**GUIDELINES FOR USE**

1. Is the patient less than two years old and diagnosed with infantile spasms?

   If yes, **approve for 28 days with a maximum of #8 vials (each 5mL vial contains 400 units).**
   If no, do not approve.

   **DENIAL TEXT:** The guideline named **CORTICOTROPIN (H.P. Acthar Gel)** requires a diagnosis of infantile spasms in patients less than 2 years of age. For all other FDA indications, consider the use of IV corticosteroids.

   **FDA approved indications include:**
   - infantile spasm, acute multiple sclerosis, psoriatic arthritis, rheumatoid arthritis including juvenile rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus or 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, and anterior segment inflammation), symptomatic sarcoidosis, or 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.

---

**RATIONALE**

Ensure appropriate therapeutic use of this long acting corticotropin formulation.

The recommended regimen for use in infantile spasms is a daily dose of 150 units/m² (divided into twice daily intramuscular injections of 75 units/m²) then a gradual taper over a 2-week period. A suggested taper schedule is 30 units/m² every morning for 3 days, 15 units/m² every morning for 3 days, 10 units/m² every morning for 3 days, and then 10 units/m² every other morning for 6 days.

8 vials per 28 days supply based on dosage of 150 units/m²/day with an estimate of 0.7m² body surface area, estimated maximum for a child less than 40 pounds (two years old).

The American Academy of Neurology guidelines for treatment of infantile spasms state that response is usually within 2 weeks and current clinical data is insufficient to determine optimum dosage and duration.

**CONTINUED ON NEXT PAGE**
CORTICOTROPIN

RATIONALE (CONTINUED)

Questcor states that the H.P. Acthar Gel vial expires 28 days after initial puncture, when stored under ideal conditions (per USP standard guidelines).

FDA APPROVED INDICATIONS

Acthar Gel is indicated for the treatment of infantile spasms, for acute exacerbations of multiple sclerosis, and for numerous other diseases and disorders. (See below).

INFANTILE SPASMS: Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

MULTIPLE SCLEROSIS: Treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

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 (selected cases may require low-dose maintenance therapy), and ankylosing spondylitis.

COLLAGEN DISEASES: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus or 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, and 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.

CONTINUED ON NEXT PAGE
CORTICOTROPIN

REFERENCES


Created: 08/17
Effective: 12/01/17