Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Repository Corticotropin (Self-administered)**

Effective: April 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Acthar (corticotropin) is an adrenocorticotropic hormone analogue indicated:

- **Infantile spasms**
  As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- **Multiple sclerosis**
  For the treatment of acute exacerbations of multiple sclerosis in adults.

Cortrophin (corticotropin) is an adrenocorticotropic hormone analogue indicated:

- **Multiple sclerosis**
  For the treatment of acute exacerbations of multiple sclerosis in adults.

Controlled trials have shown 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.

The recommended dosage regimen for infantile spasms is a daily dose of 150 U/m^2 (divided into twice daily intramuscular injections of 75 U/m^2) administered over a two-week period. Dosing should then be gradually tapered over a two week period to avoid adrenal insufficiency.

The recommended dosage regimen for acute exacerbations of multiple sclerosis is a daily intramuscular or subcutaneous dose of 80 to 120 units for two to three weeks for acute exacerbations. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

Per the package labeling, corticotropin may be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state. Acthar (corticotropin) and Cortrophin (corticotropin) was originally approved by the FDA in 1952 and 1954 before there was a requirement of clinical evidence of effectiveness. Since corticotropin received approval prior to the Kefauver-Harris Drug Amendments were signed into law in 1962, the drug has additional disorders and diseases included on the package label but there is no supporting evidence of effectiveness. These disorders or diseases are all responsive to corticosteroid therapy and corticotropin has not been proven to be superior to corticosteroids for any of these conditions.

Clinical Guideline Coverage Criteria

Infantile Spasms

The plan may authorize coverage of Acthar for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of infantile spasms (i.e., West Syndrome)

AND

2. Patient is two (2) years of age or younger

Multiple Sclerosis

The plan may authorize coverage of Acthar or Cortrophin for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of an acute exacerbation of multiple sclerosis

AND

2. Prescribed by or in consultation with expertise in treatment of multiple sclerosis

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Previous failure of intravenous corticosteroid therapy
    b. Intolerance or contraindication to corticosteroid therapy

Limitations

1. Repository Corticotropin Injection is unproven for treatment of conditions other than infantile spasms and multiple sclerosis. Requests for coverage of all other indications will be reviewed for medical necessity.
2. For infantile spasms, approval duration is 6 months.
3. For multiple sclerosis, approval duration is 1 month.
4. For all indications other than infantile spasms or multiple sclerosis, approval duration is 6 months.
5. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Acthar gel (repository corticotropin injection) [package insert]. Bedminster, NJ: Mallinckrodt ARD Inc.; 2024 Feb.
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3. Berkovich R. Treatment of acute relapses in multiple sclerosis. Neurotherapeutics. 2013 Jan;10(1):97-105.
4. Filippini G, Brusaferri F, Sibley WA, Citterio A, Ciucci G, Midgard R, Candelise L. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database Syst Rev. 2000;(4): CD001331.
5. Go C, Mackay M, Weiss S, et al. 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.
6. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. Cochrane Database Syst Rev. 2013;(6):CD001770.
7. Mackay MT, Weiss SK, Adams-Webber T, et al. Practice parameter: medical treatment of infantile spasms: report of the American Acedmy of Neurology and the Child Neurology Society. Neurology 2004;62;1668-81.
8. Purified Cortrophin (repository corticotropin injection USP) [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; 2025 Feb.
9. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology. 1989 Jul;(7):969
10. Wanigasinghe J, Arambepola C, Sri Ranganathan S, et al. Randomized, Single-Blind, Parallel Clinical Trial on Efficacy of Oral Prednisolone Versus Intramuscular Corticotropin on Immediate and continued Spasm Control in West Syndrome. Pediatr Neurol. 2015 Sep;53(3):193-9.
11. Wilmshurst JM, Gaillard WD, Vinayan KP, et al. Summary of recommendations for the management of infantile seizures: Task Force Report for the ILAE Commission of Pediatrics. Epilepsia. 2015 Aug;56(8):1185-97.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

1. July 11, 2023: No changes
2. October 2023 e-vote: Removed “If the request is for Acthar, documented previous failure or adverse event, or contraindication to Cortrophin” from Multiple Sclerosis (eff 11/1/2023).
3. July 9, 2024: No changes (eff 7/9/24)
4. May 13, 2025: No changes (eff 5/13/25).
5. September 9, 2025: Clarified that coverage aligns with FDA-approved indications for the individual agents (eff 10/1/25).
6. March 10, 2026: Effective April 1, 2026, removed the requirement of trial with oral corticosteroids.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.