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

Cortrophin™ Gel (repository corticotropin)

HCPCS: J0802

Policy:

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

A. The use of Cortrophin Gel is considered not medically necessary for the treatment of any condition

***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:

- Cortrophin Gel is an extended release preparation of adrenocorticotropic hormone (ACTH). ACTH is a hormone in the body, which stimulates the adrenal cortex gland to secrete natural steroids (cortisol, corticosterone, and aldosterone).

- Cortrophin Gel was first approved in 1954. It was discontinued in the 1980s, fell out of use due to the commercial availability of corticosteroids (such as prednisone, hydrocortisone, methylprednisolone).

- Although Cortrophin Gel is FDA approved for a variety of inflammatory conditions, there is insufficient evidence to establish efficacy for these indications, or superiority to less costly alternatives (such as generic corticosteroids). There are a lack of clinical studies comparing the effectiveness of corticotropin injections to corticosteroids in corticosteroid-responsive conditions. In addition, there is no reliable evidence of the effectiveness of corticotrophin injections in patients who have failed to respond to corticosteroids. Since repository corticotropin stimulates steroid production in the body, the warnings of repository corticotropin use is similar to those found with steroid supplementation. Side effects or intolerance to corticosteroids are largely expected with the use of repository corticotropin given the medication stimulates steroid production in the body. Therefore, the use of these products for indications other than infantile spasms is considered not medically necessary.

- Acthar Gel® is the other FDA approved repository corticotropin product. It is approved for all the same indications as Cortrophin Gel in addition to infantile spasms. Cortrophin went through a supplemental new drug application showing

its manufacturing and control processes align with current FDA standards so it only includes its original indications and not infantile spasms as that was approved for Acthar around 2010. Guidelines from The American Academy of Neurology and the Practice Committee of the Child Neurology Society for the treatment of infantile spasms in children (2012) recommends use of ACTH as the preferred treatment choice for infantile spasms.

References:

1. Purified Cortrophin™ Gel [prescribing information]. Baudette, MN: ANI Pharmaceuticals; November 2021.
2. Go CY, Mackay MT, Weiss SK, et al; Child Neurology Society; American Academy of Neurology. 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 Jun 12;78(24):1974-80.
3. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. Cochrane Database Syst Rev. 2013;6:CD001770.
4. Hussain, S. Child Neurology Foundation: Infantile Spasms. Available at: https://www.childneurologyfoundation.org/disorder/infantile-spasms/. Accessed on November 17, 2021.

<table>
<tr><td colspan="3">Policy History</td></tr>
<tr><td>#</td><td>Date</td><td>Change Description</td></tr>
<tr><td>1.4</td><td>Effective Date: 02/13/2025</td><td>Annual review – no changes to the criteria were made</td></tr>
<tr><td>1.3</td><td>Effective Date: 02/08/2024</td><td>Annual review – no changes to the criteria were made</td></tr>
<tr><td>1.2</td><td>Effective Date: 02/02/2023</td><td>Annual review – no changes to the criteria were made</td></tr>
<tr><td>1.1</td><td>Effective Date: 02/24/2022</td><td>UM medical management system update for BCBS and BCN
<table>
<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>1.0</td><td>Effective Date: 02/10/2022</td><td>New Policy</td></tr>
</table>

** 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