UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1000-13
Program	Prior Authorization/Notification
Medication	Repository Corticotropins - Acthar Gel® (Repository corticotropin injection), Purified Cortrophin Gel™ (Repository corticotropin injection USP)
P&T Approval Date	5/2012, 4/2013, 2/2014, 5/2014, 5/2015, 4/2016, 4/2017, 4/2018, 4/2019, 4/2020, 5/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

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 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 Gel 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), and ankylosing spondylitis.[1]
- **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus andsystemic 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]

Purified Cortrophin Gel™ (Repository corticotropin injection USP) is an adrenocorticotropic hormone (ACTH) analogue indicated for:

- **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. Acute gouty arthritis.[5]
- **Collagen diseases:** During an exacerbation or as maintenance therapy in selected cases of: Systemic lupus erythematosus. Systemic dermatomyositis (polymyositis).[5]
- **Dermatologic diseases:** Severe erythema multiforme (Stevens-Johnson syndrome). Severe psoriasis.[5]

- **Allergic states:** Atopic dermatitis. Serum sickness.[5]
- **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. Anterior segment inflammation.[5]
- **Respiratory diseases:** Symptomatic sarcoidosis.[5]
- **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.[5]
- **Nervous system:** Acute exacerbations of multiple sclerosis.[5]

Additional evidence supports the use of repository corticotropin 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]:

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

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

Authorization will be issued for 3 weeks by OptumRx.

2. **Reauthorization**

a. **Acthar Gel and Purified Cortrophin 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. **Acthar Gel and Purified Cortrophin 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.

D. Other Conditions:

1. **Initial Authorization**

a. **Purified Cortrophin Gel** will be approved based on **one** the following criteria:

(1) **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, or acute gouty arthritis.

-OR-

(2) **Collagen diseases:** During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus or systemic dermatomyositis (polymyositis).

-OR-

(3) **Dermatologic diseases:** Severe erythema multiforme (Stevens-Johnson syndrome) or severe psoriasis.

-OR-

(4) **Allergic states:** Atopic dermatitis or serum sickness.

-OR-

(5) **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, or anterior segment inflammation.

-OR-

(6) **Respiratory diseases:** Symptomatic sarcoidosis.

-OR-

(7) **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.

Authorization will be issued for 12 months by OptumRx.

2. **Reauthorization**

a. **Purified Cortrophin Gel** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Purified Cortrophin Gel therapy

Authorization will be issued for 12 months by OptumRx.

[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.; June 2023.
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.
5. Purified Cortrophin Gel [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; October 2023.

Program	Prior Authorization/Notification - H.P. Acthar Gel (Repository corticotropin injection)
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.
4/2019	Annual review with no change to clinical coverage. Updated reference.
4/2020	Annual review with no change to clinical coverage. Updated reference.
5/2021	Annual review with no change to clinical coverage. Updated reference.
3/2022	Added Purified Cortrophin Gel to program. Updated program name, background and references.
3/2023	Annual review with minor formatting updates to coverage criteria. Added state mandate footnote and updated references.
3/2024	Annual review with no changes to criteria. Updated references.