Amphastar Pharmaceuticals, Inc.; December 2015. Available at: https://pdf.hres.ca/dpd_pm/00033372.PDF Accessed February 03, 2021.
3. Cosyntropin Drug Monograph. Clinical Pharmacology. Tampa, FL: Gold Standard Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com. Accessed February 03, 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. Accessed February 03, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1) Clinical policy title was updated as "Cosyntropin". 2) Line of business policies applies to All lines of business. 3) Appendix D was updated. 4) References were reviewed and updated.	02/03/2021	03/09/2021