JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP025
		Effective Date	10/10/2012
		Review Date	01/15/2020
	Subject **H.P. Acthar Gel (Corticotropin Injection)**	*Revision Date*	11/10/2021
		Page	1 of 3

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Acthar

Table of Contents		Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	1
IV.	EXCLUSIONS	1
V.	RECOMMENDED DOSAGE	2
VI.	CODES	2
VII.	REFERENCES	2
VIII.	APPROVALS	2

I. POLICY

A. Injectable repository corticotropin will require prior authorization for benefit coverage and to ensure appropriate use. The procedure for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Injectable repository corticotropin may be approved for patients less than 2 years of age with a documented diagnosis of infantile spasms (West's syndrome) who are unable to receive vigabatrin or have failed to respond to vigabatrin.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval for infantile spasm will be for 3 months.
B. Approval for continuation of therapy can be extended in 6-month intervals with documentation showing continued benefit to treatment.

IV. EXCLUSIONS

A. Injectable repository corticotropin will NOT be approved for experimental or investigational indications including, but not limited to the following:
   1. Use for diagnostic testing of adrenocortical function, as it has not been proven to be superior to cosyntropin for this purpose
   2. Use for the treatment of multiple sclerosis exacerbations, as it has not been proven superior to oral or intravenous methylprednisolone
   3. Use for the treatment of sarcoidosis, as it has not been proven superior to corticosteriods
   4. Use for relapses of nephrotic syndrome refractory to oral prednisone, as strong clinical evidence is lacking regarding its efficacy in this condition
   5. Use in pregnant women with low levels of maternal blood ACTH

6. Patients with scleroderma
7. Patients with osteoporosis
8. Patients with systemic fungal infection, ocular herpes simplex, latent infection or recent surgery
9. Patients with history of or current peptic ulcer
10. Patients with congestive heart failure or uncontrolled hypertension

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSAGE

All FDA approved dosage(s) and dosing interval(s) for the FDA approved indication(s).

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

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

VII. REFERENCES

1. Questcor Pharmaceuticals. Prescribing Information: H. P. Acthar Gel. October 2010.
2. NICE Guidelines. TA79: Newer drugs for epilepsy in children.
3. Mackay MT, Weiss SK, Adams-Weber T, et al. Practice Parameter: Medical treatment of infantile spasms. *Neurology* 2004; 62: 1668.
4. Graziella F et al for the Cochrane Multiple Sclerosis Group. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. 30 OCT 2002
5. Klimek R, Klimek M, Gralek P, Jasiczek D. Causal ACTH-Depot Therapy during Pregnancies following Infertility Treatment. Obstet Gynecol Int. Epub 2012 May 15.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background information/definitions
07/25/2017	policy section-updated language to match operational processes
07/27/2017	Updated Exclusions section regarding physician samples
09/29/2017	Clarification of excluded diagnoses

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		Page	3 of 3

07/18/2018	Updated clinical criteria and excluded diagnoses
06/05/2019	Converted from MEDS policy to MMDP policy
01/15/2020	No policy changes-presented policy for USFHP adoption effective 3/1/2020
11/10/2021	Removed Priority Partners as an applicable LOB

Review/Revision Dates: 10/10/2012, 11/01/2012, 4/20/2016, 07/25/2017, 07/27/2017, 09/29/2017, 7/18/2018, 06/05/2019, 07/17/2019, 01/15/2020, 11/10/2021