

<b>POLICY NAME</b>	Acthar Gel (corticotropin)	<b>POLICY #</b>	1742P
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## Criteria

### Criteria for Coverage for West Syndrome (infantile spasms)

- ☐ 1.1 Documentation of West Syndrome
- ☐ 1.2 Documentation showing that member is less than 2 years of age
- ☐ 1.3 Approval period: 4 week treatment regimen within a 6 month approval duration
- ☐ 1.4 Reauthorization requires documentation that member shown substantial clinical benefit from therapy

## Excluded Diagnoses

- ☐ **1.5** The use of Acthar for the treatment of acute exacerbations of multiple sclerosis is not considered medically necessary.
  - Acthar gel showed no clinical benefit, greater number of adverse effects, and required longer duration of treatment vs. IV methylprednisolone
  - Acthar gel administered either intramuscularly or subcutaneously at a dose of 80 U/day for 5 days. No significant treatment difference was observed. No direct comparison to methylprednisolone performed.
  - Health Alliance does not consider known adverse events associated with corticosteroid use to be a contraindication preventing future use.
- ☐ **1.6** FDA labeling suggests that H.P. Acthar may be useful in the following conditions, but it is not FDA- indicated. H.P. Acthar is unproven and not medically necessary in the following situations
  - Testing of adrenocortical function ☐ Use cosyntropin instead
  - Musculoskeletal 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), Ankylosing spondylitis.
  - Skin Diseases: ☐ During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).
  - Dermatologic Diseases: ☐ Severe erythema multiforme, Stevens-Johnson syndrome, atopic dermatitis
  - Serum sickness
  - Eye 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; anterior segment inflammation.
  - Lung Diseases: ☐ Symptomatic sarcoidosis.
  - Diuresis in nephrotic syndrome: Criteria Statement of the Policy References ☐ 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.
  - Any indication outside of infantile spasms CPT Codes HCPCS Codes J0801 Injection, corticotropin (acthar gel)