

### Clinical Pharmacy Program Guidelines for Acthar Gel

Program	Prior Authorization
Medication	Acthar Gel (repository corticotropin injection)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2018
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

#### 1. Background:

Acthar Gel is an adrenocorticotrophic hormone (ACTH) analogue. Repository corticotropin injection and ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of repository corticotropin injection induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is influenced by the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated plasma cortisol suppresses ACTH release. Repository corticotropin injection also binds to melanocortin receptor. Both endogenous ACTH and repository corticotropin injection have a trophic effect on the adrenal cortex which is mediated by cyclic adenosine monophosphate (cyclic AMP).

**Acthar Gel is unproven and not medically necessary for treatment of the following disorders and diseases:**

1. Rheumatic Disorders: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis
2. Collagen Diseases: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
3. Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome
4. Allergic States: Serum sickness
5. 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, anterior segment inflammation
6. Respiratory Diseases: Symptomatic sarcoidosis
7. 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
8. Any indication outside of the proven indications above

## 2. Coverage Criteria:

**Acthar Gel (repository corticotropin injection) is proven and medically necessary for the treatment of:**

1. Infantile spasm (i.e., West Syndrome)<sup>1</sup> for up to 4 weeks when **all** of the following criteria are met:

a. Diagnosis of infantile spasms (i.e., West Syndrome);

**-AND-**

b. Patient is less than 2 years old;

**-AND-**

c. H.P. Acthar Gel dosing for infantile spasm is as follows:

(1) Initial dose: 75 U/m<sup>2</sup> intramuscular (IM) twice daily for 2 weeks

(2) After 2 weeks, dose should be tapered according to the following schedule: 30 U/m<sup>2</sup> IM in the morning for 3 days; 15 U/m<sup>2</sup> IM in the morning for 3 days; 10 U/m<sup>2</sup> IM in the morning for 3 days; and 10 U/m<sup>2</sup> IM every other morning for 6 days (3 doses);

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

**Acthar Gel is not medically necessary for treatment of acute exacerbations of multiple sclerosis.**

## 3. References:

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Program	Prior Authorization
<b>Change Control</b>	
Date	Change
9/2018	Updated template to align with other pharmacy programs.
5/2019	Annual review. No changes to criteria.
4/2020	Annual review. Removed “H.P.” to align with other programs. Updated references.