SPECIALTY GUIDELINE MANAGEMENT

H.P. ACTHAR GEL (repository corticotropin injection)

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Infantile spasms:
H.P. Acthar Gel is indicated as monotherapy for the treatment of infantile spasms 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.

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, 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

Compendial Use
• Diagnostic testing of adrenocortical function

All other indications are considered experimental/investigational and are not covered benefits.

B. EXCLUSIONS
• Receipt of live or live attenuated vaccines in patients receiving immunosuppressive doses of H.P. Acthar Gel
• Suspected congenital infection in 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

C. INITIAL CRITERIA FOR APPROVAL

1. Infantile Spasms
Authorization of 6 months may be granted to members who are less than 2 years of age for the treatment of infantile spasms.

2. Diagnostic Testing of Adrenocortical Function
Authorization of 1 dose may be granted to members who are prescribed H.P. Acthar Gel for diagnostic testing of adrenocortical function when member cannot be tested with Cosyntropin.

3. Multiple Sclerosis
Authorization of 3 weeks may be granted to members for the treatment of acute exacerbations of multiple sclerosis when the member has had an inadequate response to at least a 3-month trial of parenteral glucocorticoids.

4. Nephrotic Syndrome
Authorization of 3 months may be granted to members for the treatment of nephrotic syndrome when H.P. Acthar Gel is requested for induction of diuresis or for remission of proteinuria in a member who has had an inadequate response to at least a 3-month trial of parenteral glucocorticoids.

5. Rheumatic Disorders
Authorization of 3 months may be granted to members who are prescribed H.P. Acthar Gel as adjunctive treatment for rheumatic disorders (eg, psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis) when the member has had an inadequate response to at least a 3-month trial of parenteral glucocorticoids.

6. Collagen Diseases
Authorization of 3 months may be granted to members for the treatment of collagen diseases (eg, systemic lupus erythematosus, systemic dermatomyositis, polymyositis) when the member has had an inadequate response to at least a 3-month trial of parenteral glucocorticoids.

7. Dermatologic Diseases
Authorization of 3 months may be granted to members for the treatment of dermatologic disorders (eg, severe erythema multiforme, Stevens-Johnson syndrome) when the member has had an inadequate response to at least a 3-month trial of parenteral glucocorticoids.

8. Ophthalmic Diseases
Authorization of 3 months may be granted to members for the treatment of ophthalmic diseases (eg, keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation) when the member has had an inadequate response to at least a 3-month trial of parenteral glucocorticoids.

9. Symptomatic Sarcoidosis
Authorization of 3 months may be granted to members for the treatment of symptomatic sarcoidosis when the member has had an inadequate response to at least a 3-month trial of parenteral glucocorticoids.
10. Serum Sickness
Authorization of 1 month may be granted to members for the treatment of serum sickness when the member has had an inadequate response to at least a 3-month trial of parenteral glucocorticoids.

D. CONTINUATION OF THERAPY
1. Infantile Spasms
Authorization of 6 months may be granted to members requesting H.P. Acthar Gel for continuation of therapy when the member has shown substantial clinical benefit from therapy.

2. All Other Indications
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

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.

1. The following dosing limits apply:
   - Multiple sclerosis: 120 units per day
   - Nephrotic syndrome: 160 units per 7 days
   - All other diagnoses other than infantile spasms: 80 units per day

REFERENCES