H.P. ACTHAR

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Length of Authorization</th>
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<td>H.P. Acthar</td>
<td>corticotropin, ACTH</td>
<td>Per Medical Guidelines</td>
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Approvable Criteria:

A. Diagnostic testing of adrenocortical function; or

B. West syndrome (infantile spasms); or

C. Any of the following Food and Drug Administration (FDA)- approved indications after the member has failed corticosteroid therapy:

1. Allergic states: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment, for example, atopic dermatitis, bronchial asthma, contact dermatitis, seasonal or perennial allergic rhinitis, serum sickness; or

2. Collagen diseases: During an exacerbation or as maintenance therapy in selected cases, for example, acute rheumatic carditis, systemic dermatomyositis (polymyositis), systemic lupus erythematosus; or

3. Dermatologic diseases: Bullous dermatitis herpetiformis, exfoliative dermatitis, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis, severe seborrheic dermatitis; or

4. 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; or

5. Endocrine disorders: Hypercalcemia associated with cancer, non-suppurative thyroiditis; or

6. Gastrointestinal diseases: To tide the member over a critical period of the disease in regional enteritis, ulcerative colitis; or

7. Hematologic disorders: Acquired (autoimmune) hemolytic anemia, secondary thrombocytopenia in adults, erythroblastopenia (RBC anemia), congenital (erythroid) hypoplastic anemia, or

8. Neoplastic diseases: For palliative management of acute leukemia of childhood, leukemias and lymphomas in adults; or

9. Nervous system diseases: Acute exacerbations of multiple sclerosis; or

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10. Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, for example, allergic conjunctivitis, allergic corneal marginal ulcers, anterior segment inflammation, chorioretinitis, diffuse posterior uveitis and choroiditis, herpes zoster ophthalmicus, iritis and iridocyclitis, keratitis, optic neuritis, sympathetic ophthalmia; or

11. Respiratory diseases: Aspiration pneumonitis, berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with anti-tuberculous chemotherapy, Loeffler's syndrome not manageable by other means, symptomatic sarcoidosis; or

12. Rheumatic disorders: As adjunctive therapy for short-term administration (to tide the member over an acute episode or exacerbation) in acute gouty arthritis, acute non-specific tenosynovitis, acute and subacute bursitis, ankylosing spondylitis, epicondylitis, post-traumatic arthritis, psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), synovitis of osteoarthritis; or

13. Miscellaneous: Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculous chemotherapy.

BHP considers repository corticotropin experimental and investigational for all other indications.

SPECIALTY PHARMACY PRODUCT

Dosing Guidelines:

For immunosuppression or for the treatment of inflammation:

- **Corticotropin injection** – Adults: 20 units IM or SC four times per day (dosage range is 40—80 units per day). Children: 1.6 units/kg/day or 50 units/m2/day IV or SC in 3—4 divided doses or IM as a single dose or in 2 divided doses.
- **Repository Corticotropin injection** – Adults, adolescents, and children: 40—80 units IM or SC every 24—72 hours.

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For the treatment of infantile spasms:

- Infants and Children < 2 years: 75 units/m2 IM twice daily for 2 weeks is the FDA approved regimen. The dose should then be tapered over a 2 week period to avoid adrenal insufficiency. The manufacturer suggests the following tapering schedule: 30 units/m2 IM every morning for 3 days, 15 units/m2 IM every morning for 3 days, and 10 units/m2 IM every other morning for 6 days. Body surface area should be calculated with the following formula: BSA (m2) = \sqrt{\frac{\text{height (cm)} \times \text{weight (kg)}}{3600}}. Various other regimens have been used off label. Low doses of 5—40 units/day IM for 1—6 weeks have been recommended by some neurologists, while others recommend larger doses of 40—160 units/day IM for 3—12 months. In one study, no major difference in efficacy was found between low doses for short periods and large doses for longer periods of time; however, hypertension was more common with the larger doses. In this study, the low-dose regimen was 20 units/day IM for 2 weeks. If the patient responded, the dose was tapered and discontinued over a 1-week period. If the patient did not respond, the dose was increased to 30 units/day IM for 4 weeks, then tapered and discontinued over a 1-week period. The high-dose regimen was 150 units/m2/day IM for 3 weeks; the dose was then tapered and discontinued over 9 weeks.

For adrenocortical insufficiency diagnosis:

- Corticotropin injection – Adults: 10 – 25 units IV infused over 8 hours.
- Repository corticotropin injection - Adults, Adolescents, and Children: Up to 80 units SC or IM. A rise in urinary and plasma corticosteroid values provides direct evidence of a stimulatory effect. NOTE: The manufacturer does not specify if the dosing for children and adolescents differs from adults.

For the treatment of acute exacerbations of multiple sclerosis:

- Adults: 80—120 units IM per day in divided doses for 2—3 weeks.

References: