Pharmacy Management Drug Policy

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

**POLICY NUMBER:** Pharmacy-01
**EFFECTIVE DATE:** 2/12
**REVIEW DATE:** 3/15, 11/13, 02/13, 01/13, 12/12, 10/12, 2/12

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 SafetyNet, 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 adrenocorticotropic 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 demonstrated catastrophic side effects to corticosteroids that were unmanageable (Progress notes must be submitted) **AND**
4. Member must demonstrate severe exacerbation symptoms including severe weakness, severe loss of vision, severe coordination problems, or severe walking impairment **AND**
5. Member must have had trial and failure of plasma exchange.
6. 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.
Pharmacy Management Drug Policy

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

Last Updated: 03/09/2015

POLICY NUMBER: Pharmacy-01
EFFECTIVE DATE: 2/12
REVIEW DATE: 3/15, 11/13, 02/13, 01/13, 12/12, 10/12, 2/12
Page 2 of 4

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 SafetyNet, and Health Care Reform products only when a contract benefit for the specific service exists.

C. Nephrotic syndrome

1. Member must be followed by a nephrologist AND
2. Member must be at least at least 2 years of age AND
3. Member must have a diagnosis of nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus AND
4. Member must have demonstrated catastrophic side effects to corticosteroids that were unmanageable. (Progress notes must be submitted)
5. Initial approval will be for 6 months. Coverage beyond 6 months will require submission of progress notes demonstrating response to initial treatment as well as the need for continued treatment.

D. Other FDA-approved corticosteroid responsive conditions (listed below):

1. Member must be at least 2 years of age AND
2. Member must have demonstrated catastrophic side effects to corticosteroids that were unmanageable. (Progress notes must be submitted) AND
3. Medication is prescribed by a corresponding specialist.
4. Initial 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.

- **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 (select 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 or systemic dermatomyositis (Polymyositis).
- **Dermatologic Diseases**: treatment of severe erythema multiforme or Stevens-Johnson syndrome.
- **Allergic States**: treatment of serum sickness
- **Ophthalmic Diseases**: treatment of severe acute and chronic allergic and inflammatory process involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.
- **Respiratory Diseases**: treatment of symptomatic sarcoidosis.

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

Proprietary Information of Health Plan.
Guidelines from the American Academy of Neurology recommend that plasma exchange be considered for the second-line treatment of steroid-resistant exacerbations in relapsing forms of MS.\textsuperscript{15}

**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 withdraw 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.

**REFERENCES:**

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 SafetyNet, and Health Care Reform products only when a contract benefit for the specific service exists.