UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1000-7
Program	Prior Authorization/Notification
Medication	H.P. Acthar Gel® (Repository corticotropin injection)
P&T Approval Date	5/2012, 4/2013, 2/2014, 5/2014, 5/2015, 4/2016, 4/2017, 4/2018
Effective Date	8/1/2018; Oxford only: N/A

1. Background:

H.P. Acthar Gel® (repository corticotropin injection) is an adrenocorticotropic hormone (ACTH) analogue US Food and Drug Administration (FDA) indicated for:

- **Infantile Spasms:** As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.[1]
- **Multiple Sclerosis:** For treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease. [1]

Per labeling, it is suggested that H.P. Acthar may be used in the following conditions, however, it is not indicated for them:

- **Rheumatic Disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis. [1]
- **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).[1]
- **Dermatologic Diseases:** Severe erythema multiforme, Stevens-Johnson syndrome. [1]
- **Allergic States:** Serum sickness. [1]
- **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation. [1]
- **Respiratory Diseases:** Symptomatic sarcoidosis. [1]
- **Edematous State:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. [1]

Additional evidence supports the use of H.P. Acthar Gel in opsoclonus-myoclonus syndrome.[2,3] Opsoclonus myoclonus is a rare neurological disorder often characterized by unsteady (trembling) gait, myoclonus (brief, shock-like muscle spasms), and opsoclonus (irregular, rapid eye movements).[4]

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

2. Coverage Criteria:

A. Infantile Spasms (i.e., West Syndrome)

1. Initial Therapy

a. **H.P. Acthar Gel** will be approved based on **both** 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. 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.

B. Multiple Sclerosis

1. Initial Therapy

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

(1) Diagnosis of acute exacerbation of multiple sclerosis[1]

Authorization will be issued for 3 weeks by OptumRx.

2. Reauthorization

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

(1) OptumRx **can** review a reauthorization request for a new (different) episode of acute exacerbation of multiple sclerosis

-OR-

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

Authorization will be issued for 3 weeks.

C. 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]. Hazelwood, MO: Mallinckrodt ARD Inc,, July 2017.
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 February 1, 2017, from the National Institutes of Health Web site: https://www.ninds.nih.gov/Disorders/All-Disorders/Opsoclonus-Myoclonus-Information-Page.

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Change Control	
2/2014	Clarified reviewer designation for initial and reauthorization requests in Coverage Criteria.
5/2014	Updated background and coverage criteria to only allow coverage for IS, MS and OMS.
5/2015	Annual review with no change to clinical coverage.
4/2016	Annual review with no change to clinical coverage. Updated references.
4/2017	Annual review with no change to clinical coverage. Updated references.
4/2018	Annual review with no change to clinical coverage. Updated references.