CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Cortrophin Gel (corticotropin)
BILLING CODE	J0800 or must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Purified Cortrophin Gel is a porcine derived purified corticotropin (ACTH), The first corticotrophin injection (Acthar Gel) was approved in 1952 for a broad range of conditions. In August 2021, the FDA approved Purified Cortrophin Gel for the same indications as repository cortocotropin injection (Acthar Gel), except for infantile spasms. Currently Purified Cortrophin Gel is indicated for the following FDA approved conditions: Rheumatic disorders, Collagen diseases, Dermatologic diseases, Allergic states, Ophthalmic diseases, Symptomatic sarcoidosis, Nephrotic syndrome and Multiple Sclerosis. A recent review of Cortrophin injection for all the FDA approved indications found Cortrophin performed better than placebo but no different than corticosteroids.

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 a diagnosis of multiple sclerosis; AND
4. Member must have documentation of a current acute exacerbation; AND
5. Member must have a previous 3-day trial and failure of intravenous methylprednisolone at a dose of 1000 mg daily; AND
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.

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.

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. Trautmann A, Vivarelli M, Samuel S, et al. IPNA clinical practice recommendations for the diagnosis and management of children with steroid-resistant nephrotic syndrome. Pediatric Nephrology (2020) 35: 1529-1561
5. Lieberman KV and Pavlova-Wolf A. Adrenocorticotropic hormone therapy for the treatment of idiopathic nephrotic syndrome in children and young adults: A systematic review of early clinical studies with contemporary relevance. J Nephrol. 2017; 30:35-44

Effective date: 04/01/2023
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