UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2016 P 2028-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Prior Authorization/Medical Necessity</td>
</tr>
<tr>
<td>Medication</td>
<td>H.P. Acthar Gel® (Repository corticotropin injection)</td>
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<tr>
<td>P&amp;T Approval Date</td>
<td>5/2014, 5/2015, 9/2016</td>
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<tr>
<td>Effective Date</td>
<td>12/1/2016</td>
</tr>
</tbody>
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1. **Background:**

H.P. Acthar Gel® (repository corticotropin injection) is an adrenocorticotropic hormone (ACTH) analogue **medically necessary** for:

* Infantile Spasms: As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.¹

* Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)²,³

The H.P. Acthar package insert has listed other conditions in which it may be used. Since H.P. Acthar is more costly than an alternative drug that is at least as likely to produce equivalent therapeutic results, UHCP has determined that use of H.P. Acthar Gel is not medically necessary for treatment of the following disorders and diseases: multiple sclerosis; rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.

Coverage will be provided for members who meet the following criteria.

2. **Coverage Criteria:**

A. **Infantile Spasms (i.e., West Syndrome)**

1. **Initial Therapy**

   a. **H.P. Acthar Gel** will be approved based on **both** of the following criteria

      (1) Diagnosis of infantile spasms (West Syndrome)¹

      -AND-

      (2) Patient is less than 2 years of age¹

      **Authorization will be issued for 4 weeks by OptumRx.**

2. **Reauthorization**

   All requests for reauthorization will be **denied by OptumRx**. All requests for continuation of therapy must be submitted through the appeals process to the UnitedHealthcare Pharmacy appeals team for consideration.

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B. Orgoclonus-Myoclonus Syndrome (i.e., Kinsbourne Syndrome) (off-label)

1. Initial Authorization

   a. H.P Acthar Gel will be approved based on the following criteria:

      (1) Diagnosis of opsoclonus-myoclonus syndrome

      Authorization will be issued for 3 months by OptumRx.

2. Reauthorization

   All requests for reauthorization will be denied by OptumRx. All requests for
   continuation of therapy must be submitted through the appeals process to the
   UnitedHealthcare Pharmacy appeals team for consideration.

3. Additional Clinical Rules:

   - Supply limits and/or Step Therapy may be in place.

4. References:

   2. Pranzatelli M, Chun K, Moxness M, Tate E, Allison T. Cerebrospinal fluid
      ACTH and cortisol in opsoclonus-myoclonus: effect of therapy. Pediatr
   3. Pranzatelli, M. R., Huang, Y.-Y., Tate, E, et al. Monoaminergic effects of
      high-dose corticotropin in corticotropin-responsive pediatric opsoclonus-
      14). NINDS opsoclonus myoclonus information page. Retrieved August 24,
      2012, from the National Institutes of Health Web site: 
<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Medical Necessity - H.P. Acthar Gel (Repository corticotropin injection)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Control</strong></td>
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</tr>
<tr>
<td>5/2014</td>
<td>New Program</td>
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<tr>
<td>5/2015</td>
<td>Annual review with no change to clinical coverage.</td>
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<tr>
<td>9/2016</td>
<td>Annual review. Updated references</td>
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