Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

ACTHAR® GEL (*repository corticotropin injection*) PA CRITERIA:

ACTHAR® GEL (*repository corticotropin injection*) stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. It is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. It is also indicated for the treatment of exacerbations of multiple sclerosis in adults.

Prior authorization is required for ACTHAR® GEL. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization for Treatment of Acute Exacerbations of Multiple Sclerosis: 1 Month

1. Age of the patient is 18 years or older; **AND**
2. Documented diagnosis of multiple sclerosis (MS); **AND**
3. Patient is currently experiencing an acute exacerbation of MS; **AND**
4. Failure of a recent trial (within the last 30 days) of at least a 3-day course of corticosteroid therapy for acute exacerbations of MS, unless contraindicated or clinically significant adverse effects are experienced; **AND**
5. Patient is currently using disease modifying therapy for MS; **AND**
6. Patient does not have any contraindications to ACTHAR GEL (e.g., scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, or sensitivity to proteins of porcine origin); **AND**
7. Prescribed by or in consultation with a neurologist; **AND**
8. The daily dose not exceed 120 units per day.

Initial Authorization for Infantile Spasms: 3 Months

1. Age of the patient is within the age range as recommended by the FDA label for this indication; **AND**
2. Documented diagnosis of infantile spasms; **AND**
3. Documentation of the patient's current body surface area (BSA) in m^2; **AND**
4. Prescribed by or in consultation with a neurologist; **AND**
5. Request is for ACTHAR GEL vial; **AND**
6. Dose does not exceed 150 units/m^2 per day.

Re-Authorization for Infantile Spasms: 1 Month

1. Age of the patient is within the age range as recommended by the FDA label for this indication; **AND**
2. Documentation of positive clinical response to therapy; **AND**
3. Documentation of the patient's current body surface area (BSA) in m^2; **AND**
4. Prescribed by or in consultation with a neurologist; **AND**
5. Request is for ACTHAR GEL vial; **AND**
6. Dose does not exceed 150 units/m^2 per day.

ACTHAR® GEL (*repository corticotropin injection*) Dosing:

- Infantile Spasms: Doses must be administered intramuscularly using the ACTHAR GEL vial. The recommended dose is 150 units/m^2 divided into twice daily injections of 75 units/m^2. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period.
- Acute Exacerbations of Multiple Sclerosis: Daily intramuscular or subcutaneous doses of 80 to 120 units for 2-3 weeks may be administered. It may be necessary to taper the dose.
- Other Disorders and Diseases: Individualize dosing depending on the disease and patient. The usual dose is 40 to 80 units given intramuscularly or subcutaneously every 24 to 72 hours. It may be necessary to taper the dose.

Formulation:

- ACTHAR® GEL is available as:
    - 5 mL multi-dose vial containing 80 USP units/mL, for intramuscular or subcutaneous use.
    - 40 USP units/0.5 mL ACTHAR GEL single-dose pre-filled SelfJect injector for subcutaneous injection.
    - 80 USP units/mL ACTHAR GEL single-dose pre-filled SelfJect injector for subcutaneous injection.