

## Specialty Pharmacy Program

### H.P. Acthar<sup>®</sup> Gel (corticotropin)

#### DESCRIPTION

H.P. Acthar Gel is prolonged-release preparation of adrenocorticotrophic hormone (ACTH). ACTH stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances.

#### APPROVAL DURATION

- Diagnostic testing of adrenocortical function: one time
- Infantile spasms: 6 months
- Other FDA-approved indications: lifetime

#### APPROVAL CRITERIA

- I. H.P. Acthar Gel is used for diagnostic testing of adrenocortical function; OR
- II. H.P. Acthar Gel is used as treatment of West syndrome (infantile spasms); OR
- III. H.P. Acthar Gel is used for any of the following FDA-approved disorders AFTER failure of corticosteroid therapy:
  - A. Allergic States: seasonal or perennial allergic rhinitis; bronchial asthma; contact dermatitis; atopic dermatitis; serum sickness; OR
  - B. Collagen Diseases: systemic lupus erythematosus; systemic dermatomyositis (polymyositis); acute rheumatic carditis; OR
  - C. Dermatologic Diseases: Pemphigus; bullous dermatitis herpetiformis; severe erythema multiforme (Stevens-Johnson syndrome); exfoliative dermatitis; severe psoriasis; severe seborrheic dermatitis; mycosis fungoides; OR
  - D. Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus; OR
  - E. Endocrine Disorders: Nonsuppurative thyroiditis; hypercalcemia associated with cancer; OR
  - F. Gastrointestinal Diseases: ulcerative colitis; regional enteritis; OR
  - G. Hematologic Disorders: Acquired (autoimmune) hemolytic anemia; secondary thrombocytopenia in adults; erythroblastopenia (RBC anemia); congenital (erythroid) hypoplastic anemia; OR
  - H. Neoplastic Diseases: For palliative management of: leukemias and lymphomas in adults; acute leukemia of childhood; OR
  - I. Nervous System Diseases: Acute exacerbations of multiple sclerosis; OR
  - J. Ophthalmic Diseases: allergic conjunctivitis; keratitis; herpes zoster ophthalmicus; iritis and iridocyclitis; diffuse posterior uveitis and choroiditis; optic neuritis; sympathetic ophthalmia; chorioretinitis; anterior segment inflammation; allergic corneal marginal ulcers; OR
  - K. Respiratory Diseases: Symptomatic sarcoidosis; Loeffler's syndrome not manageable by other means; berylliosis; fulminating or disseminated pulmonary tuberculosis when used concurrently with antituberculous chemotherapy; aspiration pneumonitis; OR
  - L. Rheumatic Disorders: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis; acute and subacute bursitis; acute nonspecific tenosynovitis; acute gouty arthritis; post-traumatic arthritis; synovitis of osteoarthritis; epicondylitis; OR
  - M. Miscellaneous: Tuberculous meningitis with subarachnoid block or impeding block when used concurrently with appropriate antituberculous chemotherapy; trichinosis with neurologic or myocardial involvement.