

Acthar HP® (corticotropin, ACTH) (Intramuscular/Subcutaneous)

Policy Number: PS509POLmrX

Effective Date: 01/01/2016

Review Date:

I. Initial Approval Criteria

Infantile spasms (West Syndrome)†

- Patient age less than 2; AND
- Clinical Documentation indicating patient suffers from infantile spasms (West Syndrome); AND
- Must be used as monotherapy; AND
- Documentation that patient does not have a suspected congenital infection

†FDA Approved Indication(s)

II. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria in section III; AND
- Disease response with treatment as indicated by resolution of symptoms and/or normalization of laboratory tests; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: GI bleeding; gastric ulcer; hypertension; hypokalemia; severe depression; frank psychotic manifestations; posterior subcapsular cataracts; glaucoma

Length of Authorization

Coverage will be provided for 1 month and may be renewed

III. Dosage/Administration

Indication	Dose
Infantile Spasms	75 units/m ² /dose given twice daily for 2 weeks, then taper the over a 2 week period

IV. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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- Acthar H.P Gel 80 units/ml : 7 vials per 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

Infantile Spasms

Male 63 billable units every 28 days

Female 63 billable units every 28 days

V. Billing Code/Availability Information

Jcode:

J0800 – Acthar H.P. Gel (Questcor Pharmaceuticals) 80 units injection: up to 40 units = 1 billable unit

NDC:

Acthar H.P Gel 80 units/ml injection: 63004-8710-xx (Mallinckrodt Pharmaceuticals)

VI. References

1. Acthar HP [package insert]. Hazelwood, MO; Mallinckrodt Pharmaceuticals Inc; January 2015. Accessed August 2015.
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. *Neurology* 2012;78;1974-1980.
3. Goodin DS, Frohman EM, Garmany GP Jr, Halper J, Likosky WH, Lublin FD, Silberberg DH, Stuart WH, van den Noort S. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology* 2002 Jan 22;58(2):169-78.
4. Hussain SA, Shinnar S, Kwong G, et al. Treatment of infantile spasms with very high dose prednisolone before high dose adrenocorticotrophic hormone. *Epilepsia*. 2014 Jan;55(1):103-7. doi: 10.1111/epi.12460. Epub 2013 Nov 8.
5. Hrachovy RA, Frost JD, Glaze DG et al. High-dose, long-duration versus low-dose, short duration corticotropin therapy for infantile spasms. *J Pediatr* 1994;124:803-806.
6. 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. *Epilepsia*. 2004 Mar;45(3):255-62.
7. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a U.S. consensus report. *Epilepsia*. 2010 Oct;51(10):2175-89.

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8. Filippini G, Brusafferri F, Sibley WA, Citterio A, Ciucci G, Midgard R, Candelise L. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database of Systematic Reviews 2000, Issue 4. Art. No.: CD001331. DOI: 10.1002/14651858.CD001331. Last updated April 20, 2013.
9. 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. Neurology 2004;62:1668-81.
10. First Coast Service Options, Inc. Local Coverage Determination (LCD): Corticotropin (L29125; L29143). Centers for Medicare & Medicaid Services, Inc. Updated on 07/01/2014 with effective date 10/01/2011. Accessed August 2015.
11. First Coast Service Options, Inc. Local Coverage Determination (LCD): Corticotropin (L33811). Centers for Medicare & Medicaid Services, Inc. Updated on 07/01/2014 with effective date 10/01/2015. Accessed August 2015.

Appendix 1 – Covered Diagnosis Codes

ICD-9 Codes	Diagnosis
345.60	Infantile spasms, without mention of intractable epilepsy
345.61	Infantile spasms, with intractable epilepsy

ICD-10	ICD-10 Description
G40.821	Epileptic spasms, not intractable, with status epilepticus
G40.822	Epileptic spasms, not intractable, without status epilepticus
G40.823	Epileptic spasms, intractable, with status epilepticus
G40.824	Epileptic spasms, intractable, without status epilepticus

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicarecoverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 9 (N)	NCD/LCD Document (s): L29125; L29143
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ICD-9 Codes	Diagnosis
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135	SARCOIDOSIS
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ICD-9 Codes	Diagnosis
274.00 - 274.03	GOUTY ARTHROPATHY, UNSPECIFIED - CHRONIC GOUTY ARTHROPATHY WITH TOPHUS (TOPHI)
283.0	AUTOIMMUNE HEMOLYTIC ANEMIAS
284.01 - 284.09	CONSTITUTIONAL RED BLOOD CELL APLASIA - OTHER CONSTITUTIONAL APLASTIC ANEMIA
285.9	ANEMIA UNSPECIFIED
287.41 - 287.49	POSTTRANSFUSION PURPURA - OTHER SECONDARY THROMBOCYTOPENIA
363.20 - 363.22	CHORIORETINITIS UNSPECIFIED - HARADA'S DISEASE
372.00 - 372.06	ACUTE CONJUNCTIVITIS UNSPECIFIED - ACUTE CHEMICAL CONJUNCTIVITIS
373.00 - 373.02	BLEPHARITIS UNSPECIFIED - SQUAMOUS BLEPHARITIS
377.30	OPTIC NEURITIS UNSPECIFIED
391.9	ACUTE RHEUMATIC HEART DISEASE UNSPECIFIED
477.0 - 477.9	ALLERGIC RHINITIS DUE TO POLLEN - ALLERGIC RHINITIS CAUSE UNSPECIFIED
493.00 - 493.92	EXTRINSIC ASTHMA UNSPECIFIED - ASTHMA UNSPECIFIED WITH (ACUTE) EXACERBATION
503	PNEUMOCONIOSIS DUE TO OTHER INORGANIC DUST
507.0 - 507.8	PNEUMONITIS DUE TO INHALATION OF FOOD OR VOMITUS - PNEUMONITIS DUE TO OTHER SOLIDS AND LIQUIDS
555.0 - 555.9	REGIONAL ENTERITIS OF SMALL INTESTINE - REGIONAL ENTERITIS OF UNSPECIFIED SITE
556.0 - 556.9	ULCERATIVE (CHRONIC) ENTEROCOLITIS - ULCERATIVE COLITIS UNSPECIFIED
690.10 - 690.18	SEBORRHEIC DERMATITIS UNSPECIFIED - OTHER SEBORRHEIC DERMATITIS
692.0	CONTACT DERMATITIS AND OTHER ECZEMA DUE TO DETERGENTS

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692.1	CONTACT DERMATITIS AND OTHER ECZEMA DUE TO OILS AND GREASES
692.2	CONTACT DERMATITIS AND OTHER ECZEMA DUE TO SOLVENTS
692.3	CONTACT DERMATITIS AND OTHER ECZEMA DUE TO DRUGS AND MEDICINES IN CONTACT WITH SKIN
692.4	CONTACT DERMATITIS AND OTHER ECZEMA DUE TO OTHER CHEMICAL PRODUCTS
692.5	CONTACT DERMATITIS AND OTHER ECZEMA DUE TO FOOD IN CONTACT WITH SKIN
692.6	CONTACT DERMATITIS AND OTHER ECZEMA DUE TO PLANTS

ICD-9 Codes	Diagnosis
	(EXCEPT FOOD)
710.0	SYSTEMIC LUPUS ERYTHEMATOSUS
710.4	POLYMYOSITIS
999.51 - 999.59	OTHER SERUM REACTION DUE TO ADMINISTRATION OF BLOOD AND BLOOD PRODUCTS - OTHER SERUM REACTION
V71.89	OBSERVATION FOR OTHER SPECIFIED SUSPECTED CONDITIONS

Jurisdiction(s): 9 (N)	NCD/LCD Document (s): L33811
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ICD-10 Codes	Diagnosis
D61.01 - D61.09	Constitutional (pure) red blood cell aplasia - Other constitutional aplastic anemia
D64.9	Anemia, unspecified
D69.51 - D69.59	Posttransfusion purpura - Other secondary thrombocytopenia
D86.0 - D86.9	Sarcoidosis of lung - Sarcoidosis, unspecified
H01.001 - H01.029	Unspecified blepharitis right upper eyelid - Squamous blepharitis unspecified eye, unspecified eyelid
H30.001 - H30.049	Unspecified focal chorioretinal inflammation, right eye - Focal chorioretinal inflammation, macular or paramacular, unspecified eye
H30.20 - H30.93	Posterior cyclitis, unspecified eye - Unspecified chorioretinal inflammation, bilateral
H46.9	Unspecified optic neuritis
I01.9	Acute rheumatic heart disease, unspecified
J30.0 - J30.9	Vasomotor rhinitis - Allergic rhinitis, unspecified
J44.0 - J45.998	Chronic obstructive pulmonary disease with acute lower respiratory infection - Other asthma
J63.0 - J63.6	Aluminosis (of lung) - Pneumoconiosis due to other specified inorganic dusts
J69.0 - J69.8	Pneumonitis due to inhalation of food and vomit - Pneumonitis due to inhalation of other solids and liquids
K50.00 - K50.919	Crohn's disease of small intestine without complications - Crohn's disease, unspecified, with unspecified complications

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K51.00 - K51.919	Ulcerative (chronic) pancolitis without complications - Ulcerative colitis, unspecified with unspecified complications
L20.83	Infantile (acute) (chronic) eczema
L21.0 - L21.9	Seborrhea capitis - Seborrheic dermatitis, unspecified
L23.1	Allergic contact dermatitis due to adhesives
L23.3	Allergic contact dermatitis due to drugs in contact with skin
L23.6	Allergic contact dermatitis due to food in contact with the skin
L23.7	Allergic contact dermatitis due to plants, except food
L24.0	Irritant contact dermatitis due to detergents
L24.1	Irritant contact dermatitis due to oils and greases
L24.2	Irritant contact dermatitis due to solvents
L24.4	Irritant contact dermatitis due to drugs in contact with skin
L24.5	Irritant contact dermatitis due to other chemical products
L24.6	Irritant contact dermatitis due to food in contact with skin
L24.7	Irritant contact dermatitis due to plants, except food
L25.1	Unspecified contact dermatitis due to drugs in contact with skin
L25.3	Unspecified contact dermatitis due to other chemical products
L25.4	Unspecified contact dermatitis due to food in contact with skin
L25.5	Unspecified contact dermatitis due to plants, except food
M02.211 - M02.29	Postimmunization arthropathy, right shoulder - Postimmunization arthropathy, multiple sites
M1A.00X0 - M1A.09X1	Idiopathic chronic gout, unspecified site, without tophus (tophi) - Idiopathic chronic gout, multiple sites, with tophus (tophi)
M1A.20X0 - M1A.9XX1	Drug-induced chronic gout, unspecified site, without tophus (tophi) - Chronic gout, unspecified, with tophus (tophi)
M10.00 - M10.29	Idiopathic gout, unspecified site - Drug-induced gout, multiple sites
M32.0 - M32.9	Drug-induced systemic lupus erythematosus - Systemic lupus erythematosus, unspecified
M33.20 - M33.29	Polymyositis, organ involvement unspecified - Polymyositis with other organ involvement
T80.61XA - T80.69XS	Other serum reaction due to administration of blood and blood products, initial encounter - Other serum reaction due to other serum, sequela
Z03.6	Encounter for observation for suspected toxic effect from ingested substance

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	ruled out
Z03.89	Encounter for observation for other suspected diseases and conditions ruled out Bottom of Form

Medicare Part B Administrative Contractor (MAC) Jurisdictions

E	CA, HI, AS, GU, CNMI	Noridian Administrative Services (NAS)
F	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Administrative Services (NAS)
5	KS, NE, IA, MO	Wisconsin Physicians Service (WPS)
6	MN, WI, IL	National Government Services (NGS)
H	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions
8	MI, IN	Wisconsin Physicians Service (WPS)
9 (N)	FL, PR, VI	First Coast Service Options
10 (J)	TN, GA, AL	Cahaba Government Benefit Administrators
11 (M)	NC, SC, VA, WV	Palmetto GBA
12 (L)	DE, MD, PA, NJ, DC	Novitas Solutions
K	NY, CT, MA, RI, VT, ME, NH	National Government Services (NGS)
15	KY, OH	CGS Administrators, LLC