PRIOR AUTHORIZATION POLICY

POLICY: Acthar Gel Prior Authorization Policy
- H.P. Acthar® Gel (repository corticotropin injection for intramuscular or subcutaneous use – Mallinckrodt)

REVIEW DATE: 03/31/2021

OVERVIEW

H.P. Acthar gel (Acthar), an adrenocorticotropic hormone (ACTH) analog, is indicated for the following uses:[1]

- **Infantile spasms**, treatment of, in infants and children < 2 years of age.
- **Multiple sclerosis (MS), treatment of exacerbations** in adults.

Although data are limited, the prescribing information notes that Acthar may also be used for the following disorders and diseases:[1]

- **Allergic states**, such as serum sickness.
- **Collagen diseases**, during an exacerbation or as a maintenance therapy in selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- **Dermatologic diseases**, such as severe erythema multiforme and Stevens-Johnson syndrome.
- **Edematous state** including 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.
- **Respiratory diseases** such as symptomatic sarcoidosis.
- **Rheumatoid disorders**, as an 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], and ankylosing spondylitis.
- **Ophthalmic diseases** including 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, and anterior segment inflammation.

Guidelines

Several guidelines discuss Acthar.

- **American Academy of Neurology and the Child Neurology Society** published an evidence-based guideline for the medical treatment of infantile spasms (2012).[2] ACTH is a first-line agent for the short-term treatment of infantile spasms.
- **Infantile Spasms Working Group** published a US consensus report on infantile spasms in 2010.[3] Most patients with this condition (90%) present within the first year of life. ACTH is an effective first-line therapy for infantile spasms.
- **Kidney Disease Improving Global Outcomes (KDIGO)** published clinical practice guidelines for glomerulonephritis (2012).[6] Due to limited data, recommendations cannot be made regarding ACTH.
- **National MS Society** has recommendations regarding corticosteroids in the management of MS (2008).[4] High-dose corticosteroids are the accepted standard of care short-term. The most common regimen is 500 to 1,000 mg of intravenous methylprednisolone given daily for 3 to 5 days, with or without an oral steroid tapering regimen (most often prednisone) for 1 to 3 weeks. Acthar and high-dose intravenous methylprednisolone have been shown to possess similar efficacy in the management of MS relapses.[5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Acthar. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Acthar as well as monitoring required for adverse events and efficacy, approval requires Acthar to be prescribed by or in consultation with a physician who specializes in the conditions being treated. All denials will be forwarded to the Medical Director.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Acthar is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Infantile Spasms, Treatment.** Approve Acthar for 1 month if the patient meets the following criteria (A and B):
   A) Child is < 2 years of age; AND
   B) Medication is prescribed by a physician who has consulted with or specializes in neurology.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Acthar is not recommended in the following situations:

1. **Multiple Sclerosis as "Pulse Therapy" on a Monthly Basis.** Preliminary data have investigated use of Acthar given as 80 units administered intramuscularly once a day for 3 days once a month.[7] This is not an accepted use of Acthar and more data are needed.

2. **Treatment of Proteinuria in Diabetic Nephropathy.** At this time, limited data are available[8] and Acthar is not established for this use.

3. **Treatment of Nephrotic Syndrome.** Very limited data have investigated the use of Acthar in patients with diagnoses including idiopathic membranous nephropathy, membranoproliferative glomerulonephritis, focal segmental glomerulosclerosis, minimal change disease, immunoglobulin A nephropathy, class V systemic lupus erythematosus (SLE) glomerulonephritis, monoclonal diffuse proliferative glomerulonephritis, and lupus nephritis.[9-25] Recommendations for use cannot be made at this time.

4. **Dermatomyositis or Polymyositis.** Data are limited in this clinical scenario[26,27] and controlled trials are needed before Acthar can be considered an established or recommended therapy.

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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