



MEDICAL COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 12/20/11  
LAST REVIEW DATE: 05/13/14  
LAST CRITERIA REVISION DATE: 05/13/14  
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## H.P. ACTHAR® GEL INJECTION (repository corticotropin injection)

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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### Description:

H.P. Acthar Gel is a preparation of the natural form of adrenocorticotrophic hormone (ACTH) in gelatin to provide a prolonged release after intramuscular or subcutaneous injection. ACTH works by stimulating the adrenal cortex to produce cortisol, corticosterone and a number of other hormones. It is primarily used for treating infantile spasms (West syndrome) and has been investigated for diagnostic testing of adrenocortical function and for treating a variety of other conditions. H.P. Acthar Gel injection may also be referred to as repository corticotropin injection.



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## H.P. ACTHAR GEL INJECTION (repository corticotropin injection) (cont.)

### Description: (cont.)

The product label for H.P. Acthar gel lists a number of corticosteroid-responsive conditions as indications for repository corticotropin injection, including:

- Rheumatic disorders: Adjunctive therapy for individuals with acute episodes or exacerbations of psoriatic arthritis, rheumatoid arthritis (selected cases may require low-dose maintenance therapy) and ankylosing spondylitis
- Collagen diseases: Treatment of selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis)
- Dermatologic diseases: Treatment of severe erythema multiforme and Stevens-Johnson syndrome
- Allergic states: Treatment of serum sickness
- Ophthalmic diseases: Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as optic neuritis, and anterior segment inflammation
- Respiratory diseases: Treatment of symptomatic sarcoidosis
- Edematous state: Treatment of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or due to lupus erythematosus

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### Criteria:

**H.P Acthar Gel Injection (repository corticotropin injection) will be reviewed by the medical director(s) and/or clinical advisor(s).**

**See Resources section for FDA-approved dosage and duration.**

- FDA-approved dosage and duration of H.P. Acthar Gel injection for the treatment of infantile spasms (West syndrome) for individuals under 2 years of age is considered **medically necessary**.
- FDA-approved dosage and duration of H.P. Acthar Gel injection for the treatment of corticosteroid-responsive conditions is considered **medically necessary** with documentation of **ONE** of the following:
  1. Medical contraindications to corticosteroids that are not also expected to occur with use of H.P. Acthar Gel
  2. Intolerance to corticosteroids that are not also expected to occur with use of H.P. Acthar Gel
- H.P. Acthar Gel injection for use in diagnostic testing of adrenocortical function is considered **not medically necessary** based upon insufficient evidence to support improvement of the net health outcome.



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## H.P. ACTHAR GEL INJECTION (repository corticotropin injection) (cont.)

### Criteria: (cont.)

- H.P. Acthar Gel injection for treatment of conditions that are not responsive to corticosteroid therapy or if above criteria not met is considered **experimental or investigational** based upon insufficient evidence to support improvement of the net health outcome.

These indications include, *but are not limited to*:

- Acute gout
- Childhood epilepsy
- Tobacco cessation

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### Resources:

1. 5.01.17 BCBS Association Medical Policy Reference Manual. Repository Corticotropin Injection. Re-issue date 12/12/2013, issue date 02/14/2008.
2. American College of Rheumatology, Dinesh Khanna ea. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 2: Therapy and Antiinflammatory Prophylaxis Acute Gouty Arthritis. *Arthritis Care & Research*. 10/2012;64(10):1447-1461.
3. Berg A, Arnadottir M. ACTH-induced improvement in the nephrotic syndrome in patients with a variety of diagnoses. *Nephrol dial Transplant*. 2004;19(5):1305-1307.
4. Berg A, Nilsson-Ehle P, Arnadottir M. Beneficial effects of ACTH on the serum lipoprotein profile and glomerular function in patients with membranous nephropathy. *Kidney Int*. 1999;56:1534-1543.
5. Daoussis D, Antonopoulos I, Yiannopoulos G, Andonopoulos AP. ACTH as first line treatment for acute gout in 181 hospitalized patients. *Joint Bone Spine*. May 2013;80(3):291-294.
6. FDA. H.P. Acthar Gel (repository corticotropin) Injection. 10/15/2010.

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## **H.P. ACTHAR GEL INJECTION (repository corticotropin injection) (cont.)**

### **Resources:** (cont.)

FDA Product Approval Information for H.P. Acthar Gel (repository corticotropin) Injection:

- FDA-approved indication: As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

For the treatment of exacerbations of multiple sclerosis in adults.

May be used for the following disorders and diseases: rheumatic, collagen, dermatologic, allergic states, ophthalmic, respiratory and edematous state (see below for detailed information).

According to the FDA label sections 1.3-1.9, may be used in the treatment of the following conditions:

- 1.3 Rheumatic Disorders: Adjunctive therapy for individuals with acute episodes or exacerbations of psoriatic arthritis, rheumatoid arthritis (selected cases may require low-dose maintenance therapy) and ankylosing spondylitis.
  - 1.4 Collagen Diseases: Treatment of selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
  - 1.5 Dermatologic Diseases: Treatment of severe erythema multiforme and Stevens-Johnson syndrome.
  - 1.6 Allergic States: Treatment of serum sickness.
  - 1.7 Ophthalmic Diseases: Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as optic neuritis, and anterior segment inflammation.
  - 1.8 Respiratory Diseases: Treatment of symptomatic sarcoidosis).
  - 1.9 Edematous State: Treatment of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or due to lupus erythematosus.
- FDA-approved dosage: In the treatment of infantile spasms, the recommended dose is 150 U/m<sup>2</sup> divided into twice daily intramuscular injections of 75 U/m<sup>2</sup>. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period.

In the treatment of acute exacerbations of multiple sclerosis, daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks may be administered. It may be necessary to taper the dose.

In the treatment of other disorders and diseases, dosing will need to be individualized depending on the disease under treatment and the medical condition of the patient. It may be necessary to taper the dose.