Corticotropin-ACTH:

Acthar® Gel (repository corticotropin injection)
Cortrophin™ Gel (repository corticotropin injection)
(Intramuscular)

Document Number: IC-0003

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I. Length of Authorization

Coverage will be provided for 1 month and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Acthar Gel 80 units/mL injection (5 mL multi-dose vial): 4 vials per 28 days
- Cortrophin Gel 80 units/mL injection (5 mL multi-dose vial): 4 vials per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 35 billable units (1377 USP units) every 28 days

III. Initial Approval Criteria [1,2,5-18,47-52]

Infantile Spasms (West Syndrome) (Acthar † Φ; Cortrophin ‡[48-53])

- Patient is under 2 years of age; **AND**
- Clinical documentation indicating patient has a diagnosis of infantile spasms (West Syndrome); **AND**
- Must be used as monotherapy; **AND**
- Documentation that patient does not have a suspected congenital infection

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

Use of repository corticotropin injection for indications including, but not limited to, those additionally listed in the product labeling are not supported by substantial clinical evidence.
Repository Corticotropin Injection was originally approved by the U.S. Food and Drug Administration (FDA) in 1952 as HP ACTH and in 1954 as Cortrophin, for a variety of disorders and diseases that at the time were thought to benefit from steroid mediated immunosuppression. The initial approval of H.P. ACTH and CORTROPHIN gels occurred prior to the Kefauver-

Harris amendment to the Federal Food, Drug and Cosmetic Act of 1962, which introduced the requirement of "substantial evidence" of two adequate and well controlled trials. At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing patients with conditions originally treated with adrenocorticotropic hormone powder that were transferred to treatment with the approved product and gave dosing guidance for treatment of these individual conditions. These data would be grossly inadequate to support approval of a new drug or new indications by the Agency under current standards requiring evidence from adequate and well-controlled clinical trials. A Drug Efficacy Study Implementation (DESI) review of corticotrophin injection (Acthar NDA 022432) was initiated in 1971 and finalized in 1977.[4] Cortrophin was approved via sNDA November 2021.

IV. Renewal Criteria [1,2]

Authorizations can be renewed based on the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as indicated by resolution of symptoms and/or normalization of laboratory tests; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infections, severe electrolyte imbalances, gastric bleeding or ulcer, hypertension, hypokalemia, severe depression, frank psychotic manifestations, posterior subcapsular cataracts, glaucoma, anaphylaxis, etc.

V. Dosage/Administration [1,4,47-50]

Indication	Dose
Infantile Spasms	Administer 75 units/m² intramuscularly given twice daily for 2 weeks, then taper the dose over a 2 week period (e.g., 30 units/m² in the morning for 3 days; 15 units/m² in the morning for 3 days; 10 units/m² in the morning for 3 days; and 10 units/m² every other morning for 6 days).

VI. Billing Code/Availability Information

HCPCS code:

- J0800 – Injection, corticotropin, up to 40 units; up to 40 units = 1 billable unit (applicable to Acthar only)
- J3490 – Unclassified Drugs (applicable to Cortrophin ONLY)

NDC:

- H.P. Acthar Gel 80 units/mL (5 mL multi-dose vial): 63004-8710-xx
- Purified Cortrophin Gel 80 USP units/mL (5 mL multi-dose vial): 62599-0860-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G40.821	Epileptic spasms, not intractable, with status epilepticus
G40.822	Epileptic spasms, not intractable, without status epilepticus
G40.823	Epileptic spasms, intractable, with status epilepticus
G40.824	Epileptic spasms, intractable, without status epilepticus

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC