Acthar Gel

Description

H. P. Acthar Gel (corticotropin; ACTH)

Background
According to the US Food and Drug Administration, H.P. Acthar gel (repository corticotropin injection, ACTH) was approved for marketing in 1952. Since that time Acthar gel has shown to produce positive therapeutic outcomes in disease states such as infantile spasms, nephrotic syndrome and multiple sclerosis (1).

Effectiveness of H.P. Acthar Gel (ACTH) for treatment of infantile spasms was shown in a single blinded clinical trial in which patients received either a 2 week course of treatment with H.P. Acthar Gel or prednisone. The study compared the number of patients in each group who were treatment responders (1).

Studies have also shown that patients with nephrotic syndrome have had successful outcomes with Acthar Gel after failing other therapies. ACTH treatment produced a lasting remission with few side effects. Findings showed monotherapy ACTH was as effective for nephrotic patients as the combination therapy of methylprednisolone and a cytotoxic agent (1-2).

Studies of the use of H.P. Acthar Gel for multiple sclerosis have showed a protective effect against progression, stabilization of the disease, and also marked improvement in patients with acute relapse of MS after the use of ACTH (1, 3-4).

Regulatory Status
FDA-approved indications: Acthar gel is an adrenocorticotropic hormone (ACTH) which is indicated for: (1)
1. Treatment of infantile spasms in infants and children under 2 years of age
2. Treatment of exacerbations of multiple sclerosis in adults over 18 years of age
3. Treatment of nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus to induce a diuresis or a remission
4. H.P. Acthar Gel may be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; and respiratory

H.P. Acthar Gel should never be given intravenously. Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of H.P. Acthar Gel.

H.P. Acthar Gel is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origin.

H.P. Acthar Gel is contraindicated in children less than 2 years of age with suspected congenital infections.

Related policies
Ampyra, Aubagio, Gilenya, MS Injectables, Tecfidera, Tysabri

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

H.P. Acthar Gel may be considered medically necessary when prescribed by a neurologist for the treatment of infantile seizures; when prescribed by a neurologist for exacerbations of multiple sclerosis. Must have tried and failed corticosteroid therapy and used in combination with a maintenance MS therapy. When prescribed by a nephrologist for nephrotic syndrome must have tried and failed corticosteroid therapy.

Acthar gel is considered investigational for all other indications.

Prior-Approval Requirements

Diagnoses
Patient must have **ONE** of the following:

1. Infantile spasms (in children < 2 years of age)
   a. Prescribed by a neurologist

2. Exacerbations of multiple sclerosis (in adults ≥18 years of age)
   a. Inadequate response to a 3 month trial of parenteral glucocorticoids therapy
   b. Inadequate response to a 3 month trial of interferon beta therapy
   c. Prescribed by a neurologist
   d. Used in combination with a maintenance MS therapy

3. Nephrotic syndrome
   a. Inadequate response to a 3 month trial of parenteral glucocorticoids therapy
   b. Prescribed by a nephrologist

**Prior – Approval Renewal Requirements**
Same as above

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Duration</th>
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<tbody>
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<td>Infantile spasms</td>
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**Prior – Approval Renewal Limits**

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Rationale

Summary
H.P. Acthar Gel stimulates the release of endogenous cortisol. It is approved for a number of indications that are more generally treated with corticosteroids. Indications that are supported by published clinical literature are covered by the prior approval criteria.

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of H.P. Acthar Gel while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2011</td>
<td>Updated criteria to mirror FDA indications for infantile spasms in infants and children less than 2 years of age and exacerbations of multiple sclerosis in adults.</td>
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<tr>
<td>May 2012</td>
<td>Updated criteria to include FDA indication for nephrotic syndrome</td>
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<tr>
<td>March 2013</td>
<td>Annual editorial review. Remove tried and failed corticosteroid from infantile spasms. Addition of the following to the criteria: Not intended for IV administration, patient must not have scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins or porcine origin. No administration of live or live attenuated vaccines with immunosuppressive doses of Acthar Gel. No congenital infections in children under 2 years of age. Revised limitations to 6 months in light of use for nephrotic syndrome and MS.</td>
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<tr>
<td>June 2013</td>
<td>Annual editorial review and reference update</td>
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### 5.30.10

<table>
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<tr>
<th>Section:</th>
<th>Prescription Drugs</th>
<th>Effective Date:</th>
<th>January 1, 2017</th>
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<tbody>
<tr>
<td>Subsection:</td>
<td>Endocrine and Metabolic Drugs</td>
<td>Original Policy Date:</td>
<td>June 9, 2011</td>
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- **December 2014**: Annual editorial review and reference update
- **March 2015**: Annual editorial review and reference update
- **May 2015**: Addition of specialist and change of duration on approvals for MS and infantile spasms
- **June 2015**: Annual editorial review and reference update
- **September 2015**: Annual review
- **September 2016**: Annual editorial review and reference update
  - Addition of inadequate response to a 3 month trial of parenteral glucocorticoids therapy to MS and Nephrotic indications
  - Addition of Inadequate response to a 3 month trial of interferon beta therapy
  - Policy number change from 5.08.10 to 5.30.10
- **December 2016**: Annual editorial review

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2016 and is effective on January 1, 2017.

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