Corticotropin Therapy (HP Acthar®)

NDC CODE(S) 63004-8710-XX ACTHAR 80 UNIT/ML Gel (QUESTCOR)
63004-8710-XX ACTHAR 80UNIT/ML Solution (MALLINCKRODT PH)

DESCRIPTION

Corticotropin is a highly purified sterile preparation of adrenocorticotropic hormone (ACTH). It is currently only commercially available in gelatin to provide a prolonged release in tissues after subcutaneous or intramuscular injection. ACTH stimulates the adrenal cortex to produce multiple hormones, including cortisol, corticosterone and aldosterone.

POLICY

- Corticotropin therapy for the treatment of infantile spasms (West syndrome) is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Corticotropin therapy for diagnostic testing of adrenocortical function is considered ***not medically necessary***.
- Corticotropin therapy for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

Infantile spasms (West Syndrome)

- 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

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 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 gel 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 Acthar powder that were transferred to treatment with Acthar Gel 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 was initiated in 1971 and finalized in 1977.3

RENEWAL CRITERIA

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in the Initial Approval Criteria; 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, etc.

DOSAGE/ADMINISTRATION

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).

LENGTH OF AUTHORIZATION

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

DOSING LIMITS

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

- 35 billable units every 28 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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Policy

Medical Policy Manual **Approved Revision: Do Not Implement until 8/31/21**

EFFECTIVE DATE 8/31/2021

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