I. Medication Description

Repository corticotropin injection (H.P. Acthar® Gel) is a purified, sterile preparation of the natural form of adrenocorticotrophic hormone (ACTH) in gelatin to provide a prolonged release after intramuscular or subcutaneous injection. ACTH works by stimulating the adrenal cortex to produce cortisol, corticosterone, and a number of other hormones.

According to the product information, repository corticotropin injection is indicated for the diagnostic testing of adrenocortical function. This labeling information also notes that H.P. Acthar Gel “has limited therapeutic value in those conditions responsive to corticosteroid therapy, in such cases, corticosteroid therapy is considered to be the treatment of choice.”

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage determination requires clarification of applicable benefit (i.e. pharmacy or medical benefit). This is determined by how the medication is being administered (by a healthcare professional – medical benefit; by self or non-healthcare professional caregiver – pharmacy benefit).

Coverage is provided for the following diagnoses:

- Infantile spasms (West’s syndrome)- will be applied to pharmacy benefit unless otherwise requested
- Treatment of acute exacerbations of multiple sclerosis (MS) in adults:
  - Acthar is prescribed by, or in consultation with a neurologist AND
  - The patient is being treated for an acute exacerbation of MS and therefore is not using Acthar as “pulse therapy” (defined as use on a once monthly or routine basis to prevent MS exacerbations) AND
  - Member has had a trial of plasma exchange with inadequate response AND
  - One of the following applies:
    - The patient cannot use high-dose IV corticosteroids (e.g., methylprednisolone) because of a confirmed medical contraindication OR
- The patient has tried high-dose IV corticosteroids for the current MS exacerbation/relapse and the patient has experienced a severe or limiting adverse effect of the high-dose corticosteroid
- Any of the following (when there are medical contraindications or intolerance to any, or documented therapeutic failure with at least one corticosteroid and the medication is prescribed by an appropriate corresponding specialist):
  - Rheumatic disorders as adjunctive therapy in psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis
  - Collagen diseases such as systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
  - Dermatologic diseases such as severe erythema multiforme, Stevens-Johnson syndrome
  - Serum sickness
  - Ophthalmic diseases such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
  - Symptomatic sarcoidosis
  - Edematous state (to induce a diuresis or a remission of proteinuria in the nephritic syndrome without uremia of the idiopathic type or that due to lupus erythematosus)

IV. **Quantity Limitations**

- Quantities greater than 1 vial per month (i.e. 400 units per month) will require additional authorization. Authorization will be based on FDA-approved dosing guidelines and will take into consideration the duration of the treatment period as well as the taper period that is requested by the treating physician.
- Coverage for the treatment of one episode at a time will be provided, if applicable.

V. **Coverage Duration**

- Infantile spasms: 4 weeks (2 weeks of treatment, and 2 weeks of taper)
- Acute exacerbations of MS: 5 weeks (up to 3 weeks of treatment, followed by taper)
- Other indications: dosing duration will need to be individualized depending on the disease under treatment and the medical condition of the patient. It may be necessary to taper the dose.
- Coverage may be renewed upon request

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:
- Clinical response to past treatment with H.P. Acthar Gel® was demonstrated AND
- There is an absence of unacceptable toxicity from the drug AND
- The original coverage criteria are again met

VII. **Billing/Coding Information**

- J0800: 1 billable unit is equivalent to up to 40 units of medication
• H.P. Acthar Gel is supplied in 5ml vials, 80 units per each ml (400 units per vial).
• Pertinent diagnoses:

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>ICD-10</th>
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<tbody>
<tr>
<td>Infantile spasm (West Syndrome)</td>
<td>G40.821, G40.822</td>
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<tr>
<td>Multiple sclerosis</td>
<td>G35</td>
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<td>Psoriatic arthritis</td>
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<td>Rheumatoid arthritis</td>
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<td>Ankylosing spondylitis</td>
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<td>Systemic lupus erythematous</td>
<td>M32.10</td>
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<td>Systemic dermatomyositis (polymyositis)</td>
<td>M33.20, M33.90</td>
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<td>Erythema multiforme</td>
<td>L51.0-L51.3, L51.8, L51.9</td>
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<td>Serum sickness</td>
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<td>Iridocyclitis</td>
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<td>Optic neuritis</td>
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<td>Sarcoidosis</td>
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<td>Edematous state</td>
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</table>

VIII. Summary of Policy Changes

• 9/1/11: New policy
• 9/15/12: No changes
• 3/15/13: Additional criteria for use in acute exacerbations of MS; Policy pertains to Medicaid/Family Health Plus population
• 3/15/14: Addition of requirement for plasma exchange prior to approval for the treatment of acute MS exacerbation
• 3/15/15: Requirements of high-dose steroids not limited to IV for diagnoses other than MS exacerbation; specialist prescriber required; renewal criteria refers to original coverage criteria
• 6/15/15: No policy changes
• 7/1/15: Formulary distinctions made
• 6/15/16: No policy changes

IX. References

1. H.P. Acthar® Gel prescribing information: Questcor Pharmaceuticals, Inc. 26118 Research Rd, Hayward, CA 94545. Revised 1/2015.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.