

## PHARMACY POLICY STATEMENT

### Marketplace

<b>DRUG NAME</b>	<b>Acthar Gel (repository corticotropin injection)</b>
BILLING CODE	J0800
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office
STATUS	Prior Authorization Required

Acthar is a corticotropin initially approved by the FDA in 1952. It is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. The mechanism of action of Acthar Gel in the treatment of infantile spasms is unknown. Acthar Gel and endogenous ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of Acthar Gel induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is under the influence of the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated plasma cortisol suppresses ACTH release. Acthar Gel is also reported to bind to melanocortin receptors. The trophic effects of endogenous ACTH and Acthar Gel on the adrenal cortex are not well understood beyond the fact that they appear to be mediated by cyclic AMP.

**Acthar Gel (repository corticotropin injection)**

**CareSource considers Acthar Gel (repository corticotropin injection) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
10/08/2018	New policy for H.P.Acthar created. Policy placed in the new format.
01/22/2021	Changed name to Acthar. Increased the quantity limit to 3 vials (15 mL) per 28 days. Adjusted specialist name. Added that BSA or height/weight must be provided to calculate quantity. Reworded reauth requirement to be more specific. Added member must be under 2 years of age for reauth. Added that member must experience relapse in spasm symptoms after Acthar was discontinued. Updated references.
05/05/2022	Transferred to new format. Updated references. Added medication must be used as monotherapy.

References:

1. H.P. Acthar Gel [package insert]. Hazelwood, MO: Mallinckrodt ARD Inc.; October 2021.
2. AAN/CNS evidence-based guideline update on medical treatment of infantile spasms. *Neurology* 2012; 78 (24): 1974 – 80. doi: 10.1212/WNL.0b013e318259e2cf.
3. Wilmschurst JM, Gaillard WD, Vinayan KP, et al. Summary of recommendations for the management of infantile seizures: Task Force Report for the ILAE Commission of Pediatrics. *Epilepsia*. 2015;56(8):1185-1197. doi:10.1111/epi.13057.
4. Nelson GR. Management of infantile spasms. *Transl Pediatr*. 2015;4(4):260-270. doi:10.3978/j.issn.2224-4336.2015.09.01.
5. Gold Standard, Inc. Corticotropin ACTH. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc; 2012. Available from: <http://www.clinicalpharmacology.com>.
6. Management and progno