CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Acthar Gel (repository corticotropin injection)
BILLING CODE	Medical - J0800
BENEFIT TYPE	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) will be considered for coverage under the **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, ophthalmic 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.
10/6/2022	Updated benefit to medical only due to OH single PBM.

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: 10/1/2022
Revised date: 10/06/2022