

ACTHAR GEL (corticotropin (ACTH))

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

- 1. Infantile spasms (in children < 2 years of age)
 - a. Prescribed by a neurologist
 - b. **NO** dual therapy with Cortrophin Gel (corticotropin)
- 2. Exacerbations of multiple sclerosis (in adults ≥18 years of age)
 - a. Prescribed by a neurologist
 - b. Used in combination with a maintenance MS therapy
 - c. Submission of medical records (e.g., chart notes, laboratory values) documenting **ONE** of the following:
 - i. FDA labeled contraindication to oral or parenteral glucocorticoid therapy
 - ii. An inadequate response or intolerance to a 1 month trial of oral or a 1 week trial of parenteral glucocorticoid therapy
 - d. NO dual therapy with Cortrophin Gel (corticotropin)
 - e. Patient **MUST** have tried the preferred product (Cortrophin Gel) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 3. Nephrotic syndrome
 - a. Prescribed by a nephrologist
 - Submission of medical records (e.g., chart notes, laboratory values)
 documenting an inadequate response or intolerance to a 1 month trial
 of ONE of the following:
 - i. Oral glucocorticoid therapy
 - ii. Immunosuppressant such as:
 - 1. Cyclophosphamide
 - 2. Cyclosporine
 - 3. Tacrolimus
 - 4. Mycophenolate mofetil



Federal Employee Program. (corticotropin (ACTH))

- c. Submission of medical records (e.g., chart notes, laboratory values) documenting baseline levels of protein in urine indicative of proteinuria and low levels of albumin in blood indicative of hypoalbuminemia
- d. **NO** dual therapy with Cortrophin Gel (corticotropin)
- e. Patient **MUST** have tried the preferred product (Cortrophin Gel) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage

Prior - Approval Limits Duration

Infantile spasms 1 month
Exacerbations of multiple sclerosis 1 month
Nephrotic syndrome 6 months

Prior – Approval Renewal Requirements

Diagnoses

Patient must have **ONE** of the following:

- 1. Infantile spasms (in children < 2 years of age)
 - a. Prescribed by a neurologist
 - b. **NO** dual therapy with Cortrophin Gel (corticotropin)
- 2. Exacerbations of multiple sclerosis (in adults ≥18 years of age)
 - a. Prescribed by a neurologist
 - b. Used in combination with a maintenance MS therapy
 - c. Submission of medical records (e.g., chart notes, laboratory values) documenting 30 day lapse since previous exacerbation
 - d. **NO** dual therapy with Cortrophin Gel (corticotropin)
 - e. Patient **MUST** have tried the preferred product (Cortrophin Gel) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 3. Nephrotic syndrome



ACTHAR GEL Federal Employee Program. (corticotropin (ACTH))

- a. Prescribed by a nephrologist
- b. Submission of medical records (e.g., chart notes, laboratory values) documenting a decrease in urine protein level and increase serum albumin level
- c. **NO** dual therapy with Cortrophin Gel (corticotropin)
- d. Patient MUST have tried the preferred product (Cortrophin Gel) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval Renewal Limits

Same as above