



Department:	Pharmacy	Original Approval:	07/31/2018
Policy #:	PM154	Last Approval:	08/27/2018
Title:	Corticotropin (H.P. Acthar Gel)		
Approved By:	UM Committee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Corticotropin (Acthar): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: Diagnosis-Age-Medication list (current and past)- Labs/Diagnostics.

BACKGROUND

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 may be used for the following disorders and diseases: exacerbations of multiple sclerosis in adults rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.¹

DEFINITIONS

None

INDICATIONS/CRITERIA

Medicaid Members	<i>Continue to criteria for approval below.</i>
Medicare Members	<i>Step-utilization of Part D drugs not required.</i>

Coverage of HP Acthar gel is recommended in those who meet one of the following criteria:

FDA- Approved Indications

1. Infantile spasms (West syndrome)

Criteria. Patient must meet the following criteria (A, B, C, D, and E).

- A. Less than 2 years of age
- B. Diagnosed with infantile spasms confirmed by EEG
- C. Will be used as monotherapy
- D. Documentation that patient does not have a suspected congenital infection

- E. Prescribed by or in consultation with a pediatric neurologist

Dosing in the treatment of infantile spasms: The recommended dose is 150 U/m² divided into twice daily intramuscular injections of 75 U/m². After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period.¹

Initial Approval/Extended Approval

A) *Initial Approval*. Initial approval is for 4 weeks

B) *Extended Approval*. Reauthorization of 4 weeks for continuation of therapy when the prior treatment has shown substantial clinical benefit from therapy.

Duration of Therapy in the Treatment of infantile spasms: 30 days

Labs/Diagnostics- none

Waste Management for All Indications:

HP Acthar is available in a 5ml multi-dose vial containing 80 USP units per ml. Two to four vials are usually needed for a 4 week supply.

Conditions Not Recommended for Approval

The use of H.P. Acthar for the treatment of all other indications listed in the FDA product labeling has not been proven to be superior to conventional therapies (e.g., corticosteroids, immunosuppressive agents) and has a significantly higher cost than the standard of care agents. Use of H. P. Acthar for these conditions is considered not medically necessary and is not a covered benefit.

- A. Exacerbations of multiple sclerosis in adults
- B. Rheumatic Disorders: as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis
- C. Collagen Diseases: during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- D. Dermatologic Diseases: severe erythema multiforme, Stevens-Johnson syndrome
- E. Allergic States: serum sickness
- F. 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

- G. Respiratory Diseases: symptomatic sarcoidosis
- H. 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

SPECIAL CONSIDERATIONS

- Must be administered by intramuscular (IM) or subcutaneous (SQ) injection
- Cannot be administered in infants with suspected congenital infections or to patients with 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.
- Cannot be administered with live or live attenuated vaccines

LIMITATIONS/EXCLUSIONS

Please refer to a product line’s certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References	
	<ol style="list-style-type: none"> 1. H.P. Acthar Injection Gel [prescribing information]. Bedminster, NJ: Mallinckrodt Pharmaceuticals; 4/2018 2. Go, C.Y., Mackay, M.T., Weiss, S.K. et al. Evidence-based guideline update: Medical treatment of infantile spasms: Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. <i>Neurology</i> 2012;78;1974-1980. 3. Hussain SA, Shinnar S, Kwong G, et al. Treatment of infantile spasms with very high dose prednisolone before

	<p>high dose adrenocorticotrophic hormone. <i>Epilepsia</i>. 2014 Jan;55(1):103- 7. doi: 10.1111/epi.12460. Epub 2013 Nov 8.</p> <p>4. Hrachovy RA, Frost JD, Glaze DG et al. High-dose, long-duration versus low-dose, short duration corticotropin therapy for infantile spasms. <i>J Pediatr</i> 1994;124:803-806.</p> <p>5. Kivity S, Lerman P, Ariel R, et al. Long-term cognitive outcomes of a cohort of children with cryptogenic infantile spasms treated with high-dose adrenocorticotrophic hormone. <i>Epilepsia</i>. 2004 Mar;45(3):255-62.</p> <p>6. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a U.S. consensus report. <i>Epilepsia</i>. 2010 Oct;51(10):2175-89.</p> <p>7. M. 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. <i>Neurology</i> 2004;62;1668-81.</p>
CFR	
WAC	WAC 284-43-2050
RCW	
Contract Citation	<input checked="" type="checkbox"/> WAH
	<input checked="" type="checkbox"/> IMC
	<input checked="" type="checkbox"/> MA
Other Requirements	
NCQA Elements	

Revision History

Revision Date	Revision Description	Revision Made By
07/31/2018	New policy	Jennifer Farley, PharmD
08/27/2018	Approval	UM Committee