

Pharmacy Management Drug Policy

SUBJECT: H.P. Acthar Gel® (Repository Corticotropin Injection) - for Infantile Spasms , Multiple Sclerosis Exacerbations

POLICY NUMBER: PHARMACY-01

EFFECTIVE DATE: 2/2012

LAST REVIEW DATE: 5/16/2019

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

H.P. Acthar Gel® (Repository corticotropin injection) is an adrenocorticotrophic hormone (ACTH) analogue, which stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone and other androgenic substances. Elevated plasma cortisol levels suppress ACTH release. Repository corticotropin 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.

POLICY:

Based upon our assessment and review of the peer-reviewed literature H.P. Acthar gel® has been medically proven to be effective and therefore, **medically necessary** for the following:

A. Infantile spasms

1. Member must be followed by a neurologist **AND**
2. Member must be less than 2 years of age **AND**
3. Member must have diagnosed infantile spasms supported by documented electroencephalographic (EEG) features
4. Recommended dosage is 150U/m² (divided into twice daily intramuscular injections of 75U/m²) over a two week period.
 - i. Taper as follows to avoid adrenal insufficiency: 30 U/m² in the morning for 3 days; 15 U/m² in the morning for 3 days; 10 U/m² in the morning for 3 days; and 10 U/m² every other morning for 6-days.
5. Coverage beyond 1 month (2 week treatment + 2 week recommended taper) will require submission of progress notes demonstrating taper schedule and failure or need for continued treatment.

B. Acute exacerbations of multiple sclerosis

1. Member must be followed by a neurologist **AND**
2. Member must be at least 18 years of age **AND**
3. Member must have had previous treatment with steroids and experienced unmanageable side effects that required hospitalization or significant clinical intervention (examples include steroid induced mania, sepsis, etc) **AND**
4. Member must demonstrate severe exacerbation symptoms including severe weakness, severe loss of vision, severe coordination problems, or severe walking impairment **AND**
5. Approval will be for 1 month. Coverage beyond 1 month will require submission of progress notes demonstrating response to initial treatment as well as need for continued treatment.

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Based upon our criteria and review of the peer-review literature, Acthar gel for the treatment of all other indications is considered **not medically necessary** and will be excluded. There has been no guideline/literature support to indicate that Acthar gel would be more effective or better tolerated than corticosteroids. The clinical evidence does not support the use of Acthar gel for indications including, but not limited to, the following:

C. Nephrotic Syndrome

D. Rheumatic Disorders

Psoriatic Arthritis, Rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis

E. Collagen Diseases

Systemic lupus erythematosus, systemic dermatomyositis (polymyositis)

F. Dermatologic Disease

Severe erythema multiforme or Stevens-Johnson syndrome

G. Allergic States

Serum sickness

H. Ophthalmic Diseases

Acute and chronic allergic and inflammatory process involving the eye and its adexa

I. Respiratory Diseases

Sarcoidosis

POLICY GUIDELINES:

1. Prior-authorization is contract dependent.
2. Quantity limit of 5ml per 30 ds.
3. Repository corticotropin can cause HPA suppression with the potential for adrenal insufficiency after withdrawal of medication. Patient must be monitored for signs of insufficiency including weakness, hyperpigmentation, weight loss, hypotension, and abdominal pain. Symptoms are often difficult of define in infants. Caregivers must be instructed on signs and symptoms of adrenal insufficiency
4. Tapering dose upon discontinuation of treatment can minimize adrenal insufficiency
5. Repository corticotropin can cause GI bleeding and gastric ulcer. Use cautiously in patients with certain GI disorders
6. Repository corticotropin may be associated with CNS effects (mood swings, insomnia, irritability, personality alterations, and depression). Cautiously use in patients with psychotic manifestations and hypothyroidism.
7. Multiple Sclerosis Corticosteroid-responsive condition policy rationale: Clinical studies evaluating the efficacy and use of Acthar gel are extremely limited. There have been no studies that show ACTH to be more effective than corticosteroids. Studies that do exist to compare corticosteroids to ACTH have found corticosteroids to be equally safe and effective for the treatment of acute MS exacerbations.^{9,10, 13,14}
8. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.

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UPDATES:

Date:	Revision:
5/19	P&T Approval/Reviewed
11/18	Reviewed
9/18	Reviewed
11/17	Reviewed
7/16	Revised
3/15	Revised
11/13	Revised
2/13	Revised
1/13	Revised
12/12	Revised
10/12	Revised
2/12	Created

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