



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

Medical Utilization Management (MED UM) and Pharmacy Prior Authorization Policy, #033

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.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is required .
Commercial PPO and Indemnity	Prior authorization is not required .

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.

Policy History

Date	Action
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

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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.

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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/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>