MEDICAL MUTUAL®

Drug Policy

Policy:	**201010-MRx (04-23)**	**Initial Effective Date: 12/15/2010**
Code(s):	**HCPCS J0800, J3590**	**Annual Review Date: 04/20/2023**
SUBJECT:	**Corticotropin-ACTH:** • **Acthar® Gel (repository corticotropin injection)** • **Cortrophin ™ Gel (repository corticotropin injection)**	**Last Revised Date: 04/20/2023**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

POLICY STATEMENT

This policy involves the use of HP Acthar. Prior authorization is recommended for medical benefit coverage of HP Acthar. Approval is recommended for those who meet the conditions of coverage in the **Initial Approval and Renewal Criteria, Preferred Drug (when applicable), Dosing/Administration, Length of Authorization, and Site of Care (when applicable)** for the diagnosis provided. The requirement that the patient meet the Criteria and Preferred Drug for coverage of the requested medication applies to the initial authorization only. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy.

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/m^2 in the morning for 3 days; 15 units/m^2 in the morning for 3 days; 10 units/m^2 in the morning for 3 days; and 10 units/m^2 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): 62559-0860-xx

VII. References

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FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J0800