Acthar® Gel (repository corticotropin injection)

When requesting Acthar® Gel (repository corticotropin injection), the individual requiring treatment must be diagnosed with infantile spasms and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.
(Note: All other FDA-approved indications will be reviewed by medical directors.)

Coverage Guidelines

Infantile Spasms

The individual must meet all of the following criteria for approval:

- Is less than 2 years of age;
- Acthar Gel is being administered as an intramuscular injection;
- Acthar Gel is prescribed by a physician who has consulted with or specializes in neurology.

Approval duration: 1 month

Dosing Recommendation

The recommended dose is 150 U/m^2 divided into twice daily intramuscular injections of 75 U/m^2. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period.

References

1. Acthar® Gel injection for subcutaneous and intramuscular use [prescribing information]. Bridgewater, NJ: Mallinckrodt; February 2024.
2. Tran KA, Harrod C, Bourdette DN, et al. Characterization of the clinical evidence supporting repository corticotropin injection for FDA-approved indications. A scoping review. *JAMA Intern Med*. 2022;182(2):206-217.
3. Go CY, Mackay MT, Weiss SK, 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;78:1974-1980.
4. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a US consensus report. *Epilepsia*. 2010;51(10):2175-2189.