Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCEND017.0625	**ENDOCRINE & METABOLIC DRUGS** **CORTICOTROPIN GEL** **H. P. Acthar Gel®** (repository corticotropin injection) **Cortrophin® Gel** (corticotropin injection)
Effective Date: 8/1/2025	**Review/Revised Date**: 11/09, 04/10, 06/11, 06/12, 04/13, 04/14, 04/15, 12/15, 02/16, 10/16, 03/17, 03/18, 02/19, 02/20, 03/21, 02/22, 03/23, 03/24, 03/25, 06/25 (JEF)
Original Effective Date: 01/09	**P&T Committee Meeting Date**: 12/09, 04/10, 06/11, 06/12, 04/13, 04/14, 04/15, 12/15, 04/16, 10/16 , 12/16, 04/17, 04/18, 04/19, 04/20, 04/21, 04/22, 04/24, 04/25, 06/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Commercial
Medicare Part B: self-administered drug exclusion
Medicaid

POLICY CRITERIA:

COVERED USES:
Infantile spasms

REQUIRED MEDICAL INFORMATION:
For infantile spasm: H.P. Acthar Gel® will be approved for one month of therapy at the following dose: 75 units/m(2) injected intramuscularly twice daily

Reauthorization for infantile spasm for H.P. Acthar Gel® will require medical rationale for continuing treatment, as recommended treatment duration is for two weeks followed by two-week taper to avoid adrenal insufficiency.

EXCLUSION CRITERIA:
All other indications beside infantile spasms are not considered medically necessary and are excluded for coverage.

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:

Initial authorization/reauthorization will be approved for one month.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

H.P. Acthar Gel® is a highly purified sterile preparation of the adrenocorticotropic hormone (ACTH) in 16% gelatin to provide a prolonged release after intramuscular or subcutaneous injection. ACTH stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances.

Cortrophin® Gel is a sterile preparation containing 80 USP units per mL and it contains 0.5% phenol (as preservative), 15.0% gelatin (for prolonged activity), water for injection, and the pH is adjusted with hydrochloric acid and sodium hydroxide. Additionally, it contains porcine derived ACTH (1-39). Cortrophin® Gel comes in a prefilled syringe presentation.

FDA APPROVED INDICATIONS:

H.P. Acthar Gel®

Infantile spasms: Monotherapy for the treatment of infantile spasms in infants and children under two years of age.

Multiple Sclerosis: 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.

Rheumatic Disorders: 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.

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

Dermatologic Diseases: Severe erythema multiforme, 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; 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.

Cortrophin® Gel

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.

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

Dermatologic Diseases: Severe erythema multiforme (Stevens-Johnson syndrome); severe psoriasis.

Allergic States: Atopic dermatitis; Serum sickness.

Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis; keratitis; iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis; 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.

Nervous system: Acute exacerbations of multiple sclerosis

POSITION STATEMENT:
H.P. Acthar Gel® and Cortrophin® Gel have limited therapeutic value in those conditions responsive to corticosteroid therapy. In such cases, corticosteroid therapy is considered the treatment of choice.

H.P. Acthar Gel® and Cortrophin® Gel often acts by masking symptoms of other diseases/disorders without altering the course of the other disease/disorder. Patients should be monitored carefully during and for a period following discontinuation of therapy for signs of infection, abnormal cardiac function, hypertension, hyperglycemia, change in body weight, and fecal blood loss.

Cortrophin® Gel was approved by the FDA as a new formulation or new manufacturer of corticotropin injection. No additional clinical trial information is listed within the Cortrophin® Gel package insert. According to the manufactuer, Cortrophin® Gel prefilled syringe formulation “reduces administration steps for patients using Cortrophin Gel.”

Infantile Spasms
The American Academy of Neurology updated its guidelines for infantile spasms in 2012 and states that:

- "The evidence is insufficient to recommend the use of prednisolone, dexamethasone, and methylprednisolone as being as effective as ACTH for short-term treatment of infantile spasms (Level U)."
    - Level U means that "Data are inadequate or conflicting; treatment, test or predictor unproven"
- ACTH (Level B) or vigabatrin (VGB) (Level C) may be offered for short-term treatment of infantile spasms. Evidence suggests that ACTH may be offered over VGB (Level C).
- Low-dose ACTH should be considered as an alternative to high-dose ACTH for treatment of infantile spasms (Level B). Evidence suggests that low-dose ACTH is probably as effective as high-dose ACTH for short-term treatment of infantile spasms (Class I and II evidence). [3]

The International League Against Epilepsy (ILAE) published recommendations for the management of infantile spasms in 2015. Treatment options for infantile epileptic spasms are:

- Low or high dose ACTH – considered "probably effective" with strong strength of efficacy (Level B)
- Prednisone – considered "possibly effective" with weak strength of efficacy (Level C)
- Vigabatrin – considered "possibly effective" with weak strength of efficacy (Level C), except with tuberous sclerosis complex

The ILAE recommendations state to reassess at two weeks (expert opinion) and if no spasms, then to stop ACTH therapy. If spasms continue, alternative therapies may be tried.[4]

Multiple Sclerosis: ACTH does not improve MS exacerbations through any pathway but through stimulating corticosteroid production, hence corticosteroids should produce the same, if not better results at a fraction of the cost.

Adrenal insufficiency: Cosyntropin test takes significantly less time (30 to 60 minutes); by contrast, an overnight wait is required for the ACTH test. Cosyntropin may also be less immunogenic than ACTH.

Rheumatic Disorders: Use of ACTH is not supported in the 2021 American College of Rheumatology Guidelines. Cortrophin® Gel contains an FDA approved indication for acute gouty arthritis. However, data is limited for this indication. ANI pharmaceuticals, the manufacturer of Cortrophin® Gel, announced on May 22,

2025, initiation of a Phase 4 clinical trial to compare the safety and efficacy of two dose levels (40 USP units and 80 USP units) of Cortrophin® Gel for the treatment of acute gout flares.[8]

The use of H.P. Acthar Gel is not considered medically necessary in any conditions other than infantile spasms.

BILLING GUIDELINES AND CODING:

CODES*	
J0801	Injection, corticotropin (acthar gel), up to 40 units
ADMINISTRATION	
96372	Ther/proph/diag inj sc/im
MODIFIERS†	
-JA	Administered Intravenously
-JB	Administered Subcutaneously

*Coding Notes:
• The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
† Must be billed with the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for the subcutaneous injection form of administration
• HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCE/RESOURCES:

1. H.P. Acthar Gel® Package Insert. Bedminster, NJ: Mallinckrodt ARD LLC; Dec 2024.
2. H.P. Acthar Gel®. In DRUGDEX® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.
3. Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: medical treatment of infantile spasms. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2012 Jun 12;78(24):1974-80
4. International League Against Epilepsy (ILAE) Working Group. Summary of recommendations for the management of infantile seizures: Task Force

Report for the ILAE Commission of Pediatrics. *Epilepsia.* 2015; 56(8): 1185–1197.
5. National Institute for Health and Care Excellence (NICE). Multiple sclerosis in adults: management. 2019. Accessed March 3, 2021. Available at: https://www.nice.org.uk/guidance/cg186/chapter/Recommendations#relapse-and-exacerbation.
6. 2021 American College of Rheumatology Guideline for theTreatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939.
7. Trial of purified cortophin gel for the treatment of acute gout flare. ANI Pharmaceuticals, Inc. May 22, 2025. Available at: https://investor.anipharmaceuticals.com/news-releases/news-release-details/ani-pharmaceuticals-announces-initiation-phase-4-clinical-trial.
8. Cortrophin® Gel Package Insert. Baudette, MN: ANI Pharmaceuticals, Inc. March 2025.
9. Cortrophin® Gel. In DRUGDEX® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.