Medical Policy:

H.P. Acthar® Gel (repository corticotropin) injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.09	April 2, 2025	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Repository corticotropin (H.P. Acthar® Gel) is an analogue of adrenocorticotropic hormone (ACTH) analogue indicated as monotherapy for the treatment of infantile spasms (West Syndrome) in infants and children less than 2 years of age. Additionally, for the treatment of exacerbations of multiple sclerosis in adults. Acthar is supplied as a 5 mL multi-dose vial containing 80 USP units per mL. H.P. Acthar Gel (repository corticotropin injection).

Guideline

I. Initial Approval Criteria

A. H.P. Acthar Gel is considered medically necessary for West syndrome (infantile spasms); **OR**

B. H.P. Acthar Gel is considered medically necessary when **all** of the following criteria are met:

i. Member is an adult (≥ 18 years of age) with a corticosteroid-responsive condition (including but not limited to acute exacerbations of multiple sclerosis); **AND**

ii. Member has no contraindications to (or is not limited by) a contraindication to, or intolerance of, glucocorticoid effects; **AND**

iii. There is clear documentation of why all other well-established routes for corticosteroid therapy (for example, oral prednisone and intravenous methylprednisolone) cannot be used.

Limitations/Exclusions

Acthar is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

Code	Description
J0801	Injection, corticotropin (acthar gel), up to 40 units
J0802	Injection, corticotropin (ani), up to 40 units

Applicable NDCs

Code	Description
63004-8710-XX	Acthar 80 unit/mL
63004-8711-XX	Acthar Gel 80 unit/mL
63004-8712-XX	Acthar Gel 40 unit/mL
62559-0860-XX	cortrophin 80 unit/mL

ICD-10 Diagnoses

Code	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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	05/02/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	2/28/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	9/11/2023	Added J code: J0801 Injection, corticotropin (acthar gel), up to 40 units and J code J0802 Injection, corticotropin (ani), up to 40 units
EmblemHealth & ConnectiCare	6/28/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	6/17/20022	Transferred policy to new template

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EmblemHealth & ConnectiCare	10/30/2019	Updated under the definition to include treatment of exacerbations of multiple sclerosis in adults.
EmblemHealth & ConnectiCare	8/12/2016	Added coverage for corticosteroid-responsive conditions
EmblemHealth & ConnectiCare	10/9/2015	Restricted coverage to infantile spasms as sole medically necessary indication
EmblemHealth & ConnectiCare	9/11/2015	Removed proteinuria secondary to nephrotic syndrome as a covered indication

References

1. H.P. Acthar® Gel [Product Information], Hazelwood, MO. Mallinckrodt Pharmaceuticals, Inc.; March 2019. http://www.acthar.com/pdf/Acthar-PI.pdf. Accessed October 30, 2019.
2. Mackay MT, Weiss SK, Adams-Webber T, et al. American Academy of Neurology; Child Neurology Society. Practice parameter: medical treatment of infantile spasms: report of the American Academy of Neurology and the Child Neurology Society. Neurology. 2004; 62 (10):1668-1681. http://www.neurology.org/content/62/10/1668.full.pdf. Accessed August 15, 2017.
3. Questcor Pharmaceuticals Inc. H.P. Acthar Gel (repository corticotropin injection) package insert. Union City, CA: Questcor Pharmaceuticals Inc. Oct 2010.
4. Jia F, Jiang H, Du L, et al. An effective initial polytherapy for children with West Syndrome. Neural *Regen Res.* Jun 15, 2013; 8(17):1623-1630. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4145964/. Accessed August 15, 2017.
5. Hamano S, Tanaka M, Mochizuki M, et al. Long-term follow-up study of West syndrome: Differences of outcome among symptomatic etiologies. J Pediatr. 2003; 143(2):231-235.
6. Specialty-matched clinical peer review.

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