CORTICOTROPIN (H.P. ACTHAR GEL)

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORTICOTROPIN</td>
<td>H.P. ACTHAR GEL</td>
<td>02830</td>
<td></td>
<td>ROUTE = INJECTION</td>
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If the caller wishes to initiate a request then a MRF must be completed. This drug requires a written request for prior authorization. All requests for high-impact medications require review by a pharmacist prior to final approval.

GUIDELINES FOR USE

1. Is the request for a patient less than two years of age for the treatment of infantile spasms?
   - If yes, continue to #2.
   - If no, continue to #4.

2. Is the request for continuation of therapy?
   - If yes, continue to #3.
   - If no, **approve by HICL for 4 weeks.** Please use status code #057 and the following approval language:
     
     **APPROVAL TEXT:** Your request for H.P. Acthar Gel has been approved for a 4-week period.

3. Has the patient shown substantial clinical benefit while on H.P. Acthar Gel treatment?
   - If yes, **approve by HICL for 4 weeks.** Please use status code #057 and the following approval language:
     
     **APPROVAL TEXT:** Your request for H.P. Acthar Gel has been approved for a 4-week period.

   - If no, do not approve. Please use status code #238 and the denial text provided:
     
     **DENIAL TEXT:** Per your health plan’s Corticotropin (H.P. Acthar Gel) guideline, authorization for renewal requires that the patient has shown substantial clinical benefit while on therapy. Your physician did not indicate that there was a substantial clinical benefit while on therapy and therefore your request was not approved.

4. Is the request for the treatment of acute exacerbation of multiple sclerosis?
   - If yes, continue to #5.
   - If no, do not approve. Please use status code #238 and the denial text provided:
     
     **DENIAL TEXT:** Per your health plan’s Corticotropin (H.P. Acthar Gel) guideline, this medication is only covered for patient’s less than two years of age with a diagnosis of infantile spasms or for patients experiencing acute exacerbation of multiple sclerosis. Your physician did not indicate that you are being treated for one of these conditions and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

5. Did the provider provide chart notes, including dosage and duration of treatment detailing the inadequate response received with IV methylprednisolone for the current exacerbation?

If yes, approve by HICL for 3 weeks; requested quantity not to exceed 120 units per day. Please use status code #057 and the following approval language:

**APPROVAL TEXT:** Your request for H.P Acthar Gel has been approved for [requested/approved quantity] for a 3-week period.

If no, do not approve. Please use status code #238 and the denial text provided:

**DENIAL TEXT:** Per your health plan’s Corticotropin (H.P. Acthar Gel) guideline, this medication is only covered for the treatment of acute exacerbations of multiple sclerosis if you first tried IV methylprednisolone for the current exacerbation. Your physician did not provide documentation detailing the inadequate response you received with IV methylprednisolone for the current exacerbation and therefore your request was not approved.

**RATIONALE**
Ensure appropriate therapeutic use of H.P. Acthar Gel.

**FDA APPROVED INDICATIONS**
The indication-specific program provides coverage for specific, but not all FDA labeled or comendial supported drug use based on plan design and the scope of the pharmacy benefit. This program provides coverage for H.P. Acthar Gel for the treatment of infantile spasms and exacerbations of multiple sclerosis if all of the approval criteria are met.

A. **Infantile Spasms:** as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
B. **Multiple Sclerosis:** treatment of acute exacerbations of multiple sclerosis in adults

The use of H.P. Acthar for the treatment of all other indications listed in the FDA product labeling has not been proven to be superior to conventional therapies (e.g., corticosteroids, immunosuppressive agents) and has a significantly higher cost than the standard of care agents. Use of H.P Acthar for these conditions is considered not medically necessary and is not a covered benefit.

A. **Rheumatic 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 and ankylosing spondylitis
B. **Collagen Diseases:** during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus or systemic dermatomyositis (polymyositis)
C. **Dermatologic Diseases:** severe erythema multiforme, Stevens-Johnson syndrome
D. **Allergic States:** serum sickness
E. **Ophthalmic 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, and anterior segment inflammation

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FDA APPROVED INDICATIONS (CONTINUED)

F. **Respiratory Diseases**: symptomatic sarcoidosis  
G. **Edematous State**: 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

REFERENCES