H.P. Acthar® Gel (Repository Corticotropin Injection)

Indication:

"H.P. Acthar Gel is an adrenocorticotropic hormone (ACTH) analogue indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.
H.P. Acthar Gel is indicated for the treatment of exacerbations of multiple sclerosis in adults.
H.P. Acthar Gel may be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state."[1]

Dosage Form/Strength:
Injection: 80 unit/mL

Criteria for Approval:

- Patient does not have any of the following contraindications to the use of H.P. Acthar:
  - Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine (pig) origin.

  AND
- Patient meets all of the criteria listed for his/her diagnosis in Table 1.

Table 1: Diagnoses and Approval Criteria for Each Diagnosis					
West Syndrome (infantile spasms)	Patient is <2 years old; **AND**	Clinic notes and a letter of medical necessity have been submitted including previous treatments.			
Multiple Sclerosis	Patient is ≥18 years of age; **AND**	Patient is currently using a medication labeled for the treatment of multiple sclerosis to slow disease progression and reduce the frequency of exacerbations (i.e. Avonex®, Copaxone®, Rebif®, or Tecfidera); **AND**	Patient is currently experiencing an acute exacerbation of multiple sclerosis; **AND**	Either the patient has tried and failed oral or parenteral corticosteroid therapy OR The patient has a documented contraindication or intolerance to prior corticosteroid therapy; **AND**	A letter of medical necessity and clinic notes have been submitted.
Ankylosing Spondylitis	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			
Optic Neuritis	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			
Polymyositis/ Systemic Dermatomyositis	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			
Proteinuria in Nephrotic Syndrome	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			
Psoriatic arthritis	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			
Rheumatoid Arthritis (RA)	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			
Symptomatic Sarcoidosis	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			

Table 1 (continued): Diagnoses and Approval Criteria for Each Diagnosis					
Systemic Lupus Erythematosus (SLE)	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			
Uveitis	Clinic notes must be submitted; **AND**	Letter of medical necessity must be submitted which documents prior medications tried			

Criteria for Reauthorization Approval:

- Patient meets all of the criteria for the initial authorization; **AND**,
- There is documented evidence of a positive clinical response to H.P. Acthar therapy; **AND**,
- Clinic notes must be submitted, detailing the patient's response to therapy.

Criteria for Denial:

- Patient has any of the following contraindications to use of H.P. Acthar:
  - Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin; **OR**,
- Patient does not have at least one of the following diagnoses:
  - Infantile Spasms (West Syndrome), an acute exacerbation of Multiple Sclerosis, Ankylosing Spondylitis, Optic Neuritis, Polymyositis/Systemic Dermatomyositis, Proteinuria in Nephrotic Syndrome, Psoriatic arthritis, Rheumatoid Arthritis (RA), Symptomatic Sarcoidosis, Systemic Lupus Erythematosus (SLE), or Uveitis; **OR**,
- Clinic notes and a letter of medical necessity have not been submitted; **OR**,
- For a diagnosis of Infantile Spasms (West Syndrome):
  - Patient is ≥2 years old; **OR**,

- For a diagnosis of multiple sclerosis:
    - Patient is not currently experiencing an acute exacerbation of multiple sclerosis
    - Patient is less than 18 years of age
    - Patient is not currently using a medication labeled for the treatment of multiple sclerosis to slow disease progression and reduce the frequency of exacerbations
    - Patient has not tried, or does not have a clinical reason not to try an oral or IV corticosteroid

Criteria for Reauthorization Denial:

- Patient does not meet all of the criteria for the initial authorization; **OR**,
- There is no documented evidence of a positive clinical response to Acthar therapy; **OR**,
- Clinic notes were not submitted which detail the patient's response to therapy.

Length of Authorization:

- Infantile Spasms:
    - Initial coverage may be approved for up to six months.
    - Subsequent re-authorizations may be issued for up to an additional 6 months.
- Acute Exacerbation of Multiple Sclerosis:
    - Coverage may be approved for up to 21 days.
- Ankylosing Spondylitis, Optic Neuritis, Polymyositis/Systemic Dermatomyositis, Proteinuria in Nephrotic Syndrome, Psoriatic arthritis, Rheumatoid Arthritis (RA), Symptomatic Sarcoidosis, Systemic Lupus Erythematosus (SLE), or Uveitis:
    - Initial coverage may be approved for up to six months, or at the clinical discretion of the reviewing pharmacist.
    - Subsequent re-authorizations may be issued for up to a year, or at the clinical discretion of the reviewing pharmacist.

Quantity Limit:

1. The dispensing limit is 80units/day (30 mL = 6 vials) per 30 days.

Mechanism of Action:

"The mechanism of action of H.P. Acthar Gel in the treatment of infantile spasms is unknown. H.P. Acthar Gel and endogenous ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of H.P. Acthar Gel induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is under the influence of the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated Plasma cortisol suppresses ACTH release. H.P. Acthar Gel is also reported to bind to melanocortin receptors. The trophic effects of endogenous ACTH and H.P. Acthar Gel on the adrenal cortex are not well understood beyond the fat that they appear to be mediated by cyclic AMP. ACTH rapidly disappears from the circulation following its intravenous

administration; in people, the plasma half-life is about 15 minutes. The pharmacokinetics of H.P. Acthar Gel have not been adequately characterized. The maximal effects of a trophic hormone on a target organ are achieved when optimal amounts of hormone are acting continuously. Thus, a fixed dose of H.P. Acthar Gel will demonstrate a linear increase in adrenocortical secretion with increasing duration for the infusion." [1]

References / Footnotes:

[1] H.P. Acthar® Gel Prescribing Information. Mallinckrodt Pharmaceutical, Hazelwood, MO. Revised 1/2015. < http://www.acthar.com/pdf/Acthar-PI.pdf> Accessed 3/11/2016.