



## H.P. Acthar® Gel (repository corticotropin injection)

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### Definition

Repository corticotropin (H.P. Acthar® Gel) is an analogue of adrenocorticotrophic hormone (ACTH) analogue indicated as monotherapy for the treatment of infantile spasms (West Syndrome) in infants and children less than 2 years of age. Acthar is supplied as a 5 mL multi-dose vial containing 80 USP Units per mL. H.P. Acthar Gel (repository corticotropin injection).

### Related Medical Guideline

[Off-Label Use of FDA-Approved Drugs and Biologicals](#)

### Guideline

- A. H.P. Acthar Gel is considered medically necessary for West syndrome (infantile spasms)
- B. H.P. Acthar Gel is considered medically when **all** of the following criteria are met:
  1. Member is an adult ( $\geq$  18 years of age) with a corticosteroid-responsive condition (including but not limited to acute exacerbations of multiple sclerosis)
  2. Member has no contraindications to (or is not limited by) a contraindication to, or intolerance of, glucocorticoid effects
  3. There is clear documentation of why all other well-established routes for corticosteroid therapy (for example, oral prednisone and intravenous methylprednisolone) cannot be used.

### Limitations/Exclusions

Acthar is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

### Applicable Procedure Codes

J0800	Injection, corticotropin, up to 40 units
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### Applicable Diagnosis Codes

G35	Multiple sclerosis
G40.821	Epileptic spasms, not intractable, with status epilepticus
G40.822	Epileptic spasms, not intractable, without status epilepticus
G40.823	Epileptic spasms, intractable, with status epilepticus
G40.824	Epileptic spasms, intractable, without status epilepticus

### Revision History

8/12/2016: Added coverage for corticosteroid-responsive conditions.

10/9/2015: Restricted coverage to infantile spasms as sole medically necessary indication.

9/11/2015: Removed proteinuria secondary to nephrotic syndrome as a covered indication.

### References

1. H.P. Acthar® Gel [Product Information], Hazelwood, MO. Mallinckrodt Pharmaceuticals, Inc.; January 2015. <http://www.acthar.com/pdf/Acthar-PI.pdf>. Accessed August 15, 2017.
2. Mackay MT, Weiss SK, Adams-Webber T, et al. American Academy of Neurology; Child Neurology Society. Practice parameter: medical treatment of infantile spasms: report of the American Academy of Neurology and the Child Neurology Society. *Neurology*. 2004; 62 (10):1668-1681. <http://www.neurology.org/content/62/10/1668.full.pdf>. Accessed August 15, 2017.
3. Questcor Pharmaceuticals Inc. H.P. Acthar Gel (repository corticotropin injection) package insert. Union City, CA: Questcor Pharmaceuticals Inc. Oct 2010.
4. Jia F, Jiang H, Du L, et al. An effective initial polytherapy for children with West Syndrome. *Neural Regen Res*. Jun 15, 2013; 8(17):1623-1630. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4145964/>. Accessed August 15, 2017.
5. Hamano S, Tanaka M, Mochizuki M, et al. Long-term follow-up study of West syndrome: Differences of outcome among symptomatic etiologies. *J Pediatr*. 2003; 143(2):231-235.
6. Specialty-matched clinical peer review.