<table>
<thead>
<tr>
<th>Policy Title:</th>
<th>H.P. Acthar Gel (repository corticotropin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date:</td>
<td>01/01/2020</td>
</tr>
<tr>
<td>Review Date:</td>
<td>9/18/2019, 12/18/19, 1/22/20, 3/4/2021</td>
</tr>
<tr>
<td>Revision Date:</td>
<td>9/18/2019, 1/22/20, 3/4/2021</td>
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<tr>
<td>Department:</td>
<td>PHA</td>
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**Purpose:** To support safe, effective and appropriate use of H.P. Acthar Gel (repository corticotropin).

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**
H.P. Acthar Gel (repository corticotropin) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**
Coverage of H.P. Acthar Gel (repository corticotropin) will be reviewed prospectively via the prior authorization process based on criteria below.

**Initial Criteria:**
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

**Infantile Spasms:**
- Patient has a diagnosis of Infantile Spasms (West Syndrome); AND
- Patient is less than 24 months old; AND
- Must be used as monotherapy; AND
- Patient is receiving a dose of up to 150 U/m²/day in divided doses over a 2 week period and will not be treated for more than 4 weeks

**Multiple Sclerosis:**
- Patient is diagnosed with an exacerbation of multiple sclerosis; AND
- Must be prescribed by a neurologist; AND
- Patient is 18 years of age or older; AND
- Patient must have documented contraindication or intolerance (i.e. severe anaphylaxis) to IV corticosteroids (i.e. IV methylprednisolone or IV dexamethasone); AND
- H.P. Acthar dose will not exceed 120 units daily and will not exceed a duration of three weeks.

For Rheumatic Disorders, Collagen Diseases, Dermatologic Disorders, Allergic States, Ophthalmic Diseases, Respiratory Disease, and Edematous States:

- Must have an adequate trial of at least two IV corticosteroids with an inadequate response or significant side effects/toxicity for the following diagnoses:
  - Psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (select cases may require low-dose maintenance therapy), ankylosing spondylitis:
    - Must be used as an adjunctive therapy for short-term administration (to tide patient over an acute episode or exacerbation); AND
    - Must be prescribed by a rheumatologist
  - Systemic lupus erythematosus or systemic dermatomyositis (polymyositis)
    - May be used during an exacerbation or maintenance therapy; AND
    - Must be prescribed by a dermatologist or rheumatologist
  - Severe erythema multiforme or Stevens-Johnsons syndrome
  - Severe acute or chronic allergic or inflammatory processes involving the eye and its adnexa such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
    - Must be prescribed by an ophthalmologist
  - Systemic lupus erythematosus or systemic dermatomyositis
  - Severe erythema multiforme or Stevens-Johnsons syndrome
  - Serum sickness
  - Severe acute or chronic allergic or inflammatory processes involving the eye and its adnexa such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
    - Must be prescribed by an ophthalmologist
  - Symptomatic sarcoidosis
  - Nephrotic syndrome without uremia of the idiopathic type or lupus erythematosus
    - Must be used to induce a diuresis or remission of proteinuria; AND
    - Must be prescribed by a nephrologist; AND
    - Must be experiencing an acute exacerbation of nephrotic syndrome; AND
    - Must have a documented trial and failure of, intolerance to, or contraindication to treatment with a cytotoxic/immunosuppressive regimen (i.e. cyclophosphamide, cyclosporine, mycophenolate); OR
    - Must currently be using conventional symptomatic therapy regimen (diuretics, ACE inhibitors, Angiotensin Receptor Blockers (ARBs), albumin).

Dosing:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Maximum units (1 billable unit = 40 units)</th>
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<tbody>
<tr>
<td>Infantile Spasms</td>
<td>35 billable units every 28 days</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>63 billable units every 21 days</td>
</tr>
</tbody>
</table>

Coverage durations:

- Initial coverage: 3 weeks for MS and 1 month for all other indications

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***
Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0800</td>
<td>Injection, corticotropin, up to 40 units</td>
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References: