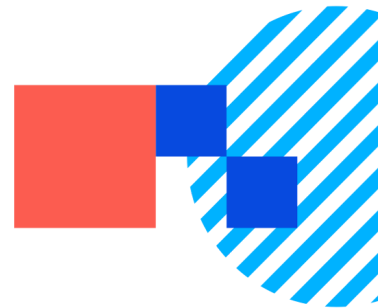




## Acthar Gel Prior Authorization Drug List A

|                  |                                       |
|------------------|---------------------------------------|
| Drug(s) Applied: | Acthar gel (repository corticotropin) |
|------------------|---------------------------------------|

### Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

#### I. Initial Therapy Criteria

##### A. Infantile spasms as indicated by chart notes within past 90 days

1. Patient is less than 24 months of age **and**
2. Patient has a documented diagnosis of infantile spasms confirmed by an electroencephalogram (EEG) demonstrating hypsarrhythmia, modified hypsarrhythmia, or other diagnostic epileptic encephalopathy features **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug Contraindications include but are not limited to:
  - a) Suspected congenital infections **and**
  - b) Systemic fungal infections **and**
  - c) Recent surgery **and**
4. ONE of the following
  - a) Patient has tried and had an inadequate response or intolerance to glucocorticoids (e.g. prednisolone) or has a contraindication to glucocorticoids **or**
  - b) Patient has tried and had an inadequate response to vigabatrin **and**
5. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurology or epileptologist)

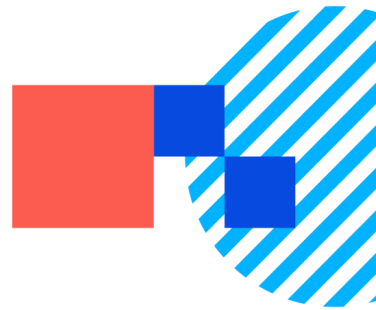
**Approval Duration:** 4 weeks (Treatment durations beyond 4 weeks are not supported by FDA labeling)

**Dosing:** 150 U/m2 divided into twice daily injections of 75 U/m2. After 2 weeks of treatment dosing should be gradually tapered and discontinued over a 2-week period. Acthar Gel single-dose pre-filled SelfJect injector is **not** to be used for the treatment of infantile spasms.

##### B. All other indications

1. Not considered medically necessary

**Approval Duration:** n/a



The effectiveness of repository corticotropin has not been demonstrated as clinically superior to conventional corticosteroids and/or immunosuppressive therapy for uses other than infantile spasms.

**References:**

1. Acthar Gel Prescribing Information. Mallinckrodt ARD, Inc. February 2024.
2. Anagnostis P, et al. Characterization of the Clinical Evidence Supporting Repository Corticotropin Injection for FDA-Approved Indications: A Scoping Review. JAMA Network Open. 2021;4(12):e2138529.
3. Nelson, Gary Rex. [Management of Infantile Spasms](#). Transl Pediatr. 2015;4(4):260-270.
4. Pellock JM, Hrachovy R, Shinnar S, et al. [Infantile spasms: a U.S. consensus report](#). Epilepsia 2010; 51:2175.
5. Ramantani, G, Bolsterli, B, Alber, M, et al. [Treatment of Infantile Spasm Syndrome: Update from the Interdisciplinary Guideline Committee Coordinated by the German-Speaking Society of Neuropediatrics](#). Neuropediatrics. 2022 Sep 22;53(6):389–401.
6. U.S. Food and Drug Administration. Center for Drug Evaluation and Research. (2010). [Application 022432Orig1s000 Internal Consult on draft labeling \(Package Insert\) for H.P. Acthar Gel](#).
7. U.S. Food and Drug Administration. Center for Drug Evaluation and Research. (2010). [Application 022432Orig1s000 Action Memo for NDA 22-432, for the use of H.P. Acthar Gel \(repository corticotrophin injection\) in the treatment of Infantile Spasms \(IS\)](#).

**Policy Owned by:** Curative PBM team