



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.

Effective Date: 02/08/2024

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 adrenocorticotrophic 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

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

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.

Policy History												
#	Date	Change Description										
1.3	Effective Date: 02/08/2024	Annual review – no changes to the criteria were made.										
1.2	Effective Date: 02/02/2023	Annual review – no changes to the criteria were made.										
1.1	Effective Date: 02/24/2022	UM medical management system update for BCBS and BCN <table border="1" style="margin-left: 20px; width: 100%;"> <thead> <tr> <th style="text-align: center;">Line of Business</th> <th style="text-align: center;">PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">BCBS</td> <td style="text-align: center;">Yes</td> </tr> <tr> <td style="text-align: center;">BCN</td> <td style="text-align: center;">Yes</td> </tr> <tr> <td style="text-align: center;">MAPPO</td> <td style="text-align: center;">No</td> </tr> <tr> <td style="text-align: center;">BCNA</td> <td style="text-align: center;">No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.0	Effective Date: 02/10/2022	New Policy										

* 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



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

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. <input type="checkbox"/> Male <input type="checkbox"/> 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	<input type="checkbox"/> Form Completely Filled Out <input type="checkbox"/> Provide chart notes	<input type="checkbox"/> 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

Confidentiality notice: This transmission contains confidential information belonging to the sender that is legally privileged. This information is intended only for use of the individual or entity named above. The authorized recipient of this information is prohibited from disclosing this information to any other party. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or action taken in reliance on the contents of this document is strictly prohibited. If you have received this in error, please notify the sender to arrange for the return of this document.