



## Drug Coverage Policy

Effective Date .....7/15/2025

Coverage Policy Number.....IP0374

Policy Title.....Cortrophin Gel

# Repository Corticotropin - Cortrophin Gel

- Purified Cortrophin™ Gel (repository corticotropin subcutaneous and intramuscular injection – ANI)

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### INSTRUCTIONS FOR USE

*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

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## Coverage Policy

**Repository corticotropin (Purified Cortrophin Gel) is considered to be experimental, investigational, or unproven due to insufficient data establishing safety, efficacy, and improved health outcomes for any condition regardless of U.S. Food and Drug Administration (FDA) approval status. Criteria will be updated as new published data are available** (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Ankylosing Spondylitis.** The American College of Rheumatology guidelines for the treatment of ankylosing spondylitis do not convey a role for ACTH in this condition.<sup>9,10</sup>
2. **Dermatomyositis or Polymyositis.** British Society for Rheumatology guidelines on the management of pediatric, adolescent, and adult patients with idiopathic inflammatory myopathy (2022) do not cite ACTH as an agent to utilize in patients with such conditions.<sup>11</sup>
3. **Diabetic Nephropathy.** ACTH is not a cited therapy or the standard of care for the management of chronic kidney disease in patients with diabetes.<sup>3,12</sup>
4. **Glomerular Kidney Diseases.**  
Note: Diagnoses can include nephrotic syndrome, membranous nephropathy, immunoglobulin A nephropathy, minimal change disease, infection-related glomerulonephritis, focal segmental glomerulosclerosis, and membranoproliferative glomerulonephritis. ACTH is not prominent in related guidelines from KDIGO (2021) and there is a lack of quality evidence regarding ACTH to support its use.<sup>3</sup> KDIGO guidelines for the management of anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (2024) do not mention ACTH.<sup>21</sup>
5. **Gout.** American College of Rheumatology guidelines for gout (2020) recommend other therapies beside ACTH for gout flare management (e.g., colchicine, non-steroidal anti-inflammatory drugs, or glucocorticoids).<sup>7</sup>
6. **Infantile Spasms, Treatment.** Purified Cortrophin Gel is not FDA-approved for this use.<sup>1</sup>
7. **Juvenile Idiopathic Arthritis.** Related guidelines from the American College of Rheumatology regarding the treatment of juvenile idiopathic arthritis (2021) do not mention ACTH as having a role for this disease.<sup>13</sup>
8. **Lupus Nephritis.** The KDIGO guidelines for the management of glomerular disease (2021) cite many other agents besides ACTH for the management of this condition.<sup>3</sup> The European League Against Rheumatism-European Renal Association-European Dialysis and Transplantation Association joint recommendations on the management of lupus nephritis do not cite ACTH as a therapy to use in this condition.<sup>14</sup> Updated KDIGO guidelines were published regarding the management of lupus nephritis (2024) and do not mention ACTH.<sup>20</sup>
9. **Multiple Sclerosis, Acute Exacerbations.** High-dose corticosteroids, usually intravenous methylprednisolone, are the accepted standard of care short-term for acute relapses or exacerbations.<sup>4</sup>
10. **Ophthalmic Conditions.** Only limited data describes the use of ACTH in ophthalmic-related conditions (e.g., acute optic neuritis, keratitis, retinal vasculitis).<sup>2,15-17</sup> Prospective data are needed to more rigorously define the efficacy and safety of ACTH in ocular disease.

11. **Psoriatic Arthritis.** The American College of Rheumatology/National Psoriasis Foundation guidelines for the treatment of psoriatic arthritis (2018) do not mention a role for ACTH in this condition.<sup>18</sup>
12. **Rheumatoid Arthritis.** The American College of Rheumatology guidelines for the treatment of rheumatoid arthritis (2021) do not mention a role for ACTH in this disease state.<sup>19</sup>
13. **Sarcoidosis.** The European Respiratory Society published guidelines on the treatment of sarcoidosis (2021).<sup>8</sup> Repository corticotropin use should be reserved for patients who have failed prior treatments (e.g., steroids, antimetabolites). Only limited data are available. Repository corticotropin should be considered in a case by case basis only when other therapies are not effective or tolerated.

## Overview

### OVERVIEW

Cortrophin Gel, a porcine derived purified corticotrophin (adrenocorticotrophic hormone [ACTH] {1-39}) product, is indicated in the following disorders:<sup>1</sup>

- **Allergic states**, such as atopic dermatitis and serum sickness.
- **Collagen diseases**, during an exacerbation or as a maintenance therapy in selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- **Dermatologic diseases**, such as severe erythema multiforme (Stevens-Johnson syndrome) and severe psoriasis.
- **Edematous state** including 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.
- **Respiratory diseases** such as symptomatic sarcoidosis.
- **Rheumatoid disorders**, as an 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.
- **Ophthalmic diseases** including 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.

### Clinical Efficacy

A recent review regarding repository corticotropin found few randomized controlled trials supporting the clinical benefit of repository corticotropin or ACTH for various conditions (e.g., use in rheumatoid arthritis, ankylosing spondylitis, optic neuritis, systemic lupus erythematosus, and nephrotic syndrome).<sup>2</sup> Most data suggest that repository corticotropin or ACTH was not superior to corticosteroids for treating relapses in patients with multiple sclerosis.

### Guidelines

Several guidelines discuss repository corticotrophin or ACTH.

- **Kidney Disease Improving Global Outcomes (KDIGO)** published clinical practice guidelines for the management of glomerular disease (2021).<sup>3</sup> This includes diagnoses such as nephrotic syndrome, membranous nephropathy, immunoglobulin A nephropathy, minimal change disease, infection-related glomerulonephritis, focal segmental glomerulosclerosis, membranoproliferative glomerulonephritis, and lupus nephritis. ACTH is not prominent in the guidelines and there is a lack of quality evidence regarding ACTH.<sup>3</sup> Updated KDIGO

guidelines were published regarding the management of lupus nephritis (2024), as well as for the management of anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (2024).<sup>20,21</sup> ACTH is not mentioned in the guidelines.

- The **National Multiple Sclerosis Society** has recommendations regarding corticosteroids in the management of multiple sclerosis relapses or exacerbations.<sup>4</sup> High-dose corticosteroids are the accepted standard of care short-term. The most common regimen is 500 to 1,000 mg of intravenous methylprednisolone given daily for 3 to 5 days, with or without an oral steroid tapering regimen (most often prednisone) for 1 to 3 weeks. ACTH and high-dose intravenous methylprednisolone have been shown to possess similar efficacy in the management of multiple sclerosis relapses.<sup>5</sup>
- The **American College of Rheumatology** has many guidelines regarding use in rheumatoid-type conditions.<sup>6</sup> ACTH does not have a prominent role and is generally not recommended for use in any of the related American College of Rheumatology guidelines.
- The **American College of Rheumatology** has guidelines for the management of gout (2020).<sup>7</sup> For gout flare management, using colchicine, non-steroidal anti-inflammatory drugs, or glucocorticoids (oral, intraarticular, or intramuscular) are appropriate first-line therapy for gout flare over interleukin-1 inhibitors or ACTH.
- The **European Respiratory Society** published guidelines on the treatment of sarcoidosis (2021).<sup>8</sup> Repository corticotropin use should be reserved for patients who have failed prior treatments (e.g., steroids, antimetabolites). Only limited data are available. Repository corticotropin should be considered in a case by case basis only when other therapies are not effective or tolerated.

## Coding Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

### Considered Experimental/Investigational/Unproven:

HCPCS Codes	Description
J0802	Injection, corticotropin (ANI), up to 40 units

## References

1. Purified Cortrophin™ Gel subcutaneous and intramuscular injection [prescribing information]. Baudette, MN: ANI; October 2023.
2. Tran KA, Harrod C, Bourdette DN, et al. Characterization of the clinical evidence supporting repository corticotropin injection for FDA-approved indications. A scoping review. *JAMA Intern Med.* 2022;182(2):206-217.
3. Kidney Disease: Improving Global Outcomes Glomerular Diseases Working Group. KDIGO 2021 clinical practice guidelines for the management of glomerular diseases. *Kidney Int.* 2021;100:S1-S276.
4. National Multiple Sclerosis Society. Expert Opinion Paper. National Clinical Advisory Board of the National Multiple Sclerosis Society. Treatment Recommendations for Physicians. Recommendations Regarding Corticosteroids in the Management of Multiple Sclerosis. Available at: [http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/ExpOp\\_Steroids.pdf](http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/ExpOp_Steroids.pdf). Accessed on April 19, 2024.

5. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapses in MS. *Neurology*. 1989;39:969-971.
6. American College of Rheumatology. Clinical Practice Guidelines. Available at: <https://rheumatology.org/clinical-practice-guidelines>. Accessed on April 19, 2024.
7. Fitzgerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. *Arthritis Care Res (Hoboken)*. 2020;72(6):744-760.
8. Baughman RP, Valeyre D, Korsten P, et al. ERS clinical practice guidelines on treatment of sarcoidosis. *Eur Respir J*. 2021;58(6):2004079.
9. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613.
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11. Oldroyd AGS, Lilleker JB, Amin T, et al. British Society for Rheumatology guideline on management of paediatric, adolescent and adult patients with idiopathic inflammatory myopathy. *Rheumatology*. 2022;61(5):1760-1768.
12. American Diabetes Association Professional Practice Committee. Chronic Kidney Disease and Risk Management: Standards of Medical Care in Diabetes-2024. *Diabetes Care*. 2024;47(1):S219-S230.
13. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
14. Fanouriakis A, Kostopoulou M, Cheema K, et al. 2019 Update of the Joint European League Against Rheumatism and European Renal Association-European Dialysis and Transplant Association (EULAR/ERA-EDT) recommendations for the management of lupus nephritis. *Ann Rheum Dis*. 2020;79:713-732.
15. Crane AB, Sharon Y, Chu DS. Use of adrenocorticotrophic hormone in ophthalmology. *J Ocul Pharmacol Ther*. 2020;36(9):661-667.
16. Wirta D, McLaurin E, Ousler G, et al. Repository corticotropin injection (Acthar® gel) for refractory severe noninfectious keratitis: efficacy and safety from a phase 4, multicenter, open-label study. *Ophthalmol Ther*. 2021;10:1077-1092.
17. Anesi SD, Chang PY, Maleki A, et al. Treatment of noninfectious retinal vasculitis using subcutaneous repository corticotropin injection. *J Ophthalmic Vis Res*. 2021;16:219-233.
18. Singh JA, Guyatt G, Ordie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32.
19. Fraenkiel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res (Hoboken)*. 2021;73(7):924-939.
20. Kidney Disease Improving Global Outcomes lupus nephritis work group. KDIGO 2024 clinical practice guidelines for the management of lupus nephritis. *Kidney Int*. 2024;105(Suppl 1S):S1-S69.
21. Kidney Disease Improving Global Outcomes ANCA Vasculitis Work Group. KDIGO 2024 clinical practice guideline for the management of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis. *Kidney Int*. 2024;105(Suppl 3S):S71-S116.
22. cytoplasmic antibody (ANCA)-associated vasculitis. *Kidney Int*. 2024;105(Suppl 3S):S71-S116.

## Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	<b>Policy Name Change: Updated</b> Policy Name from "Purified Cortrophin Gel" to "Repository Corticotropin - Cortrophin Gel." <b>Conditions Not Covered: Removed</b> the statement "Purified Cortrophin Gel is FDA approved for the treatment of allergic states, collagen diseases, dermatologic diseases, edematous state, acute exacerbations of multiple sclerosis, respiratory diseases, rheumatoid disorders and ophthalmic diseases; however, there is insufficient clinical efficacy data supporting these uses." <b>Added</b> the following conditions: Ankylosing Spondylitis, Dermatomyositis or Polymyositis, Diabetic Nephropathy, Glomerular Kidney Diseases, Gout, Treatment of Infantile Spasms, Juvenile Idiopathic Arthritis, Lupus Nephritis, Acute Exacerbations of Multiple Sclerosis, Ophthalmic Conditions, Psoriatic Arthritis, Rheumatoid Arthritis, and Sarcoidosis.	08/15/2024
Selected revision	<b>Updated HCPCS Coding:</b> <b>Added</b> J0802	1/15/2025
Annual Revision	<b>No criteria changes</b>	7/15/2025

The policy effective date is in force until updated or retired.

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