Generic Name: Repository corticotropin injection gel

Therapeutic Class or Brand Name: Acthar Gel

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/2/2019

Date Last Reviewed / Revised: 8/20/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions (A or B) AND must meet ALL criteria listed under applicable diagnosis.

   A. Infantile spasms (West Syndrome)

      1. Confirmation of diagnosis by an electroencephalogram (EEG).
      2. Documented body surface area (BSA), dosing schedule, and dose and quantity are appropriate for patient's treatment regimen including tapering schedule.
      3. Age: under 2 years old.

   B. Multiple sclerosis with evidence of acute exacerbation

      1. Documentation of concurrent treatment with multiple sclerosis agents.
      2. Documented treatment failure, intolerance, or contraindication to a 1-month trial of oral and a 7-day trial of parenteral glucocorticoid therapy.
      3. Age: 18 years or older.

II. Must be prescribed by or in consultation with an epilepsy specialist or neurologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Acthar for the treatment of rheumatic disorders, collagen diseases, dermatologic disease, serum sickness, ophthalmic disease, symptomatic sarcoidosis, or edematous state (see other criteria for further explanation).
- Patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin.

- Concurrent administration of live or live attenuated vaccines.
- Congenital infections.
- Primary adrenocortical insufficiency or adrenocortical hyperfunction.

OTHER CRITERIA

- Repository corticotropin is not considered medically necessary for conditions, including but not limited to, rheumatic disorders, dermatologic diseases, nephrotic syndrome, ophthalmic diseases, respiratory diseases, serum sickness, or collagen diseases. Although Acthar gel is approved for these indications, available data to support use in these conditions are limited and use has been replaced by other agents.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Infantile spasms (West Syndrome): Up to the quantity and duration required for patient's documented dosing regimen and tapering schedule.
- Exacerbation of multiple sclerosis: 80 to 120 units IM or SUBQ daily for 2 to 3 weeks for acute exacerbations.

APPROVAL LENGTH

- **Authorization:** One time for a single treatment duration.
- **Re-Authorization:** One time for a single treatment duration.
    - Initial approval criteria are met.
    - An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and the medication was effective during previous exacerbation.
    - It is not used as "Pulse Therapy" on a Monthly Basis.

APPENDIX

N/A

REFERENCES

1. 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

2. 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. doi: 10.1212/wnl.39.7.969
3. Erdemir G, Rao CK, Pino AF, et al; Pediatric Epilepsy Research Consortium Infantile Spasm Work Group and International Committee. Diagnosis and management guidelines for infantile epileptic spasms syndrome around the world: A scoping review and comparative study of international approaches. *Epilepsia*. 2026 Jun 11. doi: 10.1002/epi.70329
4. Acthar Gel. Prescribing information. Keenova Therapeutics plc; 2026. Accessed July 30, 2026. https://www.acthar.com/pdf/Acthar-PI.pdf.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.