UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2028-5
Program	Prior Authorization/Medical Necessity
Medication	H.P. Acthar Gel® (Repository corticotropin injection)
P&T Approval Date	5/2014, 5/2015, 9/2016, 9/2017, 9/2018
Effective Date	12/1/2018; Oxford only: 12/1/2018

1. Background:

H.P. Acthar Gel® (repository corticotropin injection) is an adrenocorticotropic hormone (ACTH) analogue **medically necessary** for:

- **Infantile Spasms:** As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.[1]
- **Opsoclonus-myoclonus syndrome** (i.e., OMS, Kinsbourne Syndrome)[2,3]

The H.P. Acthar package insert has listed other conditions in which it may be used. Since H.P. Acthar is more costly than an alternative drug that is at least as likely to produce equivalent therapeutic results, UHCP has determined that use of H.P. Acthar Gel is not medically necessary for treatment of the following disorders and diseases: multiple sclerosis; rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.

Coverage will be provided for members who meet the following criteria.

2. Coverage Criteria:

A. <u>Infantile Spasms (i.e., West Syndrome)</u>

1. <u>Initial Therapy</u>

a. **H.P. Acthar Gel** will be approved based on **<u>both</u>** of the following criteria

(1) Diagnosis of infantile spasms (West Syndrome)[1]

-AND-

(2) Patient is less than 2 years of age[1]

Authorization will be issued for 4 weeks by OptumRx.

2. <u>Reauthorization</u>

All requests for reauthorization will be **denied by OptumRx**. All requests for continuation of therapy must be submitted through the appeals process to the

UnitedHealthcare Pharmacy appeals team for consideration.

B. Opsoclonus-Myoclonus Syndrome (i.e., Kinsbourne Syndrome) (off-label)

1. Initial Authorization

a. H.P Acthar Gel will be approved based on the following criteria:

(1) Diagnosis of opsoclonus-myoclonus syndrome[2,3]

Authorization will be issued for 3 months by OptumRx.

2. Reauthorization

All requests for reauthorization will be **denied by OptumRx**. All requests for continuation of therapy must be submitted through the appeals process to the UnitedHealthcare Pharmacy appeals team for consideration.

3. Additional Clinical Rules:

- Supply limits and/or Step Therapy may be in place.

4. References:

1. H.P. Acthar Gel [package insert].Mallinckrodt ARD Inc., April 2018.
2. Pranzatelli M, Chun K, Moxness M, Tate E, Allison T. Cerebrospinal fluid ACTH and cortisol in opsoclonus-myoclonus: effect of therapy. Pediatr Neurol. 2005;33:121-126.
3. Pranzatelli, M. R., Huang, Y.-Y., Tate, E, et al. Monoaminergic effects of high-dose corticotropin in corticotropin-responsive pediatric opsoclonus-myoclonus. Movement Disorders. 1998:13(3): 522–528.
4. National Institute of Neurological Disorders and Stroke. (2007, February 14). NINDS opsoclonus myoclonus information page. Retrieved August 3, 2017, from the National Institutes of Health Web site: https://www.ninds.nih.gov/Disorders/All-Disorders/Opsoclonus-Myoclonus-Information-Page.

Program	Prior Authorization/Medical Necessity - H.P. Acthar Gel (Repository corticotropin injection)
Change Control	
5/2014	New Program
5/2015	Annual review with no change to clinical coverage.
9/2016	Annual review. Updated references
9/2017	Annual review. Updated references.
9/2018	Annual review. Updated references.