Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/13/2025

H.P. Acthar® Gel (repository corticotropin)

HCPCS: J0801

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Diagnosis of West Syndrome (infantile spasms) in infants and children under 2 years of age
   b. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: 4 vials per 30 days
   b. Authorization Period: 60 days
   c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Repository corticotropin injection is adrenocorticotropic hormone (ACTH) from a bovine or porcine source which stimulates the adrenal cortex to produce cortisol, corticosterone, and a number of other hormones. Repository corticotropin was first approved for sale in the United States in 1952. It has been used in a number of different indications, however commercial availability of corticosteroids (e.g. hydrocortisone, prednisone, methylprednisolone), all available as much lower-cost generics have come into favor.

- H.P. Acthar is indicated for a variety of inflammatory conditions including:

    - Infantile spasms: Repository corticotropin injection is indicated as monotherapy for the treatment of infantile spasms in patients under 2 years of age.

- Multiple Sclerosis: Repository corticotropin injection is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown repository corticotropin to be effective in speeding the resolution of acute exacerbations of multiple sclerosis.

    - However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

- 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 (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis.

- Collagen Diseases: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

- Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome.

- Allergic States: Serum sickness.

- 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.

- Respiratory Diseases: Symptomatic sarcoidosis.

- 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.

- The intent of this policy is to cover repository corticotropin for infantile spasms, which in 2010 has shown sufficient evidence of effectiveness, based on cessation of spasms, and amelioration of electroencephalogram (EEG); however, it is not efficacious in the prevention of other seizure types, improvement of long term developmental outcomes, or any other outcomes. Additional indications are grandfathered given trials establishing efficacy were not required when originally approved.

- The 2010 U.S. consensus report on infantile spasms recommends initiating a taper of ACTH after two weeks of therapy at the maximum dose. Relapses are not uncommon in those who respond to initial therapy and in one study 5 of 24 patients relapsed within 12-33 months. A second course of the therapy can be administered.

- According to Micromedex, “In much of the literature, it is unclear whether natural ACTH or cosyntropin was administered for a large variety of indications

    - Diagnosis of corticotropin insufficiency, acute gout, Guillain-Barre' syndrome, control of infantile spasms, and childhood seizures, Bell's palsy, multiple sclerosis, rheumatic diseases, vitiligo, myasthenia gravis, herpes zoster, asthma and status asthmaticus, ulcerative colitis, diagnosis of Sheehan's syndrome, adjunct to smoking cessation, schizophrenia, hay fever, myoclonic encephalopathy, acute inflammatory polyneuropathy, and prevention of peripheral neuropathy, nausea, and vomiting during cisplatin chemotherapy

- There is insufficient evidence to establish efficacy for the additional indications and there is no evidence of superiority compared to cost effective alternatives (i.e. generic corticosteroids). A literature search did not identify published articles that evaluated the use of ACTH gel compared to use of corticosteroids in corticosteroid-responsive conditions. Use of ACTH gel has the potential to cause more adverse effects. Thus, given this lack of comparative data and the statement in the product information-labeling, the clinical need (and clinical impact) to use ACTH gel for

steroid-responsive conditions has not been demonstrated. Thus, use of ACTH gel in this clinical situation is not covered.

References:

1. 2011 RegenceRx- Therapeutic Class ReviewSM- Anticonvulsants: Focus on ezogabine (Potiga™) and corticotrophin gel (H.P. Acthar®).
2. Micromedex Healthcare Series [internet database]. Updated periodically. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. May 2011.
3. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. Cochrane Database Syst Rev. 2008(4):CD001770.
4. Hrachovy RA, Frost JD, Jr., Glaze DG. High-dose, long-duration versus low-dose, short-duration corticotropin therapy for infantile spasms. J Pediatr. 1994 May;124(5 Pt 1):803-6.
5. Hrachovy RA, Frost JD, Jr., Kellaway P, Zion TE. Double-blind study of ACTH vs prednisone therapy in infantile spasms. J Pediatr. 1983 Oct;103(4):641-5.
6. Baram TZ, Mitchell WG, Tournay A, Snead OC, Hanson RA, Horton EJ. High-dose corticotropin (ACTH) versus prednisone for infantile spasms: a prospective, randomized, blinded study. Pediatrics. 1996 Mar;97(3):375-9.
7. 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 May 25;62(10):1668-81.
8. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a U.S. consensus report. Epilepsia. Oct;51(10):2175-89.
9. H.P. Acthar Gel (repository corticotropin injection) [prescribing information]. Hazelwood, MO: Mallinckrodt; October 2021.
10. Glaze DG. Management and prognosis of infantile spasms. UpToDate. https://www.uptodate.com/contents/management-and-prognosis-of-infantile-spasms [accessed June 9th, 2020].

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.4</td><td>Effective Date: 02/13/2025</td><td>Annual review of medical policy. No changes to the criteria were made at this time</td></tr>
<tr><td>2.3</td><td>Effective Date: 02/08/2024</td><td>Annual review of medical policy. No changes to the criteria were made at this time</td></tr>
<tr><td>2.2</td><td>Effective Date: 04/06/2023</td><td>Updated the approval duration to allow for 60 day requirement</td></tr>
<tr><td>2.1</td><td>Effective Date: 08/04/2022</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.0</td><td>Effective Date: 08/12/2021</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.9</td><td>Effective Date: 08/13/2020</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.8</td><td>Effective Date: 08/15/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.7</td><td>Effective Date: 08/09/2018</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.6</td><td>Effective Date: 08/10/2017</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.5</td><td>Effective Date: 08/11/2016</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.4</td><td>Effective Date: 01/22/2013</td><td>UM medical management system update for BCBS and BCN
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<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
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<tr><td>1.3</td><td>Effective Date: 12/17/2012</td><td>Criteria Updates</td></tr>
<tr><td>1.2</td><td>Effective Date: 08/09/2012</td><td>Criteria Updates</td></tr>
<tr><td>1.1</td><td>Effective Date: 09/01/2009</td><td>Criteria Updates</td></tr>
<tr><td>1.0</td><td>Effective Date: 01/29/2009</td><td>New Criteria
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<tr><td>BCBS</td><td>No</td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form

Blue Cross Blue Shield Blue Care Network of Michigan

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This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
3. Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
   ☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
   ☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
4. Please specify location of administration if hospital outpatient infusion: _____
5. Please specify location of administration if hospital inpatient infusion: _____
6. Please provide the NPI number for the place of administration: _____
7. **Initiation AND Continuation of therapy:**
   a. What is the patient's diagnosis? _____
   b. What other medication has the patient received for their condition? Please list_____
      i. Please describe the response to previous therapies:
      _____
   c. Will the patient be receiving any other treatment for the listed condition while on this medication? Please list:
      _____
   d. Please list any labs values important for diagnosing or monitoring this patient's condition:
      _____
8. **Continuation of therapy:**
   a. Has the patient progressed while on this medication? ☐ yes ☐ no
   b. How has the patient's condition changed while on this medication?
      ☐ Improved: Please describe: _____
      ☐ Stable: please describe: _____
      ☐ Worsened; Please describe: _____
      ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review **(required)**

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name **Physician Signature** **Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021