Policy Title:	H.P. Acthar Gel (repository corticotropin)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	9/18/2019, 12/18/19, 1/22/20, 3/4/2021, 6/16/2022, 4/13/2023		
Revision Date:	9/18/2019, 1/22/20, 3/4/2021, 6/16/2022		

Purpose: To support safe, effective, and appropriate use of H.P. Acthar Gel (repository corticotropin).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

H.P. Acthar Gel (repository corticotropin) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of H.P. Acthar Gel (repository corticotropin) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Infantile Spasms:

- Patient has a diagnosis of Infantile Spasms (West Syndrome); AND
- Patient is less than 24 months old; AND
- Must be used as monotherapy; AND
- Documentation that patient does not have a suspected congenital infection; AND
- Dose does not exceed 75 units/m^2 intramuscularly given twice daily for 2 weeks, then taper the dose over a 2-week period (e.g., 30 units/m^2 in the morning for 3 days; 15 units/m^2 in the morning for 3 days; 10 units/m^2 in the morning for 3 days; and 10 units/m^2 every other morning for 6 days)

Dosing:

Indication	Maximum units (1 billable unit = 40 units)
Infantile Spasms	35 billable units every 28 days

Coverage durations:

- Initial coverage: 1 month

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J0800	Injection, corticotropin, up to 40 units

References:

1. H.P. Acthar Gel [package insert]. Hazelwood, MO; Mallinckrodt Pharmaceuticals Inc; March 2023. Accessed March 2023.
2. Go, C.Y., Mackay, M.T., Weiss, S.K. 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.
3. Hussain SA, Shinnar S, Kwong G, et al. Treatment of infantile spasms with very high dose prednisolone before high dose adrenocorticotropic hormone. Epilepsia. 2014 Jan;55(1):103- 7. doi: 10.1111/epi.12460. Epub 2013 Nov 8.
4. Hrachovy RA, Frost JD, Glaze DG et al. High-dose, long-duration versus low-dose, short duration corticotropin therapy for infantile spasms. J Pediatr 1994;124:803-806.
5. Kivity S, Lerman P, Ariel R, et al. Long-term cognitive outcomes of a cohort of children with cryptogenic infantile spasms treated with high-dose adrenocorticotropic hormone. Epilepsia. 2004 Mar;45(3):255-62.
6. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a U.S. consensus report. Epilepsia. 2010 Oct;51(10):2175-89.
7. M. T. Mackay, S. K. Weiss, T. Adams-Webber, et al. Practice parameter: medical treatment of infantile spasms: report of the American Academy of Neurology and the Child Neurology Society. Neurology 2004;62;1668-81