

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3000-17
Program	Step Therapy
Medication	Repository Corticotropins - Acthar Gel® (repository corticotropin injection), Purified Cortrophin Gel™ (repository corticotropin injection USP)
P&T Approval Date	5/2012, 04/2013, 2/2014, 5/2014, 5/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 3/2022, 3/2023, 3/2024, 3/2025
Effective Date	6/1/2025

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial of or contraindication to corticosteroids before providing coverage for Acthar Gel® (repository corticotropin injection) or Purified Cortrophin Gel™ (Repository corticotropin injection USP).

Acthar Gel® (repository corticotropin injection) is an adrenocorticotrophic hormone (ACTH) analogue that is Food and Drug Administration (FDA) indicated for¹:

- **Infantile Spasms:** As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.
- **Multiple Sclerosis:** For treatment of acute exacerbations of multiple sclerosis in adults.

Per labeling, it is suggested that Acthar may be used in the following conditions, however, it is not indicated for them¹:

- **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), and ankylosing spondylitis.
- **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- **Dermatologic Diseases:** Severe erythema multiforme and Stevens-Johnson syndrome.
- **Allergic States:** Serum sickness.
- **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, and anterior segment inflammation.
- **Respiratory Diseases:** Symptomatic sarcoidosis.
- **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.

Purified Cortrophin Gel™ (repository corticotropin injection USP) is an adrenocorticotrophic hormone (ACTH) analogue indicated for²:

- **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, and acute gouty arthritis.
- **Collagen diseases:** During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).

- **Dermatologic diseases:** Severe erythema multiforme (Stevens-Johnson syndrome) and severe psoriasis.
- **Allergic states:** Atopic dermatitis and serum sickness.
- **Ophthalmic diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.
- **Respiratory diseases:** Symptomatic sarcoidosis.
- **Edematous states:** 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.
- **Nervous system:** Acute exacerbations of multiple sclerosis.

Additional evidence supports the use of repository corticotropin in opsoclonus-myoclonus syndrome.³⁻⁵

In cases where conditions are corticosteroid-responsive, corticosteroid therapy is considered the treatment of choice.⁶⁻⁷

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 and Purified Cortrophin 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., Kinsbourne Syndrome)

1. **Acthar Gel and Purified Cortrophin Gel** will be approved based on the following criterion:

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

Authorization will be issued for 12 months.

C. Other Conditions

1. **Acthar Gel and Purified Cortrophin 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]. Bridgewater, NJ: Mallinckrodt ARD LLC.; February 2024.
2. Purified Cortrophin Gel [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; December 2024.
3. Pranzatelli MR, Huang YY, Tate E, et al. Monoaminergic effects of high-dose corticotropin in corticotropin-responsive pediatric opsoclonus-myoclonus. *Mov Disord.* 1998;13(3):522-528.
4. Pranzatelli MR, Chun KY, Moxness M, Tate ED, Allison TJ. Cerebrospinal fluid ACTH and cortisol in opsoclonus-myoclonus: effect of therapy. *Pediatr Neurol.* 2005;33(2):121-126.
5. Tate ED, Pranzatelli MR, Verhulst SJ, et al. Active comparator-controlled, rater-blinded study of corticotropin-based immunotherapies for opsoclonus-myoclonus syndrome [published correction appears in *J Child Neurol.* 2012 Oct;27(10):1364. Dosage error in article text]. *J Child Neurol.* 2012;27(7):875-884.
6. Filippini G, Brusafferri F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. *Cochrane Database Syst Rev.* 2000;2000(4):CD001331.
7. Olek MJ, Howard J. Treatment of acute exacerbations of multiple sclerosis in adults. In: Post TW, ed. *UpToDate.* UpToDate; 2024. Accessed January 30, 2025. [Treatment of acute exacerbations of multiple sclerosis in adults - UpToDate.](#)

Program	Step Therapy - Repository Corticotropins - Acthar Gel (repository corticotropin injection), Purified Cortrophin Gel (repository corticotropin injection USP)
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.
10/2021	Annual review. No changes to coverage criteria. Updated references.
3/2022	Added Purified Cortrophin Gel to program with same coverage criteria as Acthar Gel. Updated program name, background and references.
3/2023	Annual review with no changes. Updated references.
3/2024	Annual review with no changes to criteria. Updated references.
3/2025	Annual review with no changes to step criteria. Updated background and references.