UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for H.P. Acthar Gel

Program	Prior Authorization
Medication	Repository Corticotropin Injection (H.P. Acthar Gel®)
Pharmacy & Therapeutics Approval Date	5/15/2012
Effective Date	8/1/2016

1. Background:

H.P. Acthar Gel is an adrenocorticotropic hormone (ACTH) analogue.[1-3] Repository corticotropin injection and ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of repository corticotropin injection induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is influenced by the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated plasma cortisol suppresses ACTH release. Repository corticotropin injection also binds to melanocortin receptor. Both endogenous ACTH and repository corticotropin injection have a trophic effect on the adrenal cortex which is mediated by cyclic adenosine monophosphate (cyclic AMP).

2. Coverage Criteria:

A. Infantile Spasms

1. Infantile spasm (i.e., West Syndrome)[1] for when **all** of the following criteria are met:

   a. Diagnosis of infantile spasms (i.e., West Syndrome)

   -AND-

   b. Patient is less than 2 years old

   -AND-

   c. c. Initial dose: 75 U/m^2 intramuscular (IM) twice daily for 2 weeks. After 2 weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 U/m^2 IM in the morning for 3 days; 10 U/m^2 IM in the morning for 3 days; and 10 U/m^2 IM every other morning for 6 days (3 doses).

Authorization will be issued for 4 weeks.

B. Opsoclonus-myoclonus syndrome

1. Diagnosis of Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)

Authorization will be issued for 1 year.

C. Multiple Sclerosis

1. Diagnosis of Multiple sclerosis (MS), acute exacerbation[1]

Additional information to support medical necessity review where applicable:
H.P. Acthar Gel is **not medically necessary** for treatment of acute exacerbations of multiple sclerosis.

The H.P. Acthar package insert has listed other conditions in which it may be used. Since H.P. Acthar is more costly than an alternative drug that is at least as likely to produce equivalent therapeutic results, UnitedHealthcare Community Plan has determined that use of H.P. Acthar Gel is **unproven and not medically necessary** for treatment of the following disorders and diseases:

1. Rheumatic Disorders: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis
2. Collagen Diseases: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
3. Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome
4. Allergic States: Serum sickness
5. Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
6. Respiratory Diseases: Symptomatic sarcoidosis
7. Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
8. Any indication outside of the proven indications above

3. References:

1. H.P. Acthar Gel [prescribing information]. Questcor Pharmaceuticals, Inc., September 2012.
2. Gold Standard, Inc. Corticotropin, ACTH. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2012. Accessed March 5, 2013.
3. Corticotropin. In: DRUGDEX® [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed March 5, 2013.
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5. FDA Acthar gel NDA 22-432 Peripheral and Central Nervous System Drugs Advisory Committee Meeting. Accessed on January 23, 2012.
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16. Pranzatelli M, Chun K, Moxness M, Tate E, Allison T. Cerebrospinal fluid ACTH and cortisol in opsoclonus-myoclonus: effect of therapy. *Pediatr Neurol*. 2005;33:121-126.
17. Tate ED, Pranzatelli MR, Verhulst SJ, et al. Active comparator-controlled, rater-blinded study of corticotropin-based immunotherapies for opsoclonus-myoclonus syndrome. *J Child Neurol*. 2012 Jul;27(7):875-84.
18. Bomback AS, Tumlin JA, Baranski J, Bourdeau, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. *Drug Des Devel Ther*. 2011;5:147-153.
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Program	Program type – Prior Authorization
Change Control	
Date	Change
4/1/2013	New policy 2013D0037A. Approved by National Pharmacy & Therapeutics Committee on 5/15/2012.
6/1/2013	Annual review of policy. Clinical evidence and references updated. Added list of applicable ICD-10 codes (preview draft) in preparation for the transition from ICD-9 to ICD-10 medical coding on 10/01/14. Approved by National Pharmacy & Therapeutics Committee on 4/9/2013. Policy 2013D0037A archived.
12/1/2013	Clarified indication for infantile spasm under Coverage Rationale. Approved by National Pharmacy & Therapeutics Committee on 8/20/2013. Policy 2013D0037B archived
8/1/2014	Revised proven criteria to allow coverage for IS, OMS & MS only. Medical necessity criteria will allow coverage for IS & OMS. Updated unproven and not medically necessary criteria, CMS, Clinical Evidence and References. Approved by National Pharmacy & Therapeutics Committee on 5/21/2014. Policy 2013D0037C archived.
8/1/2015	Annual review with no changes to Coverage Rationale. Updated CMS, Benefits, Clinical Evidence and References. Approved by National Pharmacy & Therapeutics Committee on 5/20/15. Policy 2014D0037D archived.
10/1/2015	Updated Applicable Codes for ICD-10 transition. Policy 2015D0037E archived.
3/31/2016	Annual Review- Updated policy template