CareSource

PHARMACY POLICY STATEMENT **Arkansas PASSE**	
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 **NOT** MEDICALLY NECESSARY	Click Here

H.P. Acthar Gel (repository corticotropin injection) 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. **Dosage allowed:** The recommended regimen is a daily dose of 150 U/m^2 (divided into twice daily intramuscular injections of 75 U/m^2) 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.
12/21/2021	Removed prescriber specialty requirement.

References:

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2. AAN/CNS evidence-based guideline update on medical treatment of infantile spasms. Neurology 2012: 78 (24): 1974 – 80. doi: 10.1212/WNL.0b013e318259e2cf.
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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 adrenocorticotropic 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: 01/01/2022
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