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

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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

This Medical 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.

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

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

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Description:

H.P. Acthar Gel 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. It is primarily used for treating infantile spasms (West syndrome) and has been investigated for diagnostic testing of adrenocortical function and for treating a variety of other conditions. H.P. Acthar Gel may also be referred to as repository corticotropin injection.
H.P. ACTHAR GEL (repository corticotropin injection) (cont.)

**Description**: (cont.)

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. Therefore the product label for Acthar Gel includes a number of indications for use which lack sufficient published evidence to establish efficacy.

**Criteria:**

H.P Acthar Gel (repository corticotropin injection) will be reviewed by the medical director(s) and/or clinical advisor(s).

See Resources section for FDA-approved dosage and duration.

- FDA-approved dosage and duration of H.P. Acthar Gel for the treatment of infantile spasms (West syndrome) for individuals under 2 years of age is considered **medically necessary**.
- FDA-approved dosage and duration of H.P. Acthar Gel for the treatment of acute exacerbation of multiple sclerosis is considered **medically necessary** with documentation of ALL of the following:
  1. Failure of intravenous high dose corticosteroids for the current exacerbation event
  2. Medical contraindications to corticosteroids that are not also expected to occur with use of H.P. Acthar Gel for the current exacerbation event

- H.P. Acthar Gel for use in diagnostic testing of adrenocortical function is considered **experimental or investigational** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives
H.P. ACTHAR GEL (repository corticotropin injection) (cont.)

Criteria: (cont.)

- H.P. Acthar Gel for treatment of all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives

These indications include, but are not limited to:

- Acute gout
- Childhood epilepsy
- Tobacco cessation

Resources:

Literature reviewed 11/28/17. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


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

Resources: (cont.)

FDA Product Approval Information for H.P. Acthar Gel (repository corticotropin) Injection:

- FDA-approved indication: As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

For the treatment of exacerbations of multiple sclerosis in adults.

May be used for the following disorders and diseases: rheumatic, collagen, dermatologic, allergic states, ophthalmic, respiratory and edematous state (see below for detailed information).

According to the FDA label sections 1.3-1.9, may be used in the treatment of the following conditions:

1.3 Rheumatic disorders: Adjunctive therapy for short-term administration (to tide the individual over an acute episode or exacerbation) in psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), and ankylosing spondylitis

1.4 Collagen Diseases: Treatment of selected cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).

1.5 Dermatologic Diseases: Treatment of severe erythema multiforme and Stevens-Johnson syndrome.

1.6 Allergic States: Treatment of serum sickness.

1.7 Ophthalmic Diseases: Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as optic neuritis, and anterior segment inflammation.

1.8 Respiratory Diseases: Treatment of symptomatic sarcoidosis.

1.9 Edematous state: Treatment to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or due to lupus erythematosus.
H.P. ACTHAR GEL (repository corticotropin injection) (cont.)

**Resources:** (cont.)

FDA Product Approval Information for H.P. Acthar Gel (repository corticotropin) Injection: (cont.)

- **FDA-approved dosage:** In the treatment of infantile spasms, the recommended dose is 150 U/m² divided into twice daily intramuscular injections of 75 U/m². After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period.

  In the treatment of acute exacerbations of multiple sclerosis, daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks may be administered. It may be necessary to taper the dose.

  In the treatment of other disorders and diseases, dosing will need to be individualized depending on the disease under treatment and the medical condition of the patient. It may be necessary to taper the dose.
H.P. ACTHAR GEL (repository corticotropin injection) (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/language/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’ é atah níilíñgií Blue Cross Blue Shield of Arizona haadá yít’éego bíná’idiilkidgo éí doodago Háída bíjá anilyeedíí t’áadoo le’é yína’idiilkidgo beehaz’áanii hólq díí t’áá hazaadk’ehjí háká a’doowolgo bee haz’á doo bąąh ilínígóó. Aťa’ hal né’égií kojí’ bích’jí’ hodíilíiní 877-475-4799.

Chinese: 如果您，或是您正在协助的对象，有关于插入项目的名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权利免费以您的母语得到帮助和讯息。洽询一位翻译员，将拨电话 在此插入数字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لأي شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فأن لديك الحق في الحصول على المساعدة والموارد الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم العضو ب 877-475-4799.
H.P. ACTHAR GEL (repository corticotropin injection) (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuuanang, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakau ng tulungan at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 듣을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اغرچه یا کسی که شما به او کمک می‌کنید، سوال در مورد اطلاعاتی که به زبان خود را به طور رایگان دریافت نمایید، 877-475-4799، همیشه حاضر می‌باشد.

Assyrian:

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijate pomoć i informacije na Vašem jeziku. Da biste razgovarali sa pravodociem, nazovite 877-475-4799.

Thai: หากคุณ หรือคุณช่วยเหลือคนอื่นเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ขอให้ความช่วยเหลือและข้อมูลภาษาของคุณโดยไม่เกี่ยวกับค่าใช้จ่าย โทร 877-475-4799.