CareSource

PHARMACY POLICY STATEMENT Georgia Medicaid	
DRUG NAME	Acthar Gel (repository corticotropin injection)
BILLING CODE	Medical - J0800 Pharmacy - Must use valid NDC
BENEFIT TYPE	Pharmacy or Medical
SITE OF SERVICE ALLOWED	Home, Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 3 vials (15 mL total) per 28 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Acthar Gel (repository corticotropin injection) is a non-preferred product and will only be considered for coverage under the pharmacy or medical benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

INFANTILE SPASMS (West syndrome, X-linked infantile spasms syndrome)

For initial authorization:

1. **Member is an infant or a child under 2 years of age; AND**
2. **Medication must be prescribed by a pediatric neurologist or an epileptologist; AND**
3. **Member has documented diagnosis of infantile spasms in chart notes; AND**
4. Member's body surface area (BSA, m^2) **or height and weight have been provided to determine the appropriate dosage.**
5. **Dosage allowed: The recommended regimen is a maximum daily dose of 150 U/m^2 (divided into twice daily injections of 75 U/m^2) for 2 weeks. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period.** The dosing calculator is available on Acthar's **website.**

If member meets all the requirements listed above, the medication will be approved for 1 month.

For reauthorization:

1. **Member must be under 2 years of age; AND**
2. **Chart notes demonstrate clinical benefit from the initial use of medication (e.g., suppression of spasm symptoms); AND**
3. **Member experienced a relapse in spasm symptoms after Acthar was discontinued.**

If member meets all the reauthorization requirements above, the medication will be approved for an additional 1 month.

CareSource considers Acthar Gel (repository corticotropin injection) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- **Corticosteroid-responsive conditions (e.g., systemic lupus erythematosus, multiple sclerosis, Stevens-**Johnson's syndrome, oph**thalmic diseases, rheumatic disorders, serum sickness, and symptomatic**

sarcoidosis) as it has not been proven to be any more effective than corticosteroids for these indications
- All other uses of Acthar Gel are considered experimental/investigational

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.

References:

1. H.P. Acthar Gel [package insert]. Hazelwood, MO: Mallinckrodt ARD Inc.; March, 2019.
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. Wilmshurst 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 prognosis of infantile spasms. Daniel G Glaze. UpToDate [online database]. Available from: http://www.uptodate.com
7. Milanese C, La Mantia L, Salmaggi A, et al. Double-blind randomized trial of ACTH versus dexamethasone versus methylprednisolone in multiple sclerosis bouts. Clinical, cerebrospinal fluid and neurophysiological results. Eur Neurol. 1989; 29 (1): 10 – 14.
8. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology. 1989; 39 (7): 969 – 971.

Effective date: 07/01/2021
Revised date: 01/22/2021