BlueCross BlueShield of Arizona
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**PHARMACY COVERAGE GUIDELINES**
**SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE: 4/1/19**
**LAST REVIEW DATE: 2/21/19**
**LAST CRITERIA REVISION DATE:**
**ARCHIVE DATE:**

# H.P. ACTHAR® GEL (repository corticotropin) injection

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

## H.P. ACTHAR® GEL (repository corticotropin) injection (cont.)

**Criteria:**

- **Criteria for initial therapy:** H. P. Acthar Gel (repository corticotropin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in or is in consultation with a Neurologist

  2. A confirmed diagnosis of **ONE** of the following:
     - Individual under 2 years of age with infantile spasms (West Syndrome)
     - Individual 18 years of age or older with acute exacerbation of multiple sclerosis who is adherent with immune suppressing maintenance agent for multiple sclerosis **AND** has a contraindication to or is intolerant to corticosteroids that are not also expected to occur with use of H. P. Acthar Gel **AND** will not be using H. P. Acthar Gel on a monthly basis for prophylaxis of acute exacerbations of multiple sclerosis
     - Individual 18 years of age or older with a corticosteroid responsive condition who has a contraindication to or is intolerant to corticosteroids that are not also expected to occur with use of H. P. Acthar Gel

  3. There are **NO** contraindications
     - Contraindications include:
       - Intravenous administration
       - Congenital infection suspected in an infant
       - Administration of live or attenuated vaccines in an individual on immunosuppressive doses of Acthar gel
       - 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, or sensitivity to proteins of porcine origin

  **Initial approval duration**: 4 weeks
  Requests beyond 4 weeks requires a Medical Director review
  Maximum of 35 mL (7 vials) will be authorized, requests for more vials requires a Medical Director review

- **Criteria for continuation of coverage (renewal request):** H. P. Acthar Gel (repository corticotropin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in or is in consultation with a Neurologist

  2. All requests for renewal or continuation will be reviewed using initial criteria and if approved the same duration will apply

  3. Individual has been adherent with the medication

## H.P. ACTHAR® GEL (repository corticotropin) injection (cont.)

4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section
    - Significant adverse effect such as:
        - Infection
        - Adrenal insufficiency
        - Cushing's syndrome
        - Gastrointestinal perforation and bleeding

**Renewal duration**: 4 weeks

- H. P. Acthar Gel (repository corticotropin) for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
3. Insufficient evidence to support improvement of the net health outcome, and
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:
- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

**Description:**

H.P. Acthar Gel (repository corticotropin) injection is a 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. H.P. Acthar Gel is primarily used for treating infantile spasms (West syndrome), it has been investigated for diagnostic testing of adrenocortical function, and it has been used in the treatment of a variety of other conditions. H.P.

H.P. Acthar Gel was approved by the U.S. Food and Drug Administration (FDA) in 1952, before there was a requirement that innovator companies provide clinical evidence of efficacy of their product. H.P. Acthar Gel Product label says that it is indicated for infantile spasms and indicated for the treatment of acute exacerbations of multiple sclerosis. The product label includes a number of uses that lack sufficient published evidence to establish efficacy. The clinical studies section of the product labeling of H.P. Acthar Gel describes efficacy data only for infantile spasms.

Some controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. Other clinical trials comparing ACTH and methylprednisolone (MP) in treatment of acute exacerbation in multiple sclerosis have either shown no difference between treatments or have shown that the MP cohort had a more rapid or greater improvement in treatment of the acute exacerbation as

## H.P. ACTHAR® GEL (repository corticotropin) injection (cont.)

measure by the Kurtzke Disability Status Scale (DSS). Multiple sclerosis treatment guidelines recommend the use of high dose IV or oral methylprednisolone for acute exacerbations of multiple sclerosis rather than use of H.P. Acthar Gel.

Infantile spasms is a rare epileptic disorder of infancy (90% of cases are diagnosed in the first year of life). When infantile spasms are accompanied by neurodevelopmental regression and electroencephalogram (EEG) findings of hypsarrhythmia, the condition is known as West Syndrome. Characteristics of infantile spasms include mental retardation and hypsarrhythmia, a specific abnormal pattern detected by an EEG that is described as slow waves of high voltage and random pattern of spikes that vary in duration and location. Infantile spasms are characterized by sudden jerking and bending forward of the body, followed by stiffening of the body. Spasms usually last around 1-5 seconds, but can range from 2-500 spasms at any given time. Vigabatrin oral solution is another treatment available for infantile spasms. Studies suggest that hormonal treatment (prednisolone, ACTH) resolve infantile spasms faster than vigabatrin and resolve the condition in more children, but long-term developmental and epilepsy outcomes are unknown.

Although H.P. Acthar Gel can be used to treat various other medical conditions responsive to corticosteroid therapy, it has not been proven to be superior to corticosteroids for any of these uses. Corticosteroid therapy is generally considered the treatment of choice. H.P. Acthar Gel has limited therapeutic value since it cannot be administered orally and its effectiveness is dependent on adrenocortical responsiveness.

There is a lack of controlled studies on ACTH for treatment of non-corticosteroid-responsive conditions who have received repository corticotropin.

H.P. Acthar Gel is available as a 5 mL vial (80 units/mL, total of 400 units). The adverse effects of H.P. Acthar Gel are related primarily to its steroid-like effects.

**Definitions:**

**Infantile spasms**:
Evidence of specific abnormal pattern detected by a video EEG with hypsarrhythmia

Response is defined as achieved and maintains complete cessation of spasms and elimination of hypsarrhythmia on a full sleep video EEG

**MS exacerbation**:
Evidence of an attack with neurologic disturbances consistent with MS that have lasted for at least 24 hours and is separated from the previous attack by at least 30 days

Response is defined as **THREE** of the following:
- Mild/minimal to no functional neurologic (pyramidal, cerebellar, brainstem, sensory) disabilities
- Ambulatory without need for assistance
- Reduction in number of exacerbations or relapses of MS
- Prolonged time to exacerbation or relapses of MS
- Reduction in hospitalizations for MS

## H.P. ACTHAR® GEL (repository corticotropin) injection (cont.)

**Resources:**

H. P. Acthar Gel (repository corticotropin) product information accessed 09-18-2018 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7b48ddec-e815-45f4-9ca0-5c0daaf56f30

5.01.17 BCBS Association Medical Policy Reference Manual. Repository Corticotropin Injection. Re-issue date 10/12/2017, viewed on 09/18/2008.

National Institute for Health and Care Excellence (NICE). Multiple sclerosis in adults: management. NICE clinical guideline CG186. London, UK: National Institute for Health and Care Excellence; October 2014

Scott TF, Frohman EM, De Seze J, Gronseth GS, Weinshenker BG: Therapeutics and Technology Assessment Subcommittee of American Academy of Neurology. Evidence-based guideline: clinical evaluation and treatment of transverse myelitis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2011; 77 (24): 2128-2134

Sellebjerg F, Barnes D, Filippini G, et al.: EFNS guideline on treatment of multiple sclerosis relapses: report of an EFNS task force on treatment of multiple sclerosis relapses. European J Neurol 2005; 12: 939-945

UpToDate: Management and prognosis of infantile spasms. Current through Aug 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/management-and-prognosis-of-infantile-spasms?search=west%20syndrome&source=search_result&selectedTitle=2~62&usage_type=default&display_rank=2

UpToDate: Clinical features and diagnosis of infantile spasms. Current through Aug 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/clinical-features-and-diagnosis-of-infantile-spasms?search=west%20syndrome&source=search_result&selectedTitle=1~62&usage_type=default&display_rank=1

UpToDate: Etiology and pathogenesis of infantile spasms. Current through Aug 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/etiology-and-pathogenesis-of-infantile-spasms?search=west%20syndrome&source=search_result&selectedTitle=3~62&usage_type=default&display_rank=3

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**Fax completed prior authorization request form to 602-864-3126** or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

# Pharmacy Prior Authorization Request Form

**Do not copy for future use. Forms are updated frequently.**
**REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.**

## Member Information

| Member Name (first & last): | Date of Birth: | Gender: | BCBSAZ ID#: |
|---|---|---|---|
| Address: | City: | State: | Zip Code: |

## Prescribing Provider Information

| Provider Name (first & last): | Specialty: | NPI#: | DEA#: |
|---|---|---|---|
| Office Address: | City: | State: | Zip Code: |
| Office Contact: | Office Phone: | Office Fax: | |

## Dispensing Pharmacy Information

| Pharmacy Name: | Pharmacy Phone: | Pharmacy Fax: |
|---|---|---|

## Requested Medication Information

| Medication Name: | Strength: | Dosage Form: |
|---|---|---|
| Directions for Use: | Quantity: / Refills: | Duration of Therapy/Use: |

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

## Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

## Clinical Information

1. **What is the diagnosis? Please specify below.**

   **ICD-10 Code:** _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

| Medication Name, Strength, Frequency | Dates started and stopped or Approximate Duration | Describe response, reason for failure, or allergy |
|---|---|---|
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5. **Are there any supporting labs or test results? Please specify below.**

| Date | Test | Value |
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# Pharmacy Prior Authorization Request Form

**6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.**
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

**Signature affirms that information given on this form is true and accurate and reflects office notes**

Prescribing Provider's Signature: Date:

**Please note**: Some medications may require completion of a drug-specific request form.

**Incomplete forms or forms without the chart notes will be returned.**

Office notes, labs, and medical testing relevant to the request that show medical justification are required.