

# Clinical Policy: Repository Corticotropin Injection (H.P. Acthar Gel)

Reference Number: PA.CP.PHAR.168

Effective Date: 01/18

Last Review Date: 07/18

[Coding Implications](#)  
[Revision Log](#)

## Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness<sup>®</sup> clinical policy for repository corticotropin injection (H.P. Acthar<sup>®</sup> Gel).

## FDA Approved Indication(s)

H.P. Acthar Gel is indicated:

- For the treatment of infantile spasms in infants and children under 2 years of age as monotherapy
- For the treatment of acute exacerbations of multiple sclerosis (MS) in adults.

## Policy/Criteria

It is the policy of health plans affiliated with Pennsylvania Health and Wellness that H.P. Acthar Gel is **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

#### A. Infantile Spasms (must meet all):

1. Age < 2 years;
2. Diagnosis of infantile spasms;
3. Prescribed by or in consultation with a neurologist;
4. Prescribed daily dose does not exceed 150 U/m<sup>2</sup> (divided into twice daily intramuscular injections of 75 U/m<sup>2</sup>).

**Approval duration: 3 months**

#### B. Multiple Sclerosis (must meet all):

1. Age ≥ 18 years;
2. Prescribed by or in consultation with a neurologist;
3. Diagnosis of multiple sclerosis (MS);
4. Prescribed for acute MS exacerbations;
5. Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids;
6. Prescribed daily dose does not exceed 120 units administered by intramuscular or subcutaneous injection.

**Approval duration: 1 months**

**Approval duration: 3 months**

# CLINICAL POLICY

## Repository Corticotropin Injection



### C. Other diagnoses/indications

1. Refer to PA.CP.PMN.53

## II. Continued Approval

### A. Infantile Spasms (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Age < 2 years;
3. Documentation indicating positive response to therapy;
4. Prescribed daily dose does not exceed 150 U/m<sup>2</sup> (divided into twice daily intramuscular injections of 75 U/m<sup>2</sup>).

**Approval duration: 3 months (one renewal limit)**

**B. Multiple Sclerosis:** HP Acthar is not indicated for continuous use for this indication. Reauthorization request must be reviewed against the initial approval criteria.

### C. Other Diagnoses/Indications (1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy. or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies

**Approval duration: Duration of request or 3 months (whichever is less); or**

2. Refer to PA.CP.PMN.53

## Background

### *Description/Mechanism of Action:*

Repository corticotropin injection is an adrenocorticotrophic hormone analogue for intramuscular or subcutaneous injection. Corticotropin 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 corticotropin 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.

### *Formulations:*

H.P. Acthar Gel, Injection: 80 units/mL (5 mL)

- Labeled for intramuscular or subcutaneous use only

## Appendices

### *Appendix A: Abbreviation Key*

ACTH: adrenocorticotrophic hormone

**CLINICAL POLICY**  
**Repository Corticotropin Injection**



MS: multiple sclerosis

*Appendix B: FDA Approved Indications Requiring Efficacy and Safety Documentation*

System	Disease State
Rheumatic disorders	Psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis
Collagen diseases	Systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
Dermatologic diseases	Erythema multiforme, Stevens-Johnson syndrome
Allergic states	Serum sickness
Ophthalmic diseases	Keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
Respiratory diseases	Symptomatic sarcoidosis

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Removed indications not supported by well-designed clinical trials. West syndrome – removed EEG requirement to confirm diagnosis; added neurologist prescriber requirement. MS- approval duration reduced to one month for initial as this medication is not indicated to use chronically and for continued approval for MS was referred to the initial criteria. References reviewed and updated.		

**References**

1. H.P. Acthar Prescribing Information. Hazelwood, MO: Mallinckrodt ARD, Inc.; January 2015. Available at <https://www.acthar.com/pdf/Acthar-PI.pdf>. Accessed November 13, 2017.
2. Go CY, Mackay MT, Weiss SK, et al. Evidenced-based guideline update: Medical treatment of infantile spasms: Report of the guideline development subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. June 12, 2012; 78(24): 1974-80. *Reaffirmed July 18, 2015*.
3. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia*. October 2010; 51(10): 2175-89.
4. Berkovich R, Agius M. Mechanisms of action of ACTH in the management of relapsing forms of multiple sclerosis. *Ther Adv Neurol Disord*. March 2014; 7(2): 83–96.

5. Filippini G, Brusaferrì F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. *Cochrane Database Syst Rev.* 2000; (4): CD001331.
6. Berkovich R, Bakshi R, Amezcua L, et al. Adrenocorticotropin hormone versus methylprednisolone added to interferon B in patients with multiple sclerosis experiencing breakthrough disease: A randomized, rater-blinded trial. *Ther Adv Neurol Disord.* January 2017; 10(1): 3-17.
7. Beck L, Bombback AS, Choi M, et al. KDOQI commentary on the 2012 KDIGO clinical practice guidelines for glomerulonephritis. *Am J Kidney Dis.* 2013; 62(3): 403-441.
8. Lieberman KV and Pavlova-Wolf A. Adrenocorticotropin hormone therapy for the treatment of idiopathic nephrotic syndrome in children and young adults: A systematic review of early clinical studies with contemporary relevance. *J Nephrol.* 2017; 30: 35-44.
9. Hladunewich MA, Cattran D, Beck LH, et al. A pilot study to determine the dose and effectiveness of adrenocorticotropin hormone (H.P. Acthar® Gel) in nephrotic syndrome due to idiopathic membranous nephropathy. *Nephrol Dial Transplant.* 2014; 29: 1570-1577.
10. Hogan J, Bombback AS, Mehta K, et al. Treatment of idiopathic FSGS with adrenocorticotropin hormone gel. *Clin J Am Soc Nephrol.* December 6, 2013; 8(12): 2072-2081.
11. Chen Y, Schieppati A, Cai G, et al. Immunosuppression for membranous nephropathy: A systematic review and meta-analysis of 36 clinical trials. *Clin J Am Soc Nephrol.* May 7, 2013; 8(5): 787-796.
12. Madan A, Mijovic-Das S, Stankovic A, et al. Acthar gel in the treatment of nephrotic syndrome: A multicenter retrospective case series. *BMC Nephrol.* March 31, 2016; 17:37.
13. Thompson AJ, Kennard C, Swash M, Summers B, Yuill GM, Shepherd DI, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse inMS. *Neurology* 1989;39(7):969–71.
14. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: <http://www.clinicalpharmacology-ip.com/>.