UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2028-12
Program	Prior Authorization/Medical Necessity
Medication	Repository Corticotropins - Acthar Gel® (repository corticotropin injection), Purified Cortrophin Gel™ (repository corticotropin injection USP)
P&T Approval Date	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:

Acthar Gel® (repository corticotropin injection) and Purified Cortrophin Gel™ (repository corticotropin injection USP) are adrenocorticotropic hormone (ACTH) analogues **medically necessary** for:

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

The Acthar Gel and Purified Cortrophin Gel package inserts have listed other conditions in which they may be used without providing supporting clinical evidence. Since Acthar Gel and Purified Cortrophin Gel are more costly than alternatives that are at least as likely to produce equivalent therapeutic results, UHCP has determined that use of Acthar Gel and Purified Cortrophin 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]:

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

1. **Initial Therapy**

   a. **Acthar Gel and Purified Cortrophin Gel** will be approved based on **both** of the following criteria

      (1) Diagnosis of infantile spasms (West Syndrome)

      -AND-

      (2) Patient is less than 2 years of age

   Authorization will be issued for 4 weeks.

2. **Reauthorization**

All requests for reauthorization will be **denied**. 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. **Acthar Gel and Purified Cortrophin Gel** will be approved based on the following criteria:

(1) Diagnosis of opsoclonus-myoclonus syndrome (Kinsbourne Syndrome)

Authorization will be issued for 3 months.

2. **Reauthorization**

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

[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:

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

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, 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.
4. 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.

Program	Prior Authorization/Medical Necessity – Repository Corticotropins - Acthar Gel (repository corticotropin injection), Purified Cortrophin Gel (repository corticotropin injection USP)
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.
9/2019	Annual review. 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 change to coverage criteria. Updated references.
3/2024	Annual review with no changes to criteria. Updated references.
3/2025	Annual review. Removed references to OptumRx throughout criteria without changes to intent of criteria. Updated background and references.