

ALASKA MEDICAID
Prior Authorization Criteria

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

Approved Indications:¹

- H.P. Acthar Gel is an adrenocorticotrophic 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.

Grandfathered indications with limited safety and efficacy data:¹

- H.P. Acthar Gel may be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.

Dosage Form/Strength:

Injection: 80 unit/mL

Criteria for Approval:^{1,2,3,4,5,6}

- 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 and has a diagnosis listed in Table 1 or Table 2. (Table 2 diagnosis will require a second level review for appropriateness and strength of clinical evidence.)

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Table 1: Diagnoses and Approval Criteria for FDA Indicated 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.
Table 2: Diagnosis and Consideration Criteria For Grandfathered Indications					
Ankylosing Spondylitis	Clinic notes must be submitted; AND	Letter of medical necessity must be submitted which documents prior medications tried and at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication			
Optic Neuritis	Clinic notes must be submitted; AND	Must have had an adequate trial with two corticosteroids AND Must be prescribed by an ophthalmologist AND	Letter of medical necessity must be submitted which documents prior medications tried and at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication		

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<p>Polymyositis/ Systemic Dermatomyositis</p>	<p>Clinic notes must be submitted; AND</p>	<p>Must have had an adequate trial with an immunosuppressant and a corticosteroid AND May be used during an acute exacerbation AND Must be prescribed by a dermatologist or rheumatologist AND</p>	<p>Letter of medical necessity must be submitted which documents prior medications tried and at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication</p>		
<p>Proteinuria in Nephrotic Syndrome</p>	<p>Clinic notes must be submitted; AND</p>	<p>Being used to induce diuresis or remission of proteinuria OR Being treated for an acute exacerbation AND Must be currently taking symptomatic therapy (i.e. diuretics, ACE, ARB) AND</p>	<p>Letter of medical necessity must be submitted which documents prior medications tried and at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication</p>		
<p>Psoriatic arthritis</p>	<p>Clinic notes must be submitted; AND</p>	<p>Must have had an adequate trial with two corticosteroids AND Must be on maintenance therapy for the condition (i.e. TNF blocker, DMARD, Biologic agent) AND Being used as an adjunct for short term use to cover an acute exacerbation AND Must be prescribed by a rheumatologist or dermatologist AND</p>	<p>Letter of medical necessity must be submitted which documents prior medications tried and at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication</p>		

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Rheumatoid Arthritis (RA)	Clinic notes must be submitted; AND	Must have had an adequate trial with two corticosteroids and two NSAIDS AND Must be on maintenance therapy for the condition (i.e. TNF blocker, DMARD, Biologic agent) AND Being used as an adjunct for short term use to cover an acute exacerbation AND Must be prescribed by a rheumatologist	Letter of medical necessity must be submitted which documents prior medications tried and at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication		
Symptomatic Sarcoidosis	Clinic notes must be submitted; AND	Letter of medical necessity must be submitted which documents prior medications tried and at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication			
Systemic Lupus Erythematosus (SLE)	Clinic notes must be submitted; AND	Must have had an adequate trial with two corticosteroids and one NSAID AND Must be on maintenance therapy for the condition (i.e. immunosuppressant, Biologic agent) AND Being used as an adjunct for short term use to cover an acute exacerbation	Letter of medical necessity must be submitted which documents prior medications tried and at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication		

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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 or develops 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, or Systemic Lupus Erythematosus (SLE); **OR**,
- Clinic notes and a letter of medical necessity have not been submitted; **OR**,
- For Table 2 diagnosis at least one peer-reviewed clinical study that the patient would fit criteria for inclusion to support requested indication must be 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:
 - Coverage may be approved for up to 4 weeks.
- Acute Exacerbation of Multiple Sclerosis:
 - Coverage may be approved for up to 21 days.

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- Ankylosing Spondylitis, Optic Neuritis, Polymyositis/Systemic Dermatomyositis, Proteinuria in Nephrotic Syndrome, Psoriatic Arthritis, Rheumatoid Arthritis (RA), Symptomatic Sarcoidosis, or Systemic Lupus Erythematosus (SLE):
 - Coverage may be approved for up to 4 weeks.

Quantity Limit:

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

Mechanism of Action:¹

“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 fact 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.”

References / Footnotes:

- ¹H.P. Acthar® Gel Prescribing Information. Mallinckrodt Pharmaceutical, Bedminster, NJ. Revised 04/2018. < <http://www.acthar.com/pdf/Acthar-PI.pdf> > Accessed 08/17/2018.
- ²Bomback AS, Tumlin JA, Baranski J, Bourdeau, et al. Treatment of nephrotic syndrome with adrenocorticotrophic hormone (ACTH) gel. *Drug Des Devel Ther.* 2011;5:147-153.
- ³M. T. Mackay, S. K. Weiss, T. Adams-Webber, et al. Practice parameter: medical treatment of infantile spasms: report of the American Academy of Neurology and the Child Neurology Society. *Neurology* 2004;62;1668-81.
- ⁴National Clinical Guideline Centre. Multiple sclerosis: management of multiple sclerosis in primary and secondary care. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Oct. 36 p. (Clinical guideline; no. 186).
- ⁵M. T. Mackay, S. K. Weiss, T. Adams-Webber, et al. Practice parameter: medical treatment of infantile spasms: report of the American Academy of Neurology and the Child Neurology Society. *Neurology* 2004;62;1668-81.
- ⁶Simsarian JP, Saunders C and Smith DM. Five-day regimen of intramuscular or subcutaneous self-administered adrenocorticotrophic hormone gel for acute exacerbations of multiple sclerosis: a prospective, randomized, open-label pilot trial. *Drug Des Devel Ther.* 2011;5:381-9.