



# MASSACHUSETTS

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## Pharmacy Medical Policy Repository Corticotropin Injection

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### Policy Number: 064

BCBSA Reference Number: 5.01.17

### Related Policies

None

### Prior Authorization Information

<input checked="" type="checkbox"/> <b>Prior Authorization</b> <input type="checkbox"/> <b>Step Therapy</b> <input type="checkbox"/> <b>Quality Care Dosing</b>		<b>Pharmacy Operations:</b> Tel: 1-800-366-7778 Fax: 1-800-583-6289 Policy last updated <b>7/1/2023</b>
Pharmacy (Rx) or Medical (MED) benefit coverage	<input checked="" type="checkbox"/> <b>Rx</b> <input type="checkbox"/> <b>MED</b>	<b>To request for coverage:</b> Physicians may call, fax, or mail the attached form ( <a href="#">Formulary Exception/Prior Authorization form</a> ) to the address below.
<b>Policy applies to Commercial Members:</b> <ul style="list-style-type: none"> <li>• Managed Care (HMO and POS),</li> <li>• PPO and Indemnity</li> <li>• MEDEX with Rx plan</li> <li>• Managed Major Medical with Custom BCBSMA Formulary</li> <li>• Comprehensive Managed Major Medical with Custom BCBSMA Formulary</li> <li>• Managed Blue for Seniors with Custom BCBSMA Formulary</li> </ul>		<b>Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department</b> 25 Technology Place Hingham, MA 02043  <b>Individual Consideration:</b> Policy for requests that do not meet clinical criteria of this policy, see section labeled <a href="#">Individual Consideration</a>

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Repository corticotropin injection may be considered [MEDICALLY NECESSARY](#) for the treatment of infantile spasms (West syndrome).

Use of repository corticotropin injection is considered [INVESTIGATIONAL](#)

as a treatment of corticosteroid-responsive conditions.

Except as noted above, use of repository corticotropin injection is considered **INVESTIGATIONAL** for conditions that are not responsive to corticosteroid therapy including, but not limited to, use in tobacco cessation, acute gout, and childhood epilepsy.

Repository corticotropin injection is considered **INVESTIGATIONAL** for use in diagnostic testing of adrenocortical function.

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

### CPT Codes

CPT codes:	Code Description
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

### HCPCS Codes

HCPCS codes:	Code Description
J0800	Injection, corticotropin, up to 40 units (Acthar Gel)
J3490	Unclassified drugs (Cortrophin Purified Gel)

### ICD-10 Diagnosis Codes

ICD-10-CM diagnosis codes:	Code Description
G40.821	Epileptic spasms code range (includes infantile spasms)
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

## Description

### Repository Corticotropin Injection

Repository corticotropin injection (H.P. Acthar Gel) is a purified, sterile preparation of the natural form of adrenocorticotrophic hormone (ACTH) in gelatin to provide a prolonged release after intramuscular or subcutaneous injection. ACTH is produced and secreted by the pituitary gland; H.P. Acthar Gel uses ACTH obtained from porcine pituitaries. ACTH works by stimulating the adrenal cortex to produce cortisol, corticosterone, and a number of other hormones.

## Summary

Repository corticotropin injection is a preparation of the natural form of adrenocorticotrophic hormone (ACTH). The injection is used to treat corticosteroid-responsive conditions and as a diagnostic tool to test adrenal function.

For individuals who have infantile spasms who receive repository corticotropin injection, the evidence includes randomized controlled trials, a systematic review, and a prospective cohort study. Relevant outcomes are symptoms and change in disease status. The systematic review judged the overall quality of the studies to be poor, with fewer than half reporting method of randomization and most assessing relatively few patients. There was heterogeneity across studies and either vigabatrin or prednisolone was used as comparators. Multivariate analysis of a prospective cohort study found that children with infantile spasms who were treated with ACTH were more likely to respond than other children. However, the analysis might have been subject to residual confounding on unmeasured characteristics; further, the study did not differentiate between synthetic and natural ACTH. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2010 strongly supported the use of repository corticotropin injection for patients with infantile spasms; repository corticotropin is considered standard of care. Therefore, treatment of infantile spasms with repository corticotropin injection may be considered medically necessary.

For individuals who have corticosteroid-responsive conditions (eg, rheumatoid arthritis, dermatomyositis, sarcoidosis, nephrotic syndrome, multiple sclerosis, serum sickness) who receive repository corticotropin injection, the evidence includes randomized controlled trials and small case series. Relevant outcomes are symptoms and change in disease status. Overall, more recent studies evaluating multiple sclerosis have demonstrated that intravenous corticosteroids are at least as effective, or more effective, than repository corticotropin. Most studies assessing nephrotic syndrome have been small retrospective case studies. Ongoing studies are being conducted. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions not generally known to be responsive to corticosteroids (non-corticosteroid-responsive) such as tobacco cessation, childhood epilepsy, and acute gout who receive repository corticotropin injection, the evidence includes 3 head-to-head trials identified for use in gout. Relevant outcomes are symptoms and change in disease status. The quality of these studies was deemed very low to moderate because there were no direct placebo-controlled trials and no clinically relevant differences were detected between drugs studied. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who need diagnostic testing of adrenal function who receive repository corticotropin injection, the evidence does not include studies that compare the diagnostic accuracy of repository corticotropin injection with ACTH. Relevant outcomes are test validity and other test performance measures. The lack of published evidence precludes conclusions on the validity of using repository corticotropin as a diagnostic test for adrenal function. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts  
Pharmacy Operations Department  
25 Technology Place  
Hingham, MA 02043  
Tel: 1-800-366-7778  
Fax: 1-800-583-6289

## Policy History

Date	Action
7/2023	Reformatted Policy.
12/2021	BCBSA National medical policy review. No changes to policy statements. New references added and updated policy to add Cortrophin Purified Gel.
12/2020	BCBSA National medical policy review. No changes to policy statements. New references added.
3/2020	New pharmacy medical policy describing medically necessary and investigational indications. Repository Corticotropin (H.P. Acthar Gel) removed from policy #033 Medical Utilization Management (MED UM) and Pharmacy Prior Authorization Policy. Effective 3/2020.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Mallinckrodt Pharmaceuticals. H.P. Acthar Gel (repository corticotropin injection) INJECTION, GEL for INTRAMUSCULAR | SUBCUTANEOUS use. 2021; <http://www.acthar.com/pdf/Acthar-PI.pdf>. Accessed August 30, 2021.
2. Food and Drug Administration. Center for Drug Evaluation and Research. Summary review. Action memo for NDA 22-432, for the use of H.P. Acthar Gel (repository corticotropin injection) in the treatment of infantile spasms (IS). April 5, 2010. [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022432Orig1s0900SumR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s0900SumR.pdf) Accessed August 30, 2021.
3. Duchowny MS, Chopra I, Niewoehner J, et al. A Systematic Literature Review and Indirect Treatment Comparison of Efficacy of Repository Corticotropin Injection versus Synthetic Adrenocorticotrophic Hormone for Infantile Spasms. *J Health Econ Outcomes Res.* Jan 27 2021; 8(1): 1-9. PMID 33521161
4. Chang YH, Chen C, Chen SH, et al. Effectiveness of corticosteroids versus adrenocorticotrophic hormone for infantile spasms: a systematic review and meta-analysis. *Ann Clin Transl Neurol.* Nov 2019; 6(11): 2270-2281. PMID 31657133
5. Li S, Zhong X, Hong S, et al. Prednisolone/prednisone as adrenocorticotrophic hormone alternative for infantile spasms: a meta-analysis of randomized controlled trials. *Dev Med Child Neurol.* May 2020; 62(5): 575-580. PMID 31903560
6. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. *Cochrane Database Syst Rev.* Jun 05 2013; (6): CD001770. PMID 23740534
7. Knupp KG, Coryell J, Nickels KC, et al. Response to treatment in a prospective national infantile spasms cohort. *Ann Neurol.* Mar 2016; 79(3): 475-84. PMID 26704170
8. Fleischmann R, Furst DE, Connolly-Strong E, et al. Repository Corticotropin Injection for Active Rheumatoid Arthritis Despite Aggressive Treatment: A Randomized Controlled Withdrawal Trial. *Rheumatol Ther.* Jun 2020; 7(2): 327-344. PMID 32185745
9. Askanase AD, Zhao E, Zhu J, et al. Repository Corticotropin Injection for Persistently Active Systemic Lupus Erythematosus: Results from a Phase 4, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial. *Rheumatol Ther.* Dec 2020; 7(4): 893-908. PMID 32996096
10. Wang CS, Travers C, McCracken C, et al. Adrenocorticotrophic Hormone for Childhood Nephrotic Syndrome: The ATLANTIS Randomized Trial. *Clin J Am Soc Nephrol.* Dec 07 2018; 13(12): 1859-1865. PMID 30442868
11. Rose AS, Kuzma JW, Kurtzke JF, et al. Cooperative study in the evaluation of therapy in multiple sclerosis: ACTH vs placebo in acute exacerbation. *Trans Am Neurol Assoc.* 1969; 94: 126-33. PMID 4313957

12. Rose AS, Kuzma JW, Kurtzke JF, et al. Cooperative study in the evaluation of therapy in multiple sclerosis. ACTH vs. placebo--final report. *Neurology*. May 1970; 20(5): 1-59. PMID 4314823
13. Berkovich R. Treatment of acute relapses in multiple sclerosis. *Neurotherapeutics*. Jan 2013; 10(1): 97-105. PMID 23229226
14. Milanese C, La Mantia L, Salmaggi A, et al. Double-blind randomized trial of ACTH versus dexamethasone versus methylprednisolone in multiple sclerosis bouts. Clinical, cerebrospinal fluid and neurophysiological results. *Eur Neurol*. 1989; 29(1): 10-4. PMID 2540005
15. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. *Neurology*. Jul 1989; 39(7): 969-71. PMID 2544829
16. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotrophic hormone (ACTH) gel. *Drug Des Devel Ther*. Mar 14 2011; 5: 147-53. PMID 21448451
17. Janssens HJ, Lucassen PL, Van de Laar FA, et al. Systemic corticosteroids for acute gout. *Cochrane Database Syst Rev*. Apr 16 2008; (2): CD005521. PMID 18425920
18. Kazlauskaitė R, Evans AT, Villabona CV, et al. Corticotropin tests for hypothalamic-pituitary- adrenal insufficiency: a metaanalysis. *J Clin Endocrinol Metab*. Nov 2008; 93(11): 4245-53. PMID 18697868
19. Go CY, Mackay MT, Weiss SK, et al. Evidence-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*. Jun 12 2012; 78(24): 1974-80. PMID 22689735
20. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a U.S. consensus report. *Epilepsia*. Oct 2010; 51(10): 2175-89. PMID 20608959
21. 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*. Aug 2015; 56(8): 1185-97. PMID 26122601
22. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Rheumatol*. Jun 2020; 72(6): 879-895. PMID 32390306
23. Qaseem A, Harris RP, Forciea MA, et al. Management of Acute and Recurrent Gout: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. Jan 03 2017; 166(1): 58-68. PMID 27802508

**To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:**

<http://www.bluecrossma.org/medical-policies/sites/g/files/cspkws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>