LOUISIANA BLUE

Repository Corticotropin Injection

Policy # 00230
Original Effective Date: 07/16/2008
Current Effective Date: 07/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Vigabatrin (Sabril®)‡ is addressed separately in medical policy 00244.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider repository corticotropin injection (Acthar® Gel)‡ for the treatment of infantile spasms (West's syndrome) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of repository corticotropin injection will be considered when the following criteria are met:

- Patient has a diagnosis of infantile spasms AND is less than 2 years of age.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of repository corticotropin injection (Acthar Gel) for the treatment of psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus, systemic dermatomyositis, severe erythema multiforme, Stevens-Johnson syndrome, serum sickness, severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa (e.g., allergic conjunctivitis, keratitis, iritis, chorioretinitis), symptomatic sarcoidosis, proteinuria in the nephrotic syndrome without uremia, and acute exacerbation of multiple sclerosis to be **not medically necessary.****

Based on review of available data, the Company considers the use of repository corticotropin injection (Cortrophin™ Gel)‡ for the treatment of psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis, systemic lupus erythematosus, systemic dermatomyositis (polymyositis), severe erythema multiforme, Stevens-Johnson syndrome, severe psoriasis, atopic dermatitis, serum sickness, severe acute and chronic allergic and inflammatory processes involving

the eye and its adnexa (e.g., allergic conjunctivitis, keratitis, iritis, chorioretinitis), symptomatic sarcoidosis, proteinuria in the nephrotic syndrome without uremia, and acute exacerbation of multiple sclerosis to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of repository corticotropin injection (Acthar Gel) for conditions that are not responsive to corticosteroid therapy (including, but not limited to, use in tobacco cessation, acute gout, and childhood epilepsy) OR for any non-FDA approved indication to be **investigational.***

Based on review of available data, the Company considers the use of repository corticotropin injection (Cortrophin Gel) for the treatment of infantile spasms or any other condition not listed above as **not medically necessary**** to be **investigational.***

Background/Overview

Repository corticotropin injection (Acthar Gel, Cortrophin Gel) is a purified, sterile preparation of the natural form of adrenocorticotropic hormone (ACTH) in gelatin to provide a prolonged release after intramuscular or subcutaneous injection. ACTH works by stimulating the adrenal cortex to produce cortisol, corticosterone, and a number of other hormones.

Acthar Gel is an ACTH analogue indicated as monotherapy for the treatment of infantile spasms in infants and children less than 2 years of age. According to the package insert, Acthar gel may also be used for the following disorders and diseases: rheumatic, collagen, dermatologic, allergic states, ophthalmic, respiratory and edematous states. However, the drug was approved by the FDA in 1952 prior to the requirement that companies provide evidence of clinical efficacy.

Cortrophin gel is an ACTH analogue indicated for specific rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, edematous states, and multiple sclerosis exacerbations. This product was also initially approved by the Food and Drug Administration (FDA) before the requirement that companies provide evidence of clinical efficacy. Unlike Acthar Gel, Cortrophin Gel is not approved for the treatment of infantile spasms.

Contraindications for use of these agents include 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.

West Syndrome/Infantile Spasms
West syndrome is a rare epileptic disorder of early infancy (90% of cases are diagnosed the first year of life) consisting of three main characteristics: infantile spasm, mental retardation, and hypsarrhythmia, a specific abnormal pattern on EEG. Often the term infantile spasms is used synonymously with West syndrome. Infantile spasms are characterized by an initial contraction phase followed by a more sustained tonic phase.

Another treatment option for infantile spasms is vigabatrin (Sabril®)‡ which is available in various oral dosage forms. Sabril is indicated as monotherapy for pediatric patients with infantile spasms for whom the potential benefits outweigh the potential risk of vision loss.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Acthar is currently approved in the U.S. for the treatment of infantile spasms, multiple sclerosis exacerbations, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, symptomatic sarcoidosis, and edematous states.

Cortrophin Gel is currently approved for the following disorders:

- 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 and iridocyclitis
    - Diffuse posterior uveitis and choroiditis

  - Optic neuritis
  - Chorioretinitis
  - Anterior segment inflammation
- Respiratory diseases:
  - Symptomatic sarcoidosis
- Nervous system:
  - Acute exacerbations of multiple sclerosis

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Infantile spasms

The effectiveness of Acthar Gel as a treatment for infantile spasms was demonstrated in a single blinded (video EEG Interpreter-blinded) clinical trial in which patients were randomized to receive either a 2 week course of treatment with Acthar Gel (75 U/m^2) intramuscular twice daily or prednisone 1 mg/kg by mouth twice daily. The primary outcome was a comparison of the number of patients in each group who were treatment responders, defined as a patient having complete suppression of both clinical spasms and hypsarrhythmia on a full sleep cycle video EEG performed 2 weeks following treatment initiation, rated by an investigator blinded to treatment. Thirteen of 15 patients (86.7%) responded to Acthar Gel as compared to 4 of 14 patients (28.6%) given prednisone ($p < 0.002$). The 2-week treatment was followed by a 2-week period of taper. Nonresponders to the prednisone treatment were eligible to receive Acthar Gel treatment. Seven of 8 patients (87.5%) responded to Acthar Gel after not responding to prednisone. Similarly, the 2 nonresponder patients from the Acthar Gel treatment were eligible to receive treatment with prednisone. One of the 2 patients (50%) responded to the prednisone treatment after not responding to Acthar Gel.

A supportive single-blind, randomized clinical trial comparing high-dose, long-duration treatment (150U/m^2 once daily for 3 weeks, n = 30) of Acthar Gel with low-dose, short-duration treatment (20U once daily for 2 weeks, n = 29) for the treatment of infantile spasms was also evaluated in infants and children less than 2 years of age. Nonresponders (defined as in the previously described study) in the low-dose group received a dose escalation at 2 weeks to 30U once daily. Nominal statistical superiority of the high dose treatment, as compared to the low dose treatment, was observed for cessation of spasms but not for the resolution of hypsarrhythmia.

In 2012 the American Academy of Neurology (AAN) and the Child Neurology Society updated the evidence-based guideline for the medical treatment of infantile spasms. The guidelines note that ACTH is a first-line agent for the short-term treatment of infantile spasms. The Infantile Spasms Working Group (ISWG) published a US consensus report on infantile spasms in 2010. Data regarding ACTH use in infantile spasms were detailed and it was determined that ACTH is an effective first-line therapy for infantile spasms.

Acute Exacerbations of Multiple Sclerosis
Although Acthar is indicated for the treatment of exacerbations of MS in adults, more recent studies evaluating multiple sclerosis have demonstrated that intravenous corticosteroids are at least as effective, or more effective than repository corticotropin. Acthar has been studied in patients with acute exacerbations of MS and short-term use, usually given IM or SC for 14 or fewer days, led to benefits in signs and symptoms of MS. A double-blind, randomized controlled trial found that ACTH given IM over 14 days had similar efficacy in acute exacerbations of MS as methylprednisolone given as 1 gram IV daily for 3 days.

Other potential uses of repository corticotrophin injection
There are a limited number of small case series reporting on the use of repository corticotropin injection for other corticosteroid-responsive conditions. For example, in 2011, Bomback et al published a retrospective case series in 21 patients with idiopathic, nondiabetic nephrotic syndrome who were treated with repository corticotropin. Repository corticotropin was used as a primary therapy in 3 patients; the other 18 patients had failed a mean of 2.3 immunosuppressive regimens before using repository corticotropin. Four (19%) of the 21 patients were in complete remission, defined as stable or improved renal function with final proteinuria falling to less than 500 mg/d. An additional 7 (33%) of 21 patients had a partial remission (at least a 50% reduction in proteinuria and final proteinuria 500-3500 mg/d). Regarding these other uses of repository corticotropin injection, data and guidelines do not suggest a substantial role in therapy. Further data are needed before use in other areas can be recommended.

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Policy History

Original Effective Date: 07/16/2008
Current Effective Date: 07/01/2025

07/02/2008	Medical Director review
07/16/2008	Medical Policy Committee approval. New policy.
07/02/2009	Medical Director review
07/22/2009	Medical Policy Committee approval. No change to coverage.
12/04/2009	Medical Policy Committee approval
12/16/2009	Medical Policy Implementation Committee approval. Title changed from "ACTH Gel (Adrenocorticotropic Hormone)" to "Repository Corticotropin Injection (ACTH Gel, H.P. Acthar Gel)". No change to coverage eligibility.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Acute gout and childhood epilepsy added as investigational conditions.
12/01/2010	Medical Policy Committee review
12/15/2010	Medical Policy Implementation Committee approval. Added "in infants and children less than two years of age" to repository corticotropin injection for the treatment of infantile spasms (West's syndrome) coverage eligibility statement.
12/08/2011	Medical Policy Committee review
12/21/2011	Medical Policy Implementation Committee approval. No change to coverage.
12/06/2012	Medical Policy Committee review
12/19/2012	Medical Policy Implementation Committee approval. No change to coverage.
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. Policy now states that covered indications include infantile spasms and multiple sclerosis only. Updated background, source, rationale, investigational, and not medically necessary sections.
09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. No change to coverage.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. No change to coverage.
09/08/2016	Medical Policy Committee review

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09/21/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. No change to coverage.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Policy now states that repository corticotropin is considered not medically necessary for exacerbations of multiple sclerosis. Updated background information, rationale, and references.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. No change to coverage.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. No change to coverage.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. No change to coverage.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Added new product, Cortrophin Gel, to policy. Updated title and background information to remove reference to obsolete products.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. No change to coverage.
09/18/2023	Coding update
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J0801, J0802 Delete code effective 07/01/2025: J3490, J3590
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.