Prior Authorization Criteria for ACTHAR H.P. GEL (repository corticotropin)

The following criteria must be met for approval of H.P. Acthar Gel:

1. Diagnosis of West Syndrome* (infantile spasms) in a pediatric patient under the age of 2 years.
2. Prescribed by a neurologist
3. Patient’s current documented height and weight must be supplied for dose determination.

Acthar H.P. Gel in the treatment of West Syndrome will be approved for one course of treatment. When approved, Acthar H.P. Gel must be obtained from our specialty pharmacy.

*The diagnosis of West Syndrome must be supported by (confirmed diagnosis----epileptic spasms, arrest of psychomotor development and EEG pattern of hypersynchronia).

The dosage for the treatment of West Syndrome is 150 units/m² IM (divided into twice-daily injections of 75 units/m² IM) administered over a 2 week period. Dosing should then be gradually tapered and discontinued over a 2 week period to avoid adrenal insufficiency. If approved, coverage of up to one month will be granted.

Sudden withdrawal after prolonged use may lead to adrenal insufficiency or recurrent symptoms. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medications.
The use of Acthar H.P. gel for corticosteroid-responsive conditions has not been shown to be more effective than the use of corticosteroids. There is a lack of evidence documenting effectiveness of Acthar H.P. Gel in patients who have failed to respond to corticosteroids. Therefore, the use of Acthar H.P. Gel for any indication other than West Syndrome will be considered not medically necessary. Adverse effects with Acthar H.P. Gel are potentially life threatening problems that include depression of the immune system and modified response to infection leading to overwhelming sepsis.

Acthar H.P. gel is a natural preparation derived from a porcine source of adrenocorticotropic hormone (ACTH) in a gel that is designed to provide extended release of the ACTH following administration. ACTH stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances.