CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Acthar Gel (repository corticotropin injection)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Acthar Gel 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 and for the treatment of exacerbations of multiple sclerosis in adults. 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. A recent review found repository corticotropin injection was not superior to corticosteroids for treating relapses of MS.

Acthar Gel (repository corticotropin injection) will be considered for coverage when the following criteria are met:

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; AND
5. Medication is used as monotherapy; AND
6. **Dosage allowed/Quanity limit:** The recommended regimen is a maximum daily dose of 150 U/m^2 (divided into twice daily injections of 75 U/m^2) intramuscularly for 2 weeks. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period. Quantity Limit: 3 vials (15 mL total) per 28 days.

If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional month.

Multiple Sclerosis

For **initial** authorization:

1. Member is at least 18 years of age or older; AND
2. Medication must be prescribed by a neurologist; AND
3. Member must have documentation of a current acute exacerbation of MS; AND
4. Member must have a previous 3-day trial and failure of intravenous methylprednisolone at a dose
4. of at least 1000 mg daily; AND
5. Medication is being used as add-on treatment to disease modifying therapy (ex. Copaxone,Gilenya, Plegridy, etc.); AND
6. Member does **NOT** have **ANY** of the following:
    a. Scleroderma
    b. Osteoporosis
    c. Systemic fungal infections
    d. Ocular herpes simplex
    e. History of or the presence of a peptic ulcer
    f. Congestive heart failure
    g. Primary adrenocortical insufficiency or adrenocortical hyperfunction
7. **Dosage allowed/Quantity limit:** Administer 80-120 units daily intramuscularly or subcutaneously for 2-3 weeks. Quantity Limit: 7 vials or 42 injectors per 21 days.

If all the above requirements are met, the medication will be approved for 3 weeks.

For **reauthorization**:

1. Acthar gel will not be reauthorized.

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.
03/16/2023	Added diagnosis of multiple sclerosis (MS). Added references. Updated background information to include MS.
05/17/2024	MS: Added subcutaneous dosing and quantity limit. Infantile spasms: Clarified dosing as intramuscular only.
8/15/2024	Approved by ODM

References:

1. H.P. Acthar Gel [package insert]. Hazelwood, MO: Mallinckrodt ARD Inc.; 2024.
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.
9. Tran KA, Harrod C, Bourdette DN, Cohen DM, Deodhar AA, Hartung DM. Characterization of the Clinical Evidence Supporting Repository Corticotropin Injection for FDA-Approved Indications: A Scoping Review. JAMA Intern Med. 2022;182(2):206–217.
10. Grant AR, Day GS, Ann Marrie R, et al. Practice guidelines: Disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788
11. Filippini G, Brusaferri F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database Syst Rev. 2000;(4):CD001331. doi:10.1002/14651858.CD001331
12. Berkovich R. Treatment of acute relapses in multiple sclerosis. *Neurotherapeutics*. 2013;10(1):97-105. doi:10.1007/s13311-012-0160-7

Effective date: 10/01/2024
Revised date: 05/17/2024