H.P. Acthar® Gel (repository corticotropin injection, ACTH)  
(Intramuscular)

I. Length of Authorization

Coverage will be provided for 1 month and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:
   • H.P. Acthar Gel 80 units/mL injection (5 mL multi-dose vial): 4 vials per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:
   • 35 billable units every 28 days

III. Initial Approval Criteria

Infantile spasms (West Syndrome) 

• Patient is under 2 years of age; AND
• Clinical documentation indicating patient has a diagnosis of infantile spasms (West Syndrome): AND
• Must be used as monotherapy: AND
• Documentation that patient does not have a suspected congenital infection

Glomerular Disease

• Patient must have had an inadequate response, contraindication, or intolerance to corticosteroids: AND
• Patient must have had an inadequate response, contraindication, or intolerance to prior immunosuppressive therapy

† FDA Approved Indication(s)
Use of repository corticotropin injection for indications including, but not limited to, those additionally listed in the product labeling are not supported by substantial clinical evidence.

Repository Corticotropin Injection was originally approved by the U.S. Food and Drug Administration (FDA) in 1952 for a variety of disorders and diseases that at the time were thought to benefit from steroid mediated immunosuppression. The initial approval of H.P. ACTH gel occurred prior to the Kefauver-Harris amendment to the Federal Food, Drug and Cosmetic Act of 1962, which introduced the requirement of “substantial evidence” of two adequate and well controlled trials. At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing patients with conditions originally treated with Acthar powder that were transferred to treatment with Acthar Gel and gave dosing guidance for treatment of these individual conditions. These data would be grossly inadequate to support approval of a new drug or new indications by the Agency under current standards requiring evidence from adequate and well controlled clinical trials. A Drug Efficacy Study Implementation (DESI) review of corticotrophin injection was initiated in 1971 and finalized in 1977.3

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; AND
- Disease response with treatment as indicated by resolution of symptoms and/or normalization of laboratory tests; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infections, severe electrolyte imbalances, gastric bleeding or ulcer, hypertension, hypokalemia, severe depression, frank psychotic manifestations, posterior subcapsular cataracts, glaucoma, etc.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infantile Spasms</td>
<td>Administer 75 units/m² intramuscularly given twice daily for 2 weeks, then taper the dose over a 2 week period (e.g., 30 units/m² in the morning for 3 days; 15 units/m² in the morning for 3 days; 10 units/m² in the morning for 3 days; and 10 units/m² every other morning for 6 days).</td>
</tr>
</tbody>
</table>

VI. Billing Code/Availability Information

HCPCS code:
J0800 – Injection, corticotropin, up to 40 units; up to 40 units = 1 billable unit
NDC:
H.P. Acthar Gel 80 units/mL (5 mL multi-dose vial): 63004-8710-xx

VII. References

3. Center for Drug Evaluation and Research. APPLICATION NUMBER: 022432Orig1s000. Other Review(s). U. S. Food and Drug Administration. Washington, DC.


### Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G40.821</td>
<td>Epileptic spasms, not intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.822</td>
<td>Epileptic spasms, not intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.823</td>
<td>Epileptic spasms, intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.824</td>
<td>Epileptic spasms, intractable, without status epilepticus</td>
</tr>
<tr>
<td>N00.1</td>
<td>Acute nephritic syndrome with focal and segmental glomerular lesions</td>
</tr>
<tr>
<td>N00.2</td>
<td>Acute nephritic syndrome with diffuse membranous glomerulonephritis</td>
</tr>
</tbody>
</table>
N01.1 Rapidly progressive nephritic syndrome with focal and segmental glomerular lesions
N01.2 Rapidly progressive nephritic syndrome with diffuse membranous glomerulonephritis
N02.1 Recurrent and persistent hematuria with focal and segmental glomerular lesions
N02.2 Recurrent and persistent hematuria with diffuse membranous glomerulonephritis
N03.1 Chronic nephritic syndrome with focal and segmental glomerular lesions
N03.2 Chronic nephritic syndrome with diffuse membranous glomerulonephritis
N04.1 Nephrotic syndrome with focal and segmental glomerular lesions
N04.2 Nephrotic syndrome with diffuse membranous glomerulonephritis
N05.0 Unspecified nephritic syndrome with minor glomerular abnormality
N05.1 Unspecified nephritic syndrome with focal and segmental glomerular lesions
N05.2 Unspecified nephritic syndrome with diffuse membranous glomerulonephritis
N06.1 Isolated proteinuria with focal and segmental glomerular lesions
N06.2 Isolated proteinuria with diffuse membranous glomerulonephritis
N07.1 Hereditary nephropathy, not elsewhere classified with focal and segmental glomerular lesions
N07.2 Hereditary nephropathy, not elsewhere classified with diffuse membranous glomerulonephritis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

<table>
<thead>
<tr>
<th>Jurisdiction</th>
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<th>Contractor</th>
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<tr>
<td>F (2 &amp; 3)</td>
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<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
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<tr>
<td>6</td>
<td>MN, WI, IL</td>
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<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<tr>
<td>N (9)</td>
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<td>First Coast Service Options, Inc.</td>
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<tr>
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<tr>
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<td>Novitas Solutions, Inc.</td>
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<tr>
<td>Jurisdiction</td>
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<td>K (13 &amp; 14)</td>
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<tr>
<td>15</td>
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<td>CGS Administrators, LLC</td>
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