Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Repository Corticotropin (skilled administration)

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

Public Plans Products

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

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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** the following criteria is 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 Cotrophin for Members when **ALL** the following criteria is 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

- 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.
- For infantile spasms, approval duration is 6 months.
- For multiple sclerosis, approval duration is 1 month.
- For all indications other than infantile spasms or multiple sclerosis, approval duration is 6 months.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0801	Injection, corticotropin (Acthar Gel), up to 40 units
J0802	Injection, corticotropin (ANI), up to 40 units

References

1. Acthar gel (repository corticotropin injection) [package insert]. Bedminster, NJ: Mallinckrodt ARD Inc.; 2019 Mar.
2. Barnes MP, Bateman DE, Cleland PG, et al. Intravenous methylprednisolone for multiple sclerosis in relapse. J Neurol Neurosurg Psychiatry. 1985 Feb;48(2):157-9.
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 Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- October 1, 2023: Administrative update: Added new J Codes J0801 and J0802 to the Medical Necessity Guideline and removed expired J Code J0800
- November 14, 2023: Updated title of Medical Necessity Guideline from “Acthar (corticotropin)” to “Repository Corticotropin (Skilled Administration)”. Minor wording updates. Removed the following from Multiple Sclerosis coverage criteria “If the request is for Acthar, documented previous failure or adverse event, or contraindication to Cortrophin” (eff 12/1/2023).
- July 9, 2024: No changes (eff 7/9/24)
- May 13, 2025: No changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 5/13/25).
- September 9, 2025: Clarified that coverage aligns with FDA-approved indications for the individual agents (eff 10/1/25).
- March 10, 2026: Effective April 1, 2026, Removed requirement for oral corticosteroid therapy. Administrative update: Removed Carelink from guideline template.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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