Custom Criteria for
BlueCross Blue Shield of Arizona Commercial

H.P. ACTHAR GEL® (repository corticotropin injection) PA

GPI CODING:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>GPI</th>
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<tr>
<td>H.P. Acthar Gel (repository corticotropin injection)</td>
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DESCRIPTION:

H.P. Acthar Gel is a preparation of the natural form of adrenocorticotropic 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. It is primarily used for treating infantile spasms (West syndrome) and has been investigated for diagnostic testing of adrenocortical function and for treating a variety of other conditions. H.P. Acthar Gel may also be referred to as repository corticotropin injection. The product label for H.P. Acthar gel lists a number of corticosteroid-responsive conditions as indications for repository corticotropin injection, including:

- Rheumatic disorders: Adjunctive therapy for individuals with acute episodes or exacerbations of psoriatic arthritis, rheumatoid arthritis (selected cases my require low-dose maintenance therapy) and ankylosing spondylitis
- Collagen diseases: Treatment of selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis)
- Dermatologic diseases: Treatment of severe erythema multiforme and Stevens-Johnson syndrome
- Allergic states: Treatment of serum sickness
- Ophthalmic diseases: Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as optic neuritis, and anterior segment inflammation
- Respiratory diseases: Treatment of symptomatic sarcoidosis
- Edematous state: Treatment of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or due to lupus erythematosus

APPROVAL DURATION:

Approval duration: 3 months

CRITERIA FOR H.P. ACTHAR GEL

FDA-approved dosage and duration of H.P. Acthar Gel (repository corticotropin injection) is considered **medically necessary** for the treatment of infantile spasms (West syndrome) in individuals less than 2 years of age.

FDA-approved dosage and duration of H.P. Acthar Gel is considered **medically necessary** for the treatment of corticosteroid-responsive conditions with documentation of ONE of the following:

1. Medical contraindications to corticosteroids that are not expected to occur with use of H.P. Acthar gel
2. Intolerance to corticosteroids that are not also expected to occur with use of H.P. Acthar gel

H.P. Acthar Gel for all other indications not previously listed or if above criteria not met is considered **experimental or investigational**.

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