

H.P. Acthar® Gel (repository corticotropin injection, ACTH) (Intramuscular)

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I. Length of Authorization

- Infantile spasms: coverage will be provided for 1 month and may be renewed
- Acute MS Exacerbations: coverage will be provided for 21 days and may NOT be renewed

II. Dosing Limits

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

- H.P. Acthar Gel 80 units/mL injection (5 mL multi-dose vial): 4 vials per 28 days

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

- **Infantile Spasms**
 - 35 billable units every 28 days
- **Multiple Sclerosis**
 - 63 billable units every 21 days

III. Initial Approval Criteria

Infantile spasms (West Syndrome) †

- Patient is under 2 years of age; **AND**
- Clinical documentation indicating patient has a diagnosis of infantile spasms (West Syndrome); **AND**
- Must be used as monotherapy; **AND**
- Documentation that patient does not have a suspected congenital infection

Multiple Sclerosis †

- Patient age is least 18; **AND**
- Patient is undergoing an acute, severe debilitating exacerbation of MS; **AND**

- Patient is allergic to and/or has tried and failed to respond to high dose IV corticosteroids or high dose IV corticosteroids are not appropriate due to documented patient poor venous access

† FDA Approved Indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified 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: severe infections, severe electrolyte imbalances, gastric bleeding or ulcer, hypertension, hypokalemia, severe depression, frank psychotic manifestations, posterior subcapsular cataracts, glaucoma, etc.

V. Dosage/Administration

Indication	Dose
Infantile Spasms	75 units/m ² intramuscularly given twice daily for 2 weeks, then taper the dose over a 2 week period (e.g., 30 units/m ² in the morning for 3 days; 15 units/m ² in the morning for 3 days; 10 units/m ² in the morning for 3 days; and 10 units/m ² every other morning for 6 days).
Multiple Sclerosis	80 to 120 units IM per day in divided doses for 2 to 3 weeks

VI. Billing Code/Availability Information

Jcode:

J0800 – Injection, corticotropin, up to 40 units; up to 40 units = 1 billable unit

NDC:

H.P. Acthar Gel 80 units/mL (5 mL multi-dose vial): 63004-8710-xx

VII. References

1. H.P. Acthar Gel [package insert]. Hazelwood, MO; Mallinckrodt Pharmaceuticals Inc; July 2017. Accessed January 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. Neurology 2012;78;1974-1980.

3. 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.
4. 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.
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. *Epilepsia*. 2004 Mar;45(3):255-62.
6. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a U.S. consensus report. *Epilepsia*. 2010 Oct;51(10):2175-89.
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. *Neurology* 2004;62:1668-81.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G35	Multiple Sclerosis
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/medicare-coverage-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):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC