

Policy Type: PA/SP

Pharmacy Coverage Policy: EOCCO117

Description

Corticotropin (Acthar) is an injectable adrenocorticotrophic hormone (ACTH) analogue that stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and other weak androgenic substances.

Length of Authorization

- Initial: One month
- Renewal: One month

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
corticotropin (Acthar)	400 Units/5mL	Infantile Spasms	4 vials/28 days

Initial Evaluation

- I. Corticotropin (Acthar) may be considered medically necessary when the following criteria below are met:
 - A. Medication is prescribed by, or in consultation with, a neurologist; **AND**
 - B. A diagnosis of one of **Infantile Spasms (West Syndrome)** when the following are met::
 1. Member is under 2 years of age; **AND**
 2. Must be used as monotherapy; **AND**
 3. Documentation that patient does not have a suspected congenital infection.

- II. Corticotropin (Acthar) is considered not medically necessary when criteria above are not met and/or when used for the following disorders and diseases:
 - A. Exacerbation of Multiple Sclerosis
 - B. Rheumatic Disorder: psoriatic arthritis; rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis
 - C. Collagen Disease: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
 - D. Dermatologic Disease: severe erythema multiforme, Stevens-Johnson syndrome
 - E. Allergic states: serum sickness
 - F. Ophthalmic Disease: keratitis; iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
 - G. Respiratory Disease: symptomatic sarcoidosis
 - H. Edematous state: nephrotic syndrome

- III. Corticotropin (Acthar) is considered investigational when used for all other conditions, including but not limited to:
 - A. Uveitis
 - B. Prophylaxis of MS exacerbation
 - C. Adrenal insufficiency diagnosis
 - D. Rheumatoid Arthritis
 - E. Sarcoidosis

Renewal Evaluation

- I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
- II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
- III. Member has exhibited improvement or stability of disease symptoms (e.g., complete suppression of both clinical spasms and hypsarrhythmia on a full sleep cycle); **AND**

Supporting Evidence

- I. The safety and efficacy of corticotropin (Acthar) in the setting of infantile spasm was studied in a single blinded (video EEG interpreter blinded), randomized, active control trial where patients were randomized to receive a two week course of treatment with corticotropin (Acthar) or prednisone. The primary efficacy outcome was a comparison of the number of patients in each group who were treatment responders. Treatment response was defined as a patient having a complete suppression of both clinical spasms and hypsarrhythmia on a full sleep cycle video EEG performed at two weeks following the treatment initiation. In the trial, 13 of 15 patients (86.7%) responded to corticotropin (Acthar) as compared to 4 of 14 patients (28.6%) who received prednisone ($p < 0.002$).
- II. Treatment guidelines for the exacerbation of MS recommend corticosteroid as the first choice of therapy, with other treatment options including: corticotropin (Acthar) or plasmapheresis.

Investigational or Not Medically Necessary Uses

- I. Although the listed disorders and diseases (exacerbation of multiple sclerosis, rheumatic, collagen, dermatologic, allergic states, ophthalmic, respiratory, and edematous state) are labeled indications, at this time, corticotropin (Acthar) has not been shown to be effective due to limited data or potential safety concerns.
- II. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy for:
 - A. Uveitis
 - B. Prophylaxis of MS exacerbation
 - C. Adrenal insufficiency diagnosis

- D. Rheumatoid Arthritis
- E. Sarcoidosis

References

1. Acthar [Prescribing Information]. Bedminster, NJ: Mallinckrodt ARD LLC. March 2019.
2. National Multiple Sclerosis Society. Managing Relapses. Available at: <https://www.nationalmssociety.org/Treating-MS/Managing-Relapses#section-2>
3. Multiple Sclerosis Association of America. Treating Multiple Sclerosis Relapse. October 2017. Available at: <https://mymsaa.org/ms-information/treatments/relapses/>

Policy Implementation/Update:

Date Created	November 2019
Date Effective	December 2019
Last Updated	
Last Reviewed	

Action and Summary of Changes	Date