Pharmacy Medical Necessity Guidelines:
Repository Corticotropin Injection (Acthar, Cortrophin)

Effective: April 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-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.

COVERAGE GUIDELINES

The plan may authorize coverage of Acthar (corticotropin) or Cortrophin (corticotropin) for Members when the following criteria are met:

Infantile spasms

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

AND

2. Documentation the Member is less than or equal to 2 years of age or older

Multiple sclerosis

1. Documented diagnosis of an acute exacerbation of multiple sclerosis

AND

2. The medication is prescribed by a neurologist with expertise in treatment of multiple sclerosis

AND

3. Documentation the Member is greater than or equal to 18 years of age or older

AND

4. Documentation of one of the following:

a. Previous failure of both intravenous and oral corticosteroid therapy
b. Intolerance or contraindication to corticosteroid therapy

AND

5. If the request is for Acthar, documented previous failure or adverse event, or contraindication to Cortrophin

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. If the request is for Acthar, documentation of previous failure or adverse event, or contraindication to Cortrophin is required.
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.

CODES

None.

REFERENCES

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APPROVAL HISTORY

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

1. July 11, 2023: No changes
2. July 9, 2024: No changes (eff 7/9/24)
3. May 13, 2025: No changes (eff 5/13/25)
4. March 10, 2026: No changes (eff 4/1/26)

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.

Provider Services