UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3000-12
Program	Step Therapy
Medication	Acthar Gel® (repository corticotropin injection)
P&T Approval Date	5/2012, 04/2013, 2/2014, 5/2014, 5/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020
Effective Date	12/1/2020; Oxford only: N/A

1. Background:

Acthar Gel® (repository corticotropin injection) is an adrenocorticotropic hormone (ACTH) analogue that is 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 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 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]

In cases where conditions are corticosteroid-responsive, corticotropin has limited therapeutic value because corticosteroid therapy is considered the treatment of choice.[2]

Clinical trials comparing adrenocorticotropic hormone (ACTH) and methylprednisolone (MP) in treatment of acute exacerbation in multiple sclerosis have either shown no difference between treatments[3] or have shown that the MP cohort had a more rapid or

greater improvement in treatment of the acute exacerbation as measure by the Kurtzke Disability Status Scale (DSS).[4]

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

2. Coverage Criteria[a]:

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

1. **Acthar Gel** will be approved based on **both** of the following criteria:

   a. Diagnosis of infantile spasms (West Syndrome)

   -AND-

   b. Patient is less than 2 years of age

   Authorization will be issued for 12 months.

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

1. **Acthar Gel** will be approved based on the following criteria:

   a. Diagnosis of opsoclonus-myoclonus syndrome (OMS, Kinsbourne Syndrome)

   Authorization will be issued for 12 months.

C. Other Conditions

1. **Acthar Gel** will be approved based on the following:

   a. History of failure, contraindication, or intolerance to treatment with corticosteroids

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Supply limits and/or Notification may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Acthar Gel [package insert].Mallinckrodt ARD Inc., March 2019.
2. Gold Standard, Inc. Corticotropin, ACTH. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2012. URL: http://www.clinicalpharmacology.com. Accessed August 3, 2017.
3. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. *Neurology*. 1989;39:969–971.
4. Barnes MP, Bateman DE, Cleland PG, et al. Intravenous methylprednisolone for multiple sclerosis in relapse. *J Neurol Neurosurg Psych*. 1985;48:157-159.

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Change Control	
2/2014	Annual review with no change to coverage.
5/2014	Review to add to cycle with other programs. No change to criteria. Updated background.
5/2015	Annual review with no change to clinical coverage.
10/2015	Administrative update. Added Maryland Continuation of Care.
7/2016	Added Indiana and West Virginia coverage information.
9/2016	Annual review. No change to clinical coverage. Updated references.
11/2016	Administrative change. Added California coverage information.
9/2017	Annual review. Updated state mandate language.
9/2018	Annual review. No changes to criteria.
9/2019	Annual review. No changes to criteria. Updated references.
9/2020	Annual review. No changes to coverage criteria. Removed “H.P.” from name per package insert.