BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Acthar H.P. Gel

Policy Number: 9.112
Version Number: 2.0
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth- MCO ☐ MassHealth- ACO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Acthar H.P. Gel (corticotropin repository injection)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications unless otherwise excluded
Exclusion Criteria	Acthar will not be approved for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.
Required Medical Information	Documentation of the following: 1. A diagnosis of infantile spasms (West Syndrome); OR 2. A diagnosis of acute exacerbation of Multiple Sclerosis;AND i. Patient has a history of failure, contraindication, or intolerance to high-dose

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	corticosteroids for treatment of acute multiple sclerosis exacerbation(s).
Age Restrictions	2 years of age or under for infantile spasms 18 years or older for acute exacerbation of multiple sclerosis
Prescriber Restriction	For acute exacerbation of multiple sclerosis: Prescribed by or in consultation with a neurologist.
Coverage Duration	Infantile Spasms: 6 months Acute exacerbation of multiple sclerosis: 1 month
Other criteria	None

Applicable Coding:

Code	Medication
J0800	**Acthar HP Gel**

Clinical Background Information and References

1. Nieman LK. Evaluation of the response of ACTH in adrenal insufficiency. UptoDate®. Last updated October 29, 2014, accessed June 1, 2015. Available from: http://www.uptodate.com.
2. Glaze DG. Management and prognosis of infantile spasms. UptoDate®. Last updated February 3, 2015, accessed June 1, 2015. Available from: http://www.uptodate.com.
3. Mackay MT, Weiss SK, Adams-Webber T, 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.
4. H.P. Acthar Gel (repository corticotrophin injection) [package insert]. Hayward (CA): Questcor Pharmaceuticals, Inc. Revised January 2015.
5. Michael J Olek, DOJonathan Howard, MD. Treatment of acute exacerbations of multiple sclerosis in adults. UptoDate®. Last updated August 8, 2016, accessed June 11, 2017. Available from: http://www.uptodate.com.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.166 Acthar H.P. Gel Policy retired, new policy created; for the diagnosis of acute exacerbation of multiple sclerosis- added age restriction and provider restriction and updated approval duration to 1 month; for the diagnosis of infantile spasms- updated approval duration	1/1/2021	P&T Committee
8/12/2021	P&T Annual review: No changes	1/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date

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of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.