



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject      Repository Corticotropin  
(H. P. Acthar® Gel) in Multiple  
Sclerosis and Infantile Spasms**

**Effective Date ..... 6/15/2011  
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Coverage Policy Number ..... 8001**

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## Hyperlink to Related Coverage Policies

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### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

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## Coverage Policy

**CIGNA covers repository corticotropin (Acthar® Gel) as medically necessary for treatment of EITHER of the following indications:**

- acute exacerbations of multiple sclerosis (MS) **AND BOTH** of the following criteria:
  - failure to corticosteroid therapy
  - patient is currently treated with an immunomodulatory drug [e.g. interferon beta-1b (Betaseron®), glatiramer acetate (Copaxone®)] to control MS progression
- infantile myoclonic seizures (infantile spasms)

**CIGNA covers repository corticotropin (Acthar® Gel) as medically necessary for any other FDA-approved indication ONLY when there is failure of standard corticotropin therapy.**

**When coverage is available and medically necessary, the dosage, frequency, site of administration, and duration of therapy should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to repository corticotropin (Acthar® Gel) therapy.**

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## **FDA Approved Indications**

### **Infantile Spasms**

H.P. Acthar Gel is indicated as monotherapy for the treatment of infantile spasms (IS) in infants and children under 2 years of age.

### **Multiple Sclerosis**

H.P. Acthar Gel is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

### **Rheumatic Disorders**

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis.

### **Collagen Diseases**

During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

### **Dermatologic Diseases**

Severe erythema multiforme, Stevens-Johnson syndrome.

### **Allergic States**

Serum sickness.

### **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.

### **Respiratory Diseases**

Symptomatic sarcoidosis

### **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.

## **FDA Recommended Dosing**

### **IS in Infants and Children Under 2 Years of Age**

In the treatment of IS, H.P. Acthar Gel must be administered intramuscularly. The recommended regimen is a daily dose of 150 U/m<sup>2</sup> (divided into twice daily intramuscular injections of 75 U/m<sup>2</sup>) administered over a 2-week period. Dosing with H.P. Acthar Gel should then be gradually tapered over a 2-week period to avoid adrenal insufficiency. The following is one suggested tapering schedule: 30 U/m<sup>2</sup> in the morning for 3 days; 15 U/m<sup>2</sup> in the morning for 3 days; 10 U/m<sup>2</sup> in the morning for 3 days; and 10 U/m<sup>2</sup> every other morning for 6-days.

### **Acute Exacerbations in Adults with Multiple Sclerosis.**

The recommended dose is daily intramuscular or subcutaneous doses of 80 -120 units for 2-3 weeks for acute exacerbations. 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.

### **Other Indications for Adults and Children Over 2 Years of Age**

Dosage should be individualized according to the disease under treatment and the general medical condition of each patient. Frequency and dose of the drug should be determined by considering severity of the disease and the initial response of the patient. The usual dose of H.P. Acthar Gel is 40-80 units given intramuscularly or subcutaneously every 24-72 hours.

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

## Drug Availability

H.P. Acthar Gel is supplied as 5 mL multi-dose vial containing 80 USP Units per mL.

## General Background

### Pharmacology

H. P. Acthar Gel is a natural form of adrenocorticotrophic hormone (ACTH). Corticotropin is not a corticosteroid. However, it shares many actions of the corticosteroids due to its ability to increase endogenous corticosteroid synthesis. It is rapidly absorbed following intramuscular administration, and the repository dosage form is slowly absorbed over approximately 8–16 hours.

### Guidelines

The 2004 recommendations of the American Academy of Neurology and the Child Neurology Society remain current at this time and state ACTH is effective for the short-term treatment of infantile spasms (IS) and the resolution of hypsarrhythmia; however, there is insufficient evidence to recommend optimum dosage and duration of treatment. There is also insufficient evidence to determine whether oral corticosteroids are an effective treatment for IS.

### Adverse Reactions

ACTH side effects are significant. The majority of children will develop cushingoid obesity and become very irritable. More serious side effects may develop, including arterial hypertension, electrolyte imbalance, gastric ulcer, growth retardation, cardiomyopathy, and immunosuppression. In one study, the risk of serious side effects with ACTH was 43% in the children treated with 160 IU/day but lower in children treated with lower doses. By keeping the dose as low as efficacy allows and the duration as short as possible, morbidity and mortality can be minimized. Patients receiving ACTH should be comedicated with a proton pump inhibitor to prevent gastrointestinal bleeding and should have follow-up visits, with regular blood pressure measurements and blood workup for electrolytes.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

HCPCS Codes	Description
J0800	Injection, corticotrophin, up to 40 units

ICD-9-CM Diagnosis Codes	Description
340	Multiple sclerosis
345.60	Infantile spasms, without mention of intractable epilepsy
345.61	Infantile spasms, with mention of intractable epilepsy

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## References

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2. Mackay MT, Weiss SK, Weiss, MD; T. Adams-Webber T, et al. Practice Parameter: Medical Treatment of Infantile Spasms: Report of the American Academy of Neurology and the Child Neurology Society. American Academy of Neurology-Medical Specialty Society. Available at: [http://aan.com/professionals/practice/pdfs/infantile\\_spasms\\_clinicians.pdf](http://aan.com/professionals/practice/pdfs/infantile_spasms_clinicians.pdf). Accessed on May 17, 2011.
3. McEvoy GK, ed. AHFS 2011 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc. 2011.
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5. National Multiple Sclerosis Society. Copaxone (glatiramer acetate). Available at: [http://www.nationalmssociety.org/site/PageServer?pagename=HOM\\_LIVE\\_meds\\_glatirameracetate\\_m](http://www.nationalmssociety.org/site/PageServer?pagename=HOM_LIVE_meds_glatirameracetate_m). Accessed on November 19, 2007.
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