Pharmacy Drug Policy Checklist

POLICY NAME	Acthar Gel (corticotropin)	POLICY #	1742P

Criteria

Criteria for Coverage for West Syndrome (infantile spasms)

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

Excluded Diagnoses

- ☐ 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 methylpredinisolone
  - 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.

☐ 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)