

Generic Name: Repository corticotropin injection gel

Therapeutic Class or Brand Name: H.P. Acthar

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 3030001000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/2/2019

Date Last Reviewed / Revised: 1/15/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documented diagnosis of infantile spasms (West Syndrome) and confirmation of diagnosis by an electroencephalogram (EEG).
- II. Documented body surface area (BSA) and dosing schedule, and dose and quantity are appropriate for patient's treatment regimen including tapering schedule.
- III. Prescriber is a pediatric neurologist or an epilepsy physician specialist.
- IV. Patient must be under 2 years of age.

EXCLUSION CRITERIA

- Patients with sclerodoma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin.
- Concurrent administration of live or live attenuated vaccines.
- Congenital infections.
- Primary adrenocortical insufficiency or adrenocortical hyperfunction.

OTHER CRITERIA

- Repository corticotropin is not considered medically necessary for conditions including but not limited to: multiple sclerosis, rheumatic disorders, dermatologic diseases, nephrotic syndrome, ophthalmic diseases, respiratory diseases, serum sickness, or collagen diseases.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Up to the quantity and duration required for patient's documented dosing regimen and tapering schedule.

APPROVAL LENGTH

- **Authorization:** One time for a single treatment duration.

- **Re-Authorization:** N/A.

APPENDIX

N/A

REFERENCES

1. Wilmshurst, JM, 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. doi: 10.1111/epi.13057. Epub 2015 Jun 30. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/26122601>.
2. Go CY, 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. doi: 10.1212/WNL.0b013e318259e2cf. Available at: <https://www.ncbi.nlm.nih.gov/pubmed?term=22689735>.
3. Medi-Span®
4. H.P. Acthar® [Package Insert]. Bedminster, NJ: Mallinckrodt; March 2019. Available at: <https://www.acthar.com/pdf/Acthar-PI.pdf>.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/15/2020	1. Removed outdated references. Added "Summary of recommendations for the management of infantile seizures: Task Force Report for the ILAE Commission of Pediatrics" under References .
1/2/2019	1. New policy.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.