H.P. Acthar Gel (repository corticotropin injection)

**Line(s) of Business:**
HMO; PPO; QUEST Integration

**Original Effective Date:**
10/01/2015

**Current Effective Date:**
01/01/2017

**POLICY**

**A. COVERED INDICATIONS**

H.P. Acthar Gel is covered (subject to Criteria for Approval and Exclusions) as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

**FDA-Approved Indication(s)**
- H.P. Acthar Gel is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age

**B. INITIAL CRITERIA FOR INITIAL APPROVAL**

1. Infantile Spasms
   - Authorization of 6 months may be granted to members less than 2 years of age diagnosed with infantile spasms.

**C. CRITERIA FOR CONTINUATION OF THERAPY**

Authorization of an additional 6 months may be granted to members with infantile spasms who have shown substantial clinical benefit from therapy, if either of the following criteria is met:

a. Member was previously approved by HMSA
b. Member meets ALL of the initial criteria for approval

- H.P. Acthar Gel is indicated for the treatment of acute exacerbations of multiple sclerosis in adults
- H.P. Acthar Gel may be used for the following disorders and diseases (rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state):  
  - 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, Ankylosing spondylitis
  - During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
  - Severe erythema multiforme, Stevens-Johnson syndrome
  - Serum sickness
  - 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
Symptomatic sarcoidosis
To induce a diuresis or remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

D. EXCLUSIONS

As a treatment alternative in members who experience adverse events with corticosteroids HP Acthar Gel is not covered for any other indication, including but not limited to:
- Acute exacerbation of multiple sclerosis
- Rheumatic disorders (eg, psoriatic arthritis, rheumatoid arthritis)
- Collagen diseases (eg, systemic lupus erythematosus, dermatomyositis)
- Dermatologic diseases
- Allergic states (eg, serum sickness)
- Ophthamlic diseases
- Respiratory diseases (eg, sarcoidosis)
- Edematous states (eg, nephrotic syndrome)
- Receipt of live or live attenuated vaccines in members receiving immunosuppressive doses of HP Acthar Gel
- Suspected congenital infection (infants)
- Scleroderma
- Osteoporosis
- Systemic fungal infections
- Peptic ulcer disease (history of or the current presence)
- Ocular herpes simplex
- Congestive heart failure
- Recent surgery
- Uncontrolled hypertension
- Known hypersensitivity to porcine proteins
- Primary adrenocortical insufficiency
- Adrenocortical hyperfunction

E. INITIAL CRITERIA FOR APPROVAL

2. Infantile spasms

Authorization of 6 months may be granted to members less than 2 years of age.

F. CONTINUATION OF THERAPY

Authorization of an additional 6 months may be granted to members who have shown substantial clinical benefit from therapy if either of the following criteria is met:
- Member was previously approved by HMSA
- Member meets ALL of the initial criteria for approval

G. E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

H. F. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

**I.G. REFERENCES**


1. Revised: August 2016.