

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

Reference Number: CP.PHAR.168

Effective Date: 03/16

Last Review Date: 05/17

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for repository corticotropin injection (H.P. Acthar® Gel).

Policy/Criteria

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

I. Initial Approval Criteria

A. Infantile Spasms (must meet all):

1. Age < 2 years;
2. Diagnosis of infantile spasms;
3. Abnormal EEG confirming diagnosis of infantile spasms;
4. H.P. Acthar Gel will be used as monotherapy;
5. Prescribed daily dose does not exceed 150 U/m² (divided into twice daily intramuscular injections of 75 U/m²).

Approval duration: 3 months

B. Multiple Sclerosis (must meet all):

1. Age ≥ 18 years;
2. Prescribed by or in consultation with a neurologist;
3. Diagnosis of multiple sclerosis (MS);
4. Prescribed for acute MS exacerbations;
5. Documented adherent use of disease modifying therapy for MS;
6. Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids;
7. Prescribed daily dose does not exceed 120 units administered by intramuscular or subcutaneous injection.

Approval duration: 3 months

C. Nephrotic Syndrome (must meet all):

1. Age > 2 years;
2. Prescribed by or in consultation with a nephrologist;
3. Diagnosis of nephrotic syndrome and associated (a or b):
 - a. Systemic lupus erythematosus;
 - b. Idiopathic nephropathy/glomerulonephritis;
4. Prescribed to induce diuresis or remission of proteinuria;

5. Inadequate response or intolerance/contraindication to oral steroids;
6. Inadequate response or intolerance/contraindication to ≥ 2 of the following agents: tacrolimus, cyclosporine, mycophenolate, rituximab;
7. Prescribed daily dose does not exceed 80 units given intramuscularly or subcutaneously every 24 hours.

Approval duration: 3 months

D. Other FDA Approved Indications (must meet all):

1. Age > 2 years;
2. Diagnosis of a condition listed in Appendix B;
3. Prescribed by or in consultation with a specialist with expertise in the relevant condition;
4. Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids;
5. Documented failure of adherent use of other FDA approved agents (≥ 2 agents if available) for the relevant condition - or patient has a contraindication to the agent(s);
6. Submission of two peer-reviewed prospective clinical trials published within the last 10 years reflecting ACTH efficacy and safety for the relevant condition as part of current practice standards;
7. Prescribed daily dose does not exceed 80 units given intramuscularly or subcutaneously every 24 hours.

Approval duration: 3 months

II. Continued Approval

A. Infantile Spasms (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Age < 2 years;
3. H.P. Acthar Gel will be used as monotherapy;
4. Documentation indicating positive response to therapy;
5. Prescribed daily dose does not exceed 150 U/m^2 (divided into twice daily intramuscular injections of 75 U/m^2).

Approval duration: 3 months (one renewal limit)

B. Multiple Sclerosis (must meet all): Renewal request should be reviewed by a neurologist with expertise in MS treatment. If approved, duration of approval should be limited to 3 months.

C. Nephrotic Syndrome (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Prescribed by or in consultation with a nephrologist;
3. Documentation indicating positive response to therapy;

4. Prescribed daily dose does not exceed 80 units given intramuscularly or subcutaneously every 24 hours.

Approval duration: 3 months

D. Other FDA Approved Indications in Section I (must meet all): Renewal request should be reviewed by a physician with expertise in the relevant conditions. If approved, duration of approval should be limited to 3 months.

E. Other Diagnoses/Indications (1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 3 months (whichever is less); or

2. Refer to CP.PHAR.57 – Global Biopharm Policy.

Background

Description/Mechanism of Action:

Repository corticotropin injection is an adrenocorticotrophic hormone analogue for intramuscular or subcutaneous injection. Corticotropin and endogenous ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of corticotropin gel induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is under the influence of the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated plasma cortisol suppresses ACTH release.

Formulations:

H.P. Acthar Gel, Injection: 80 units/mL (5 mL)

- Labeled for intramuscular or subcutaneous use only

FDA Approved Indications:

H.P. Acthar Gel is an adrenocorticotrophic hormone (ACTH) analogue/intramuscular or subcutaneous injectable gel indicated for treatment of:

- **Infantile spasms:** Infants and children under 2 years of age – as monotherapy (IM injections);
- **Multiple sclerosis:** Exacerbations in adults (IM or SC injections);
- **Nephrotic syndrome:** To induce a diuresis or a remission of proteinuria in nephrotic syndrome without uremia in idiopathic nephropathy or lupus erythematosus.
- **Other indications:**
 - Rheumatic disorders: Exacerbations in psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis*, ankylosing spondylitis.
 - Collagen diseases*: Exacerbations in systemic lupus erythematosus, systemic dermatomyositis (polymyositis).
 - Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome.

CLINICAL POLICY

Repository Corticotropin Injection

- Allergic states: Serum sickness.
- Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa in keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.
- Respiratory diseases: Symptomatic sarcoidosis.

**Maintenance therapy in selected cases*

Appendices

Appendix A: Abbreviation Key

ACTH: adrenocorticotropic hormone

MS: multiple sclerosis

Appendix B: FDA Approved Indications Requiring Efficacy and Safety Documentation

System	Disease State
Rheumatic disorders	Psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis
Collagen diseases	Systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
Dermatologic diseases	Erythema multiforme, Stevens-Johnson syndrome
Allergic states	Serum sickness
Ophthalmic diseases	Keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
Respiratory diseases	Symptomatic sarcoidosis

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
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.56.H.P. Acthar and Sabril. Criteria: added contraindications; updated MS approval period 2 to 3 weeks with a week for taper if necessary; updated infantile spasm approval period to 4 weeks; updated definition of nephrotic syndrome for children and adults; included all FDA labeled indications and criteria for each. Background: limited to Description/MOA and FDA approved indications.	02/16	

CLINICAL POLICY
Repository Corticotropin Injection

Reviews, Revisions, and Approvals	Date	Approval Date
Appendices: added abbreviation key; removed the following appendices - contraindications, tentative treatment plan, examples of side effects - and included pertinent information from appendices directly into criteria.		
Added criteria for failure of oral corticosteroids for MS. Added criteria for rheumatic diseases, collagen disorders, ophthalmic diseases, and “other indications.”	03/16	03/16
Removed labeled indications and criteria that do not have clinical studies showing effectiveness and superiority over corticosteroid therapy. Retained criteria for infantile spasms and MS. For MS, added requirement for adherent use of disease modifying therapy and contraindications to both oral and injectable glucocorticoids Modified approval duration for acute MS exacerbation to max 3 weeks based on PI.	05/16	05/16
Safety information removed. Infantile spasms approval duration is increased from 4 weeks to 3 months and continuing approval x 1 is added. MS approval duration is increased from 4 weeks to 3 months. Continued approval is per Medical Director review. Nephrotic syndrome criteria are added for recalcitrant cases. Other PI indications are added for recalcitrant cases with the qualification that requests be supplemented by peer-reviewed literature. Continued approval is per Medical Director review. References updated.	05/17	05/17

References

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Repository Corticotropin Injection

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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

CLINICAL POLICY

Repository Corticotropin Injection



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.

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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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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