BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Repository Corticotropin (H.P. Acthar Gel)

File Name:	repository_corticotropin
Origination:	7/2012
Last CAP Review:	5/2019
Next CAP Review:	5/2020
Last Review:	5/2019

Description of Procedure or Service

Repository corticotropin injection (H.P. Acthar® gel) is a purified, sterile preparation of the natural form of adrenocorticotropic 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.

H.P. Acthar gel was approved by the U.S. Food and Drug Administration (FDA) in 1952, before there was a requirement that companies provide clinical evidence of efficacy.

Repository corticotropin injection is best known for the treatment of infantile spasms. This is a rare epileptic disorder of infancy (90% of cases are diagnosed in the first year of life). When infantile spasms are accompanied by neurodevelopmental regression and electroencephalogram (EEG) findings of hypsarrhythmia, the condition is known as West syndrome. Vigabatrin oral solution is another available treatment for infantile spasms.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for repository corticotropin when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Repository Corticotropin is covered

Repository corticotropin injection may be considered **medically necessary** as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age (West syndrome). Failure or intolerance to corticosteroids **is not** required for a diagnosis of infantile spasms. Duration of therapy will be 30 days.

Repository Corticotropin (H.P. Acthar Gel)

Repository corticotropin injection may be considered **medically necessary** for treatment of acute exacerbations of multiple sclerosis when the following criteria are met:

1. The patient is experiencing an acute exacerbation, AND
2. The patient is currently on therapy with a disease modifying drug (DMD) OR has a documented intolerance OR clinical contraindication to a DMD (i.e. Betaseron, Avonex, Rebif, Copaxone, Tysabri), AND
3. The patient has tried and failed corticosteroid therapy (IV or high dose oral steroids) in the past 30 days OR has an FDA labeled contraindication to corticosteroid therapy OR documented intolerance to corticosteroid therapy, AND
4. Duration of approval will be 30 days.

When Repository Corticotropin is not covered

Uses of repository corticotropin (H.P. Acthar® Gel) are considered **not medically necessary** for doses outside of FDA labeling and all indications that do not meet the medical necessity criteria listed above.

Contraindications include the following:

- Repository corticotropin (H.P. Acthar® Gel) should never be given intravenously.
- Repository corticotropin (H.P. Acthar® Gel) is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin.
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of repository corticotropin (H.P. Acthar® Gel).
- Repository corticotropin (H.P. Acthar® Gel) is contraindicated in children less than 2 years of age with suspected congenital infections.
- Treatment of conditions is contraindicated when they are accompanied by primary adrenocortical insufficiency or adrenocortical hyperfunction.

Policy Guidelines

Dosage should be individualized according to the medical condition of each patient. Frequency and dose of the drug should be determined by considering the severity of the disease and the initial response of the patient.

Although drug dependence does not occur, sudden withdrawal of repository corticotropin (H.P. Acthar Gel) after prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop treatment. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

For individuals who have infantile spasms who receive repository corticotropin injection, the evidence includes randomized controlled trials (RCTs), 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. Moreover, there was heterogeneity among studies and most used vigabatrin or prednisolone 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 may have been subject to residual confounding on unmeasured characteristics and the study did not differentiate between synthetic and natural ACTH. The evidence is insufficient to determine the effects of the technology on health outcomes.

Based on the results of clinical input, there is strong clinical support for the use of repository corticotropin injection for patients with infantile spasms and it is considered standard of care. Therefore, treatment of infantile spasms may be considered medically necessary.

A 2011 prospective, randomized, open-label pilot trial by Simsarian et al suggested that a 5-day course of "patient-administered" ACTH gel therapy may improve symptoms of acute exacerbations of multiple sclerosis.

The evidence is insufficient to determine the effects on health outcomes for conditions other than infantile spasms and acute exacerbations of multiple sclerosis.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *J0800*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

H.P. Acthar Gel product information. Questcor Pharmaceuticals, Inc. Union City, CA Retrieved 4/24/2012 from http://www.acthar.com/files/Acthar-Medication-Guide.pdf

US Food and Drug Administration (FDA). Label and approval history for H.P. Acthar Gel. Retrieved 4/24/2012 from http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist

Mackay MT, et al. 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.

BCBSA Medical Policy Reference Manual [Electronic Manual]. 5.01.17, 5/12/2011

Medical Director – 4/2012

Pellock JM, Hrachovy R, Shinner S et al. Infantile spasms: A U.S. consensus report. *Epilepsia* 2010; 5: 2175-2189

Bomback AS, Tumlin JA, Baranski J et al. Treatment of nephritic syndrome with adrenocorticotropic hormone (ACTH) gel. *Drug Design Dev Ther* 2011; 5: 147-153

Specialty Matched Consultant Advisory Panel – 5/2013

BCBSA Medical Policy Reference Manual [Electronic Manual]. 5.01.17, 12/12/2013

Senior Medical Director – 2/2014

Specialty Matched Medical Consultant – 2/2014

Specialty Matched Consultant Advisory Panel – 4/2014

BCBSA Medical Policy Reference Manual [Electronic Manual]. 5.01.17, 12/11/2014

Specialty Matched Consultant Advisory Panel – 5/2015

Simsarian JP, Saunders C, Smith DM. Five-day regimen of intramuscular or subcutaneous self-administered adrenocorticotropic hormone gel for acute exacerbations of multiple sclerosis: a prospective, randomized, open-label pilot trial. Drug Des Devel Ther. 2011; 5:381-389.

BCBSA Medical Policy Reference Manual [Electronic Manual]. 5.01.17, 12/10/2015

Specialty Matched Consultant Advisory Panel – 5/2016

BCBSA Medical Policy Reference Manual [Electronic Manual]. 5.01.17, 10/13/2016

Specialty Matched Consultant Advisory Panel – 5/2017

BCBSA Medical Policy Reference Manual [Electronic Manual]. 5.01.17, 10/12/2017

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual [Electronic Manual]. 5.01.17, 10/10/2018

Specialty Matched Consultant Advisory Panel – 5/2019

Policy Implementation/Update Information

7/1/12 New policy BCBSNC will provide coverage for repository corticotropin when it is determined to be medically necessary because the medical criteria and guidelines are met. Medical Director review 5/20/2012. Notification given 7/1/2012. Effective date 10/1/2012. (btw)

7/1/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy intent. References added. (btw)

7/30/13 Added "Lack of venous access for the administration of intravenous steroids" to the When Covered section based on CAP review. (btw)

11/24/15 Policy extensively revised. Repository corticotropin is medically necessary for infantile spasms (West syndrome) and acute exacerbations of multiple sclerosis when criteria are met. Senior Medical Director review 1/30/2014. Specialty Matched Consultant review 2/11/2014. Specialty Matched Consultant Advisory Panel review 5/27/2014. Specialty Matched Consultant Advisory Panel review 5/27/2015. References added. Notification given 11/24/2015. Policy effective date 1/26/2016. (sk)

7/1/16 References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/25/2016. No change to policy statement. (sk)

12/30/16 Reference added. Policy Guidelines updated. (sk)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)

1/26/18 Reference added. (sk)

6/8/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. No change to policy intent. (krc)

5/28/19 Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. No change to policy intent. (krc)