

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

DRUG NAME	H.P. 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— Two-5mL vials per 26 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

H.P. 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 has documented diagnosis of infantile spasms; AND
2. Member is an infant or a child under 2 years of age; AND
3. Medication must be prescribed by a pediatric neurologist or an epilepsy physician specialist.
4. **Dosage allowed:** The recommended regimen is a daily dose of 150 U/m<sup>2</sup> (divided into twice daily intramuscular injections of 75 U/m<sup>2</sup>) administered over a 2-week period.

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

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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

**CareSource considers H.P. 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 H.P. Acthar Gel (e.g., acute gout, childhood epilepsy, and use in tobacco cessation) are considered experimental/investigational

DATE	ACTION/DESCRIPTION
10/08/2018	New policy for H.P.Acthar created. Policy placed in the new format.

## References:

1. H.P. Acthar Gel [package insert]. Hazelwood, MO: Mallinckrodt ARD Inc.; July, 2017.
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. Gold Standard, Inc. Corticotropin ACTH. *Clinical Pharmacology* [database online]. Tampa, FL: Gold Standard, Inc; 2012. Available from: <http://www.clinicalpharmacology.com>.
4. Management and prognosis of infantile spasms. Daniel G Glaze. UpToDate [online database]. Available from: <http://www.uptodate.com>
5. 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.
6. 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.
7. Simsarian JP, Saunders C, Smith DM. Five-day regimen of intramuscular or subcutaneous self-prospective, randomized, open-label pilot trial. *Drug Des Devel Ther.* 2011; 5:381 – 389.
8. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotrophic hormone (ACTH) gel. *Drug Des Devel Ther.* 2011; 5:147 – 153.
9. 1Go CY, Mackay MT, Weiss SK, Stephens D, Adams-Webber T, Ashwal S, Snead, III OC. Evidence-based guideline update: Medical treatment of infantile spasms. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology.* 2012; 78(24): 1974 – 1980.
10. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. *Cochrane Database Syst Rev.* 2013.
11. French JA, Mosier M, Walker S, et al. A double-blind, placebo-controlled study of vigabatrin (3 g/day) in patients with uncontrolled complex partial seizures. *Vigabatrin Protocol 024 Investigative Cohort. Neurology* 1996;46(1):54-61.
12. Dean C, Mosier M, Penry K. Dose-response study of vigabatrin as add-on therapy in patients with uncontrolled complex partial seizures. *Epilepsia.* 1999;40(1):74-82.

Effective date: 12/13/2018

Revised date: 10/08/2018