curative

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 Pedatr. 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