CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	**Cortrophin Gel (corticotropin)**
BILLING CODE	J0800 or must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Purified Cortrophin Gel is a porcine derived purified corticotropin (ACTH) in a sterile solution of gelatin indicated in a variety of conditions such as rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, symptomatic sarcoidosis, nephrotic syndrome and multiple sclerosis (MS). Purified Cortrophin Gel is the anterior pituitary hormone which stimulates the functioning adrenal cortex to produce and secrete adrenocortical hormones. Clinical trials have provided sufficient evidence to support its use in acute exacerbations of MS. However, a recent review found Cortrophin was not superior to corticosteroids for treating relapses of MS.

Cortrophin Gel (corticotropin) will be considered for coverage when the following criteria are met:

Multiple Sclerosis

For **initial** authorization:

1. Member is at least 18 years of age or older; AND
2. Medication must be prescribed by a neurologist; AND
3. Member must have documentation of a current acute exacerbation of MS; AND
4. Member must have a previous 3-day trial and failure of intravenous methylprednisolone at a dose of at least 1000 mg daily; AND
5. Medication is being used as add-on treatment to disease modifying therapy (ex. Copaxone, Gilenya, Plegridy, etc.)
6. Member does not have ANY of the following:
    a. Scleroderma
    b. Osteoporosis
    c. Systemic fungal infections
    d. Ocular herpes simplex
    e. History of or the presence of a peptic ulcer
    f. Congestive heart failure
    g. Primary adrenocortical insufficiency or adrenocortical hyperfunction
7. **Dosage allowed/Quantity limit:** Administer 80-120 units daily intramuscularly for 2-3 weeks. Quantity Limit: 7 vials per 21 days.

If all the above requirements are met, the medication will be approved for 3 weeks.

For **reauthorization**:

Cortrophin Gel will not be reauthorized for chronic use.

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CareSource considers Cortrophin Gel (corticotropin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/22/2022	New policy for Cortrophin Gel created.
03/14/2023	Updated references. Added requirement for current use of disease modifying therapy. Clarified background information.

References:

1. Cortrophin Gel [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc; November 2021.
2. Tran KA, Harrod C, Bourdette DN, Cohen DM, Deodhar AA, Hartung DM. Characterization of the Clinical Evidence Supporting Repository Corticotropin Injection for FDA-Approved Indications: A Scoping Review. *JAMA Intern Med.* 2022;182(2):206–217.
3. Grant AR, Day GS, Ann Marrie R, et al. Practice guidelines: Disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788
4. Filippini G, Brusaferri F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database Syst Rev. 2000;(4):CD001331. doi:10.1002/14651858.CD001331
5. Berkovich R. Treatment of acute relapses in multiple sclerosis. Neurotherapeutics. 2013;10(1):97-105. doi:10.1007/s13311-012-0160-7.
6. Tran KA, Harrod C, Bourdette DN, Cohen DM, Deodhar AA, Hartung DM. Characterization of the Clinical Evidence Supporting Repository Corticotropin Injection for FDA-Approved Indications: A Scoping Review. JAMA Intern Med. 2022;182(2):206-217. doi:10.1001/jamainternmed.2021.7171

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