LifeWise
Health Plan of Washington

MEDICAL POLICY – 5.01.561

Repository Corticotropin Injection

BCBSA Ref. Policy:	5.01.17	
Effective Date:	May 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	April 22, 2024	None
Replaces:	5.01.17	

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Corticotropin is a hormone made in certain cells in the pituitary gland. (Corticotropin may also be known as ACTH or adrenocorticotropic hormone.) When corticotropin is produced in a lab and used as a treatment, it's believed that it helps the body create its own natural steroid hormones. Corticotropin injections may be approved to treat a rare seizure disorder that affects infants, known as West syndrome. Corticotropin injections have also been tried for several other conditions known to respond to steroid treatments. When medical studies compared corticotropin treatment with intravenous steroids, the studies did not show that the corticotropin treatments worked better. For this reason, corticotropin treatment is considered not medically necessary for conditions where steroids are a proven treatment. Corticotropin has also been tried for many other conditions including gout and childhood epilepsy. There isn't enough high-quality medical evidence to show whether it works. For this reason, corticotropin treatment is considered investigational (unproven) for many conditions.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Repository corticotropin injection*	**Repository corticotropin injection may be considered medically necessary for treatment of infantile spasms (West syndrome).** **Repository corticotropin injection is considered not medically necessary as a treatment of corticosteroid-responsive conditions, including, but not limited to, ANY of the following:** • Allergic states such as serum sickness • Collagen diseases such as systemic lupus erythematosus (SLE), systemic dermatomyositis (polymyositis) • Dermatologic diseases such as erythema multiforme, Stevens-Johnson syndrome • Edematous states such as lupus erythematosus • Multiple sclerosis, acute exacerbation in adults • Nephrotic syndrome – without uremia of the idiopathic type or due to lupus erythematosus • Ophthalmic diseases such as allergic and inflammatory processes of the eye: optic neuritis, keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, chorioretinitis, anterior segment inflammation • Respiratory diseases such as symptomatic sarcoidosis • Rheumatic disorders such as: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis **Repository corticotropin injection is considered not medically necessary for use in diagnostic testing of adrenocortical function.** **Note:** The brand name for repository corticotropin is H.P. Acthar Gel, Acthar Gel SelfJect, and Cortrophin

Drug	Investigational
Repository corticotropin injection	**Repository corticotropin injection is considered investigational for conditions that are not responsive to corticosteroid therapy including, but not limited to:** • Acute gout • Childhood epilepsy • Use in tobacco cessation **Repository corticotropin injection is considered investigational for all other indications.**

Documentation Requirements
The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of: • Diagnosis/condition

Coding

Code	Description
CPT	
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
HCPCS	
J0800	Injection, corticotropin, up to 40 units (code termed 10/1/2023)
J0801	Injection, corticotropin (Acthar Gel), up to 40 units (new code effective 10/1/2023)
J0802	Injection, corticotropin (ANI [Cortrophin Gel]), up to 40 units (new code effective 10/1/2023)

Related Information

H.P. Acthar gel and Purified Cortrophin Gel are used for intramuscular or subcutaneous injection and should never be used intravenously.

Product information provides the following on dosage of H.P. Acthar Gel for treatment of infantile spasms:

- In the treatment of infantile spasms, the recommended dose is 150 U/m^2 divided into twice daily intramuscular injections of 75 U/m^2. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period.

According to the manufacturer's website, beginning in 2007, H.P. Acthar Gel is only available through specialized pharmacy distribution (i.e., it is no longer available from traditional pharmaceutical wholesalers or retail pharmacies).

Diagnostic testing of adrenocortical function, known as the ACTH test, is typically done with synthetic ACTH. Synthetic ACTH products have been approved by the US Food and Drug Administration (FDA) for this purpose.

Adverse Events

Contraindications for the use of this agent 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, primary adrenocortical insufficiency, adrenocortical hyperfunction, suspected congenital infection in infants, concomitant administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of Acthar Gel, or sensitivity to proteins of porcine origin.

Repository corticotropin injection has potential adverse events similar to those that occur with other steroid medications such as an elevated blood pressure, a decrease in bone density, new infections (or activation of a previous infection), and overproduction of cortisol, which can cause symptoms of Cushing syndrome.

Consideration of Age

Any ages listed in the policy statements are based on FDA labeling.

Evidence Review

Description

Repository corticotropin injection is a preparation of the natural form of adrenocorticotropic hormone (ACTH). The injection is used to treat corticosteroid-responsive conditions and as a diagnostic tool to test adrenal function.

Background

Repository Corticotropin Injection

Repository corticotropin injection (H.P. Acthar Gel, Purified 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 is produced and secreted by the pituitary gland; H.P. Acthar Gel and Purified Cortrophin Gel uses ACTH obtained from porcine pituitaries. ACTH works by stimulating the adrenal cortex to produce cortisol, corticosterone, and a number of other hormones.

Summary of Evidence

For individuals who have infantile spasms who receive repository corticotropin injection, the evidence includes systematic reviews/meta-analyses and a prospective study. Relevant outcomes are symptoms and change in disease status. A 2013 systematic review judged the overall quality of all included studies involving various medication for infantile spasms to be poor, with fewer than half reporting method of randomization and most assessing relatively few individuals. There was heterogeneity across studies and either vigabatrin or prednisolone was used as comparators; however, the authors concluded that limited evidence from RCTs suggested that ACTH and prednisolone resolved infantile spasms more rapidly than vigabatrin. More recent meta-analyses also concluded that ACTH treatment was non-inferior to corticosteroid treatment with a similar adverse event profile and may be considered a safe and effective alternative treatment. A 2021 systematic review including six trials indirectly compared natural ACTH with synthetic ACTH therapies. Based on the limited evidence included, investigators suggested that repository corticotropin injection may be a better treatment option over synthetic ACTH therapies for improving cessation of spasms and other relevant symptoms. Multivariate analysis of a prospective cohort study found that children with infantile spasms who were treated with ACTH were more likely to respond than other children. However, the analysis might have been subject to residual confounding on unmeasured characteristics; further, the

study did not differentiate between synthetic and natural ACTH. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have corticosteroid-responsive conditions (e.g., rheumatoid arthritis, dermatomyositis, sarcoidosis, nephrotic syndrome, multiple sclerosis, serum sickness, systemic lupus erythematosus [SLE]) who receive repository corticotropin injection, the evidence includes RCTs and case series. The relevant outcomes are symptoms and change in disease status. One placebo-controlled trial supports the efficacy of repository corticotropin injection in individuals with rheumatoid arthritis and an inadequate response to corticosteroids and disease-modifying therapies. Overall, more recent studies evaluating multiple sclerosis have demonstrated that intravenous corticosteroids are at least as effective, or more effective, than repository corticotropin injection. A recent RCT in individuals with SLE found no difference in SLE Responder Index-4 responders in the repository corticotropin group compared to placebo. Most studies assessing nephrotic syndrome have been small retrospective case studies and the one RCT identified stopped early due to lack of efficacy of ACTH. Ongoing studies are being conducted. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have conditions not generally known to be responsive to corticosteroids (non-corticosteroid-responsive) such as tobacco cessation, childhood epilepsy, and acute gout who receive repository corticotropin injection, the evidence includes three head-to-head trials identified for use in gout. The relevant outcomes are symptoms and change in disease status. The quality of these studies was deemed very low to moderate because there were no direct placebo-controlled trials and no clinically relevant differences were detected between drugs studied. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who need diagnostic testing of adrenal function who receive repository corticotropin injection, the evidence does not include studies that compare the diagnostic accuracy of repository corticotropin injection with ACTH. The relevant outcomes are test validity and other test performance measures. The lack of published evidence precludes conclusions on the validity of using repository corticotropin as a diagnostic test for adrenal function. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02541955	Use of Acthar in Rheumatoid Arthritis Related Flares	40	Dec 2023
NCT03511625	The Effects of Acthar on Synovial Inflammation in Rheumatoid Arthritis	6	Dec 2023
Unpublished			
NCT03414086	Predictor of Clinical Response to Acthar in Myositis: Phase II of Acthar Clinical Trial	20	Jul 2022
NCT02030028	Open Label Study to Evaluate Efficacy and Safety of Short-Term, Adjunctive Adrenocorticotropic Hormone (ACTH) Gel in Rheumatoid Arthritis	18	June 2022 (completed)
NCT02245841	Efficacy and Safety of H.P. Acthar Gel for the Treatment of Refractory Cutaneous Manifestations of Dermatomyositis	15	July 2021 (completed)
NCT03320070[a]	A Phase 4, Multicenter, Randomized, Double Blind, Placebo Controlled Pilot Study to Assess the Efficacy and Safety of Acthar Gel in Subjects With Pulmonary Sarcoidosis	55	Nov 2021 (completed)
NCT02725177	Ocular Sarcoidosis Open-Label Trial of ACTHAR Gel	9	Mar 2022 (completed)
NCT02298491	Clinical Biomarkers of Disease Activity and Treatment Responses in Patients With CNS Sarcoidosis Treated With H.P. Acthar Gel	4	Nov 2020 (completed)
NCT02315872[a]	The Effect of ACTH (Acthar) on Measures of Chronic Fatigue in Patients With Relapsing Multiple Sclerosis	8	Dec 2018 (completed)
NCT01367964	Prevention of West Syndrome With Low-dose Adrenocorticotropic Hormone (ACTH)\	28	Dec 2018

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01386554[a]	A Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study of H.P. Acthar Gel (Acthar) in Treatment-Resistant Subjects With Persistent Proteinuria and Nephrotic Syndrome Due to Idiopathic Membranous Nephropathy (iMN)	60	May 2017 (completed)

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Clinical Input from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2010 Input

In response to requests, input was received from three physician specialty societies and one academic medical center while this policy was under review in 2010. In addition, unsolicited input was received from one foundation and three physicians. There was strong support for the use of repository corticotropin injection in the treatment of infantile spasms (West syndrome).

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology and Child Neurology Society

The American Academy of Neurology and the Child Neurology Society (2012) updated their evidence-based guidelines on the treatment of infantile spasms, which was reaffirmed in January 2018 and May 2021.[20] The guidelines included the following recommendations on the use of adrenocorticotropic hormone (ACTH):

- "ACTH (Level B) or VGB [vigabatrin] (Level C) may be offered for short-term treatment of infantile spasms."
- "Hormonal therapy (ACTH or prednisolone) may be considered for use in preference to VGB in infants with cryptogenic infantile spasms…"

Infantile Spasms Working Group

An industry-sponsored Infantile Spasms Working Group (2010) published a consensus report on the diagnosis and treatment of infantile spasms.[21] Regarding treatment, the report concluded: "At this time, ACTH and VGB (vigabatrin) are the only drugs with proven efficacy to suppress clinical spasms and abolish the hypsarrhythmic EEG [electroencephalogram] in a randomized clinical trial setting (Mackay et al., 2004) and thus remain first-line treatment."

International League Against Epilepsy

The International League Against Epilepsy Commission of Pediatrics (2015) recommendations on management of infantile seizures states that ACTH (either low or high doses) is a preferred treatment for short-term control of infantile spasms (evidence level B [probably effective]).[22] The recommendations for the management of infantile seizures were based on an international survey due to the lack of evidence-based data.

National Institute for Health and Care Excellence

The NICE (2022) published a guideline on epilepsies in children, young people, and adults that addresses infantile spasm.[23] For first-line treatment, NICE recommends combining steroids with vigabatrin which has been shown to be more effective than either steroids or vigabatrin alone in

stopping spasms. Based on NICE committee consensus opinion, the committee agreed that "steroids may not be suitable for all children under 2 years and that vigabatrin alone should be considered for those at high risk from the side effects of steroid treatment, such as those with neurological impairments and other comorbidities". There was no specific mention of repository corticotropin injection or ACTH.

American College of Rheumatology

The American College of Rheumatology (2020) published a guideline on the management of gout.[24] The guideline recommends that other agents be used first line for the treatment of a gout flare rather than ACTH. For individuals who are unable to take oral medications, parenteral corticosteroids are preferred over ACTH.

American College of Physicians

A practice guideline on acute and recurrent gout from the American College of Physicians (2017) does not provide a formal recommendation about use of ACTH.[25] However, the guideline authors state that ACTH may reduce pain in individuals with acute gout (based on moderate quality evidence). Comparative evidence suggests greater efficacy compared to corticosteroids and nonsteroidal anti-inflammatory drugs, with a potential for harm similar to corticosteroids.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 1952, H.P. Acthar Gel (Questcor Pharmaceuticals/Mallinckrodt Pharmaceuticals) was approved by the FDA. The original product label included at least 19 separate conditions, including infantile spasms. At one time, this product was indicated as an injection for diagnostic testing of adrenocortical function. In 2010, this indication was removed with an update to the product label.

In 2021, Purified Cortrophin Gel (ANI Pharmaceuticals, Inc.) was relaunched and received approval of supplemental New Drug Application (sNDA) by the FDA for certain autoimmune disorders. It includes similar indications much like the Acthar Gel noted above; however, it is not currently approved for the treatment of infantile spasms. ANI acquired the NDA from Merck & Co. in 2016. This product initially received FDA approval in 1954 but has not been in the market since the 1980s.

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History

Date	Comments
02/09/16	New policy. Policy created to include plan specific medically necessary indications; replaces policy 5.01.17. Repository corticotropin injection may be considered medically necessary when criteria are met.
06/01/16	Interim Update, approved May 10, 2016. Language clarified regarding use the drug for steroid responsive conditions. FDA labeled conditions approved in 1952 were prior to the commercial availability of corticosteroid agents and not based on studies showing efficacy. Corticosteroid agents are available at lower cost and have stronger scientific evidence regarding their efficacy for most conditions, thus making this product not medically necessary based on contract language.

Date	Comments
12/01/17	Annual Review, approved November 9, 2017. Policy updated with literature review through August 2017; no references added. Policy statements for corticosteroid-responsive conditions reorganized for clarity, including adding ophthalmic diseases.
09/21/18	Minor update. Added Consideration of Age statement.
12/01/18	Annual Review, approved November 21, 2018. Policy updated with literature review through August 2018; reference 9 added. Policy statements unchanged.
01/01/20	Annual Review, approved December 10, 2019. Policy updated with literature review through August 2019; no references added. Policy statements unchanged.
01/01/21	Annual Review, approved December 1, 2020. Policy updated with literature review through August 26, 2020; references added. Policy statements unchanged.
01/01/22	Annual Review, approved December 2, 2021. Policy updated with literature review through August 30, 2021; references added. Minor edits made for clarification to list of corticosteroid responsive conditions; intent unchanged; otherwise, policy statements unchanged.
12/01/22	Annual Review, approved November 21, 2022. Policy updated with literature review through September 02, 2022; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
10/01/23	Coding update. Added new HCPCS codes J0801 and J0802.
01/01/24	Annual Review, approved December 11, 2023. Policy updated with literature review through September 6, 2023; no references added. Policy statements unchanged.
05/01/24	Annual Review, approved April 22, 2024. Updated coverage criteria to clarify that Acthar Gel SelfJect and Cortrophin are included in the policy. Updated coverage criteria to add edematous status such as lupus erythematosus as considered not medically necessary.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-817-3056 (መስማት ለተሳናቸው: 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-817-3056 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-817-3056 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-817-3056 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-817-3056 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-817-3056 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-817-3056 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-817-3056 (ATS : 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-817-3056 (TTY: 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-817-3056 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-817-3056 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-817-3056 (TTY: 711) تماس بگیرید.