Repository Corticotropin

Overview

This policy supports medical necessity review for repository corticotropin (Acthar Gel®).

Medical Necessity Criteria

Repository corticotropin (Acthar Gel) is considered medically necessary when the following are met:

1. **Treatment of Infantile Spasms.** Individual meets BOTH of the following criteria (A and B):
   A. Individual is less than 2 years of age
   B. Medication is prescribed by, or in consultation with, a neurologist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.
Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

### Reauthorization Criteria

Repository corticotropin (Acthar Gel) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

### Authorization Duration

Initial approval duration is up to 1 month.

Reauthorization approval duration is up to 1 month.

### Conditions Not Covered

The effectiveness of repository corticotropin (Acthar Gel) has not been demonstrated as clinically superior to conventional corticosteroids and/or immunosuppressive therapy for uses other than infantile spasms, including for the treatment of multiple sclerosis, rheumatic disorders, collagen diseases, dermatologic disorders, allergic states, ophthalmic diseases, respiratory diseases, or edematous states, and is significantly more expensive. Coverage of repository corticotropin may depend on the applicable health benefit plan definition of medical necessity. Where that definition limits coverage to the most cost-effective equivalent treatment, repository corticotropin is not considered medically necessary.

Repository corticotropin (Acthar Gel) is considered not medically necessary for ANY other use including the following (this list may not be all inclusive):

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 and Acthar is not established for this use.\(^8\)
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.\(^9\text{-}25\) Recommendations for use cannot be made at this time.
4. **Dermatomyositis or Polymyositis.**
   Data are limited in this clinical scenario and controlled trials are needed before Acthar can be considered an established or recommended therapy.\(^26,27\)

### Coding / Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0800</td>
<td>Injection, corticotropin, up to 40 units</td>
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Background

OVERVIEW
H.P. Acthar gel (Acthar), an adrenocorticotrophic 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.

FDA Recommended Dosing and Availability

Infantile Spasms (IS) in Infants and Children Under 2 Years of Age
In the treatment of IS, Acthar Gel must be administered intramuscularly. The recommended regimen is a daily dose of 150 U/m² (divided into twice daily intramuscular injections of 75 U/m²) administered over a 2-week period. Dosing with Acthar Gel should then be gradually tapered over a 2-week period to avoid adrenal insufficiency. The following is one suggested tapering schedule: 30 U/m² in the morning for 3 days; 15 U/m² in the morning for 3 days; 10 U/m² in the morning for 3 days; and 10 U/m² every other morning for 6-days.

Acute Exacerbations in Adults with Multiple Sclerosis
The recommended dose is daily intramuscular or subcutaneous doses of 80 -120 units for 2-3 weeks for acute exacerbations. Dosage should be individualized according to the medical condition of each patient. Frequency and dose of the drug should be determined by considering the severity of the disease and the initial response of the patient.

Other Indications for Adults and Children Over 2 Years of Age
Dosage should be individualized according to the disease under treatment and the general medical condition of each patient. Frequency and dose of the drug should be determined by considering severity of the disease and the initial response of the patient. The usual dose of Acthar Gel is 40-80 units given intramuscularly or subcutaneously every 24-72 hours.

Although drug dependence does not occur, sudden withdrawal of Acthar Gel after prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

Drug Availability Acthar Gel is supplied as a 5 mL multi-dose vial containing 80 USP Units per mL.

Guidelines
Several guidelines discuss Acthar.
Infantile Spasms Working Group published a US consensus report on infantile spasms in 2010. 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). Due to limited data, recommendations cannot be made regarding ACTH.

National MS Society has recommendations regarding corticosteroids in the management of MS (2008). 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.

References