Clinical Policy: Repository Corticotropin Injection (H.P. Acthar Gel, Purified Cortrophin Gel)

Reference Number: CP.PHAR.168
Effective Date: 03.01.16
Last Review Date: 02.24
Line of Business: Commercial, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Repository corticotropin injection (H.P. Acthar® Gel, Purified Cortrophin™ Gel) is adrenocorticotropic hormone (ACTH) in gelatin.

FDA Approved Indication(s)

H.P. Acthar Gel is indicated for the treatment of infantile spasms in infants and children under 2 years of age as monotherapy

H.P. Acthar Gel and Purified Cortrophin Gel are indicated for the treatment of acute exacerbations of multiple sclerosis (MS) in adults

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that H.P. Acthar Gel and Purified Cortrophin Gel are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. West Syndrome (Infantile Spasms) (must meet all)**:**

1. Diagnosis of West syndrome (infantile spasms);
2. Request is for H.P. Acthar Gel;
3. Diagnosis is confirmed by electroencephalogram (EEG);
4. Prescribed by or in consultation with a neurologist;
5. Age < 2 years;
6. Dose does not exceed 150 U/m^2 per day (divided into twice daily injections of 75 U/m^2).

Approval duration: 1 month

B. Multiple Sclerosis (must meet all)**:**

1. Diagnosis of MS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Prescribed for acute exacerbations of MS;

5. Failure of a recent (within the last 30 days) trial of at least a 7-day course of corticosteroid therapy for acute exacerbations of MS, unless contraindicated or clinically significant adverse effects are experienced;
6. Member has not received treatment with H.P. Acthar Gel or Purified Cortrophin Gel for the current MS exacerbation;
7. Member has been adherent to disease modifying therapy for MS (e.g., Aubagio®, Avonex®, Betaseron®, Copaxone®, Gilenya®, Plegridy®, Rebif®);
8. For H.P. Acthar Gel requests, member must use Purified Cortrophin Gel, if available, unless contraindicated or clinically significant adverse effects are experienced;
9. Dose does not exceed 120 units (1.5 mL) per day and 6 vials total (*see Appendix D*).

Approval duration: 3 weeks

C. Nephrotic Syndrome (must meet all)**:**

1. Diagnosis of nephrotic syndrome associated with one of the following (a - f):
   a. Idiopathic membranous nephropathy (IMN);
   b. Focal segmental glomerulosclerosis;
   c. Minimal change disease (MCD);
   d. Membranoproliferative glomerulonephritis;
   e. Lupus nephritis;
   f. IgA nephropathy;
2. Prescribed by or in consultation with a nephrologist;
3. Age > 2 years;
4. Failure of oral corticosteroid therapy, unless contraindicated or clinically significant adverse effects are experienced;
5. For IMN and MCD: Failure of cyclophosphamide, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of two of the following, unless clinically significant adverse effects are experienced or all are contraindicated: tacrolimus, cyclosporine, mycophenolate, rituximab;
7. For H.P. Acthar Gel requests, member must use Purified Cortrophin Gel, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. Dose does not exceed 80 units (1 mL) per day.

Approval duration: 3 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. West Syndrome (Infantile Spasms) (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Age < 2 years;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 150 U/m^2 per day (divided into twice daily injections of 75 U/m^2).

Approval duration: 1 month (one renewal limit)

B. Multiple Sclerosis

1. Re-authorization is not permitted. H.P. Acthar is not indicated for continuous use for this indication. Members must meet the initial approval criteria.

Approval duration: Not applicable

C. Nephrotic Syndrome (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. For H.P. Acthar Gel requests, member must use Purified Cortrophin Gel, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed 80 units (1 mL) per day.

Approval duration: 3 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid, or evidence of coverage documents;

B. The following conditions have not been proven in well-designed clinical trials and use is considered experimental:

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;
2. Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus; systemic dermatomyositis (polymyositis);
3. Dermatologic diseases: severe erythema multiforme, Stevens-Johnson syndrome;
4. Allergic states: serum sickness;
5. 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;
6. Respiratory diseases: symptomatic sarcoidosis.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACTH: adrenocorticotropic hormone
EEG: electroencephalogram
FDA: Food and Drug Administration
IMN: idiopathic membranous nephropathy
MCD: minimal change disease
MS: multiple sclerosis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
tacrolimus (Prograf®)	Nephrotic syndrome: 0.05-0.075 mg/kg/day PO in two divided doses 12 hours apart	0.075 mg/kg/day
cyclosporine (Neoral®, Sandimmune®)	Nephrotic syndrome: 3.5-5 mg/kg/day PO in two equally divided doses 12 hours apart	5 mg/kg/day
cyclophosphamide	Nephrotic syndrome: 20 mg/kg/day PO for a 6-month course with alternating monthly cycles of PO and IV corticosteroids	20 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
mycophenolate (CellCept®)	Nephrotic syndrome: 2-3 g/day PO	3 g/day
Rituxan®, Riabni™, Ruxience™, Truxima® (rituximab)	Nephrotic syndrome: 375 mg/m^2 IV every week	375 mg/m^2/week
methylprednisolone (Medrol®, Solu-Medrol®)	Acute exacerbation of multiple sclerosis: IM: 160 mg IM daily for 1 week, followed by 64 mg every other day for 1 month Oral: 160 mg PO per day for 1 week, followed by 64 mg every other day for 1 month	160 mg/day
prednisone (Deltasone®)	Acute exacerbation of multiple sclerosis: 200 mg/day PO for 1 week, followed by 80 mg PO every other day for 1 month	200 mg/day
dexamethasone (Decadron®)	Acute exacerbation of multiple sclerosis: 30 mg PO QD for 1 week followed by 4 to 12 mg PO every other day for 1 month	30 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Intravenous administration;
  - Patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin;
  - Treatment of FDA approved indications accompanied by primary adrenocortical insufficiency or adrenocortical hyperfunction;
  - H.P. Acthar Gel Only:
    - Administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of H.P Acthar Gel;
    - Children under 2 years of age with suspected congenital infections;
- Boxed warning(s): none reported

Appendix D: General Information

- Common adverse reactions for H.P. Acthar Gel are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain.
- The initial approval of H.P. Acthar Gel occurred prior to the Kefauver-Harris amendment to the Federal Food, Drug and Cosmetic Act of 1962, which introduced the requirement of "substantial evidence" of two adequate and well controlled trials. At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing

patients with conditions originally treated with Acthar powder that were transferred to treatment with Acthar Gel and gave dosing guidance for treatment of these individual conditions.

- The efficacy HP Acthar Gel has in the following conditions has not been proven in well-designed clinical trials and its use is considered experimental.
  - 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
  - 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
- Although H.P. Acthar Gel use in nephrotic syndrome has not been evaluated in well-designed clinical trials, it would be appropriate to allow use after exhausting alternative treatment options with higher quality of evidence to support their use that are supported by the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines for glomerulonephritis (e.g., corticosteroids, cyclophosphamide, cyclosporine, tacrolimus, mycophenolate, Rituxan).
- For acute exacerbations in multiple sclerosis, the results of trials that analyzed direct comparisons have shown no significant differences between ACTH and methylprednisolone (MP) in both rate and degree of recovery after exacerbation. Indirect comparisons suggest a significantly greater effect of MP versus ACTH, with MP conferring greater benefit compared with ACTH (odds ratio (OR) 0.20, 95% CI 0.09 to 0.45 vs OR 0.46, 95% CI 0.28 to 0.77).
- Studies evaluating the use of ACTH in acute exacerbations of multiple sclerosis ranged from 3 to 21 days in length and evaluated a reducing course of intramuscular ACTH over 14 days, consisting of 80 units for 7 days, 40 units for 4 days, and 20 units for 3 days. To date, retreatment with ACTH has not been evaluated in clinical trials.
- For acute exacerbation of multiple sclerosis, dosage and frequency should be individualized to the patient's needs, taking into account the patient's medical condition, severity of illness, and initial response to treatment. Prolonged use may lead to adrenal insufficiency or recurrent symptoms, which make it difficult to stop treatment. It may be necessary to taper the dose and gradually discontinue.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
H.P. Acthar Gel	West syndrome (infantile spasms)	150 U/m^2 IM divided into twice daily injections of 75 U/m^2 administered over a 2-week period. After 2 weeks, H.P.	150 U/m^2/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Acthar Gel should be gradually tapered over a 2-week period	
H.P. Acthar Gel, Purified Cortrophin Gel	Acute exacerbation of MS	80-120 units IM/SC daily for 2-3 weeks	120 units/day
H.P. Acthar Gel, Purified Cortrophin Gel	Nephrotic syndrome	40-80 units IM/SC every 24-72 hours	80 units/day

VI. Product Availability

Drug Name	Availability
H.P. Acthar Gel	Multi-dose vial: 5 mL containing 80 USP units/mL
Purified Cortrophin Gel	Multi-dose vial: 1 mL, 5 mL containing 80 USP units/mL

VII. References

1. Acthar Gel Prescribing Information. Hazelwood, MO: Mallinckrodt ARD, Inc.; October 2021. Available at https://www.acthar.com/ . Accessed October 6, 2023.
2. Purified Cortrophin Gel Prescribing Information. Baudette, MN: ANI Pharmaceuticals, Inc.; June 2023. Available at: www.cortrophin.com. Accessed October 6, 2023.
3. Go CY, Mackay MT, Weiss SK, et al. Evidenced-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.* June 12, 2012; 78(24): 1974-80. *Reaffirmed May 22, 2021.*
4. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia.* October 2010; 51(10): 2175-89.
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7. Berkovich R, Bakshi R, Amezcua L, et al. Adrenocorticotropic hormone versus methylprednisolone added to interferon B in patients with multiple sclerosis experiencing breakthrough disease: A randomized, rater-blinded trial. *Ther Adv Neurol Disord.* January 2017; 10(1): 3-17.
8. Grant AR, Day GS, Ann Marrie R, et al. Practice guidelines: Disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788. Full guideline available at: https://www.aan.com/Guidelines/home/GetGuidelineContent/904.
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14. Madan A, Mijovic-Das S, Stankovic A, et al. Acthar gel in the treatment of nephrotic syndrome: A multicenter retrospective case series. *BMC Nephrol.* March 31, 2016; 17:37.
15. Thompson AJ, Kennard C, Swash M, Summers B, Yuill GM, Shepherd DI, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology 1989;39(7):969–71.
16. Clinical Pharmacology [database online]. Elsevier, Inc. Updated periodically. Available at: https://www.clinicalkey.com/pharmacology/. Accessed October 24, 2022.
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18. Rose AS, Kuzma JW, Kurtzke JF, et al. Cooperative Study in the Evaluation of Therapy in Multiple Sclerosis. ACTH vs. Placebo--Final Report. Neurology. 1968 Jun;18(6):Suppl:1-10.
19. Trautmann A, Vivarelli M, Samuel S, et al. IPNA clinical practice recommendations for the diagnosis and management of children with steroid-resistant nephrotic syndrome. Pediatric Nephrology (2020) 35: 1529-1561.
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Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0801	Injection, corticotropin (Acthar gel), up to 40 units
J0802	Injection, corticotropin (ANI), up to 40 units

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2020 annual review: no significant changes; added mL quantity limits for multiple sclerosis and nephrotic syndrome indications; references reviewed and updated.	11.04.19	02.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Revised multiple sclerosis approval duration from 4 weeks to 3 weeks and added max vial quantity of 6 vials total; revised Appendix D; references reviewed and updated.	05.11.20	08.20
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; added coding implications; references reviewed and updated.	11.04.20	02.21
Added experimental uses previously stated in Appendix D to Section III.	07.28.21	11.21
1Q 2022 annual review: RT4: added Purified Cortrophin Gel to policy; for Acthar added step through Purified Cortrophin Gel per SDC; for infantile spasm added requirement that diagnosis is confirmed by EEG per competitor analysis; references reviewed and updated.	09.21.21	02.22
Updated HCPCS Codes to include J3490 for unclassified drugs as Purified Cortrophin Gel does not yet have a specific assigned HCPCS code.	06.09.22	
Template changes applied to other diagnoses/indications and continued therapy section.	09.30.22	
1Q 2023 annual review: added the following for MS requests: Member has not received treatment with H.P. Acthar Gel or Purified Cortrophin Gel for the current MS exacerbation; references reviewed and updated.	10.24.22	02.23
Per April SDC, removed HIM line of business.	04.20.23	05.23
In Appendix D, removed statement that H.P. Acthar Gel is not FDA approved in conditions lacking efficacy established with well-designed clinical trials.	05.24.23	
Added HCPCS codes [J0801, J0802] and removed code [J0800].	10.26.23	
1Q 2024 annual review: for infantile spasm reduced approval durations from 3 to 1 month; for Purified Cortrophin Gel added 1 mL multiple dose vial formulation to Section VI; updated HCPCS codes and revised to include J0801 and J0802; references reviewed and updated.	10.06.23	02.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.