

H.P. Acthar Gel® LA

(repository corticotrophin Injection)

When requesting H.P. (histrelin acetate), subcutaneous impant, the individual requiring treatment must be diagnosed with the follwing FDA-approved indication and meet the specific coverage guidelines.

FDA-approved indication(s)

H.P. Acthar Gel® (repository corticotropin injection) is indicated for the treatment of infantile spasms and acute exacerbations of multiple sclerosis.

Coverage Guidelines

The individual meets **all** of the following criteria for approval:

Infantile Spasms:

- 1) Has the diagnosis of infantile spasms; AND
- 2) The child is less than 5 years of age; AND
- 3) Is prescribed by, or in consultation with, a neurologist or an epileptologist

Multiple Sclerosis, acute exacerbations in adults

- 1) Has the diagnosis of multiple sclerosis; AND
- 2) Is prescribed by, or in consultation with , a neurologist or a physician that specializes in the treatment of multiple sclerosis; AND
- 3) The patient is NOT using Acthar as “pulse therapy” (defined as use on a once monthly or routine basis to prevent MS exacerbation); AND
- 4) The patient cannot use high-dose IV corticosteroids (e.g., methylprednisolone) because IV access is not possible (e.g., difficulty in placing a peripheral line); OR The patient has tried high dose corticosteroids administered IV (e.g., methylprednisolone 500-1000mg daily for 3-5 days) for acute MS exacerbation or relapse; AND The patient has experienced a severe or limiting adverse effect to the high-dose corticosteroid (e.g., psychotic reaction)

Approval duration for Infantile Spasms or MS acute exacerbations: 1 month

Recommended dosing

Infantile Spasms- 150 units/m²/day (divided into twice daily IM injections of 75 units/m²) given over a 2- week period. It should then be gradually tapered over a 2-week period. The following is one suggested tapering schedule: 30 units/m² in the morning for 3 days; 15 units/m² in the morning for 3 days; 10 units/m² in the morning for 3 days, and 10 units/m² in the morning for 3 days; and 10 units/m² every other morning for 6 days.

Multiple Sclerosis, acute exacerbations in adults- 80 to 120 units daily by IM or SC injection for 2 to 3 weeks for acute exacerbations. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

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