Repository Corticotropin (H.P. Acthar Gel)

Description of Procedure or Service

Repository corticotropin (H.P. Acthar® Gel, Questor, Union City, CA) is a purified form of adrenocorticotropic hormone (ACTH) and comes from porcine pituitaries. This gel preparation provides extended release of ACTH and is given as intramuscular or subcutaneous injection. ACTH stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. It is primarily used for treating infantile spasms (West syndrome) and a variety of other disorders after the patient has failed corticosteroid therapy.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for repository corticotropin when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Repository Corticotropin is covered

Repository corticotropin (H.P. Acthar® Gel) may be medically necessary for the following conditions when:
1. The patient has limited/unsatisfactory response (i.e. no difference in symptoms) to corticosteroids (i.e. IV methylprednisolone, IV dexamethasone, or high dose oral steroids) OR
2. The patient has documented intolerance (i.e. severe anaphylaxis) to corticosteroids determined by poor tolerance of and intravenous (IV methylprednisolone, IV dexamethasone) or oral (high dose oral steroids) treatment trials AND
3. The patient is diagnosed with any of the following:

**Endocrine Disorders**
   a. Nonsuppurative thyroiditis;
   b. Hypercalcemia associated with cancer.

**Nervous System Disorders**
Acute exacerbations of multiple sclerosis. The patient should (unless contraindicated) currently be treated with an immunomodulator agent (i.e. Betaseron, Avonex, Rebif, Copaxone, Tysabri) to reduce frequency of MS exacerbations.

**Infantile Spasms**
Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. Failure or intolerance to corticosteroids is not required for a diagnosis of infantile spasms.

**Rheumatic Disorders**
As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in the following:
   a. Psoriatic arthritis (PsA);
   b. Rheumatoid arthritis (RA);
   c. Juvenile rheumatoid arthritis (JIA);
   d. Ankylosing spondylitis (AS)
   e. Acute and subacute bursitis;
   f. Acute nonspecific tenosynovitis;
   g. Acute gouty arthritis;
   h. Post-traumatic arthritis;
   i. Synovitis of osteoarthritis;
   j. Epicondylitis.

**Collagen Disorders**
During an exacerbation or as maintenance therapy in the following:
   a. Systemic lupus erythematosus;
   b. Systemic dermatomyositis (polymyositis);
   c. Acute rheumatic carditis.

**Dermatologic Disorders**
   a. Pemphigus;
   b. Bullous dermatitis herpetiformis;
   c. Severe erythema multiforme (Stevens-Johnson Syndrome);
   d. Exfoliative dermatitis;
   e. Severe psoriasis;
   f. Severe seborrheic dermatitis;
   g. Mycosis fungoides.

**Allergic States**
Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment such as:
   a. Seasonal or perennial allergic rhinitis;
   b. Bronchial asthma;
   c. Contact dermatitis;
   d. Atopic dermatitis;
   e. Serum sickness.

**Ophthalmic Disorders**
Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
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- Allergic conjunctivitis;
- Keratitis;
- Herpes zoster ophthalmicus;
- Iritis and iridocyclitis;
- Diffuse posterior uveitis and choroiditis;
- Optic neuritis;
- Sympathetic ophthalmia;
- Chorioretinitis;
- Anterior segment inflammation;
- Allergic corneal marginal ulcers.

**Respiratory Disorders**
- Symptomatic sarcoidosis;
- Loeffler's syndrome not manageable by other means;
- Berylliosis;
- Fulminating or disseminated pulmonary tuberculosis when used concurrently with antituberculous chemotherapy;
- Aspiration pneumonitis.

**Hematologic Disorders**
- Acquired (autoimmune) hemolytic anemia;
- Secondary thrombocytopenia in adults;
- Erythroblastopenia (RBC anemia);
- Congenital (erythroid) hypoplastic anemia.

**Neoplastic Disorders**
For palliative management of:
- Leukemias and lymphomas in adults;
- Acute leukemia of childhood

**Edematous States**
To induce a diuresis or a remission of proteinuria in the nephritic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

**Gastrointestinal Disorders**
To tide the patient over a critical period of the disease in:
- Ulcerative colitis;
- Regional enteritis.

**Miscellaneous**
- Tuberculous meningitis with subarachnoid block or impending block when used with appropriate antituberculous chemotherapy;
- Trichinosis with neurologic or myocardial involvement.

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**When Repository Corticotropin is not covered**

Uses of repository corticotropin (H.P. Acthar® Gel) are considered **not medically necessary** for all indications that do not meet the medical necessity criteria listed above.

Contraindications include the following:
- Repository corticotropin (H.P. Acthar® Gel) should never be given intravenously.
- Repository corticotropin (H.P. Acthar® Gel) is contraindicated in patients with
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scleroderma, osteoporosis, systemic fungal infections, ocular herpes simples, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin.

- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of repository corticotropin (H.P. Acthar® Gel).
- Repository corticotropin (H.P. Acthar® Gel) is contraindicated in children less than 2 years of age with suspected congenital infections.
- Treatment of conditions is contraindicated when they are accompanied by primary adrenocortical insufficiency or adrenocortical hyperfunction.

Policy Guidelines

Dosage should be individualized according to the medical condition of each patient. Frequency and dose of the drug should be determined by considering the severity of the disease and the initial response of the patient.

Although drug dependence does not occur, sudden withdrawal of repository corticotropin (H.P. Acthar Gel) after prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop treatment. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: J0800

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


US Food and Drug Administration (FDA). Label and approval history for H.P. Acthar Gel. Retrieved 4/24/2012 from
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http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist


Medical Director – 4/2012


Policy Implementation/Update Information

7/1/12 New policy BCBSNC will provide coverage for repository corticotropin when it is determined to be medically necessary because the medical criteria and guidelines are met. Medical Director review 5/20/2012. Notification given 7/1/2012. Effective date 10/1/2012. (btw)

7/1/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy intent. References added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.