Pharmacy Drug Policy & Procedure

Policy Name:	Acthar Gel (corticotropin)	Policy #:	1742P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Acthar Gel.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Acthar Gel under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. 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

2. 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 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.

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:

  - 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)

References

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Created Date: 11/18/10
Effective Date: 11/18/10
Posted to Website: 01/01/22
Revision Date: 08/07/24