Pharmacy Policy Bulletin

Category:	Managed Rx Coverage
Number:	J-311
Subject:	Acthar HP -Commercial Only
Effective Date Begin:	June 1, 2010
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Policy applies to: *Commercial* plans only

Background:
H.P. Acthar Gel is a highly purified preparation of adrenocorticotropic hormone (ACTH) in a gel that is designed to provide extended release of the ACTH following intramuscular or subcutaneous injection. ACTH stimulates the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Elevated plasma cortisol suppresses endogenous ACTH release.

H.P. Acthar Gel is FDA indicated for several endocrine, nervous, rheumatic, collagen, dermatologic, allergic, ophthalmic, respiratory, hematologic, neoplastic, edematous, gastrointestinal and other miscellaneous diseases.

H.P. Acthar Gel is rarely necessary for corticosteroid-responsive conditions. The labeling information states that H.P. Acthar Gel "has limited therapeutic value in those conditions responsive to corticosteroid therapy, in such cases, corticosteroid therapy is considered to be the treatment of choice." In head to head clinical studies, there were no demonstrated differences between the efficacy and safety of intravenous methylprednisolone(IVMP) and ACTH.(1,2,3,4) Currently, there is not compelling evidence to indicate that the clinical benefits are influenced by the route of glucocorticoid administration, the particular glucocorticoid prescribed, or the dosage of glucocorticoid, at least at the doses that have been studied to date.(5,9) In addition, because of uncertainties in the effect of ACTH gel on the magnitude of endogenous cortisol production, ACTH gel has the potential for inducing significant adverse effects.

Repository corticotropin should be used in the lowest dose for the shortest period of time to accomplish the therapeutic goal. It should be used only when the disease is intractable to non-steroid treatment. The usual dose of repository corticotropin is 40-80 units given intramuscularly or subcutaneously every 24 - 72 hours. In the treatment of acute exacerbations of multiple sclerosis, daily intramuscular doses of 80-120 units for 2 - 3 weeks may be administered. The product labeling notes that the chronic administration of more the 40 units daily may be associated with uncontrollable adverse effects. Adverse effects with ACTH are potentially life threatening problems that include depression of the immune system and modified response to infection leading to overwhelming sepsis. Minor side effects, estimated to occur in two thirds of patients, include behavioral changes especially irritability, changes in appetite, weight gain and alteration in sleep patterns.

Contraindications include scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, hypertension, and sensitivity to proteins of porcine origin.

Approval Criteria: When a benefit, coverage for H.P. Acthar Gel will be approved at the point of sale when all of the following are met:

1. Members who are younger than 18 years of age.
2. Members who have a paid pharmacy claim for H.P. Acthar Gel within the previous 24 months

Members who meet the criteria above will receive automatic authorization at the level of the pharmacy without documentation of additional information. Claims will adjudicate automatically. For members who do not meet these criteria, the dispensing pharmacist will be prompted that prior authorization is required. Prior authorization criteria include the following:

1. The member has limited/unsatisfactory response (i.e. no difference of symptoms) to corticosteroids (i.e. IV methylprednisolone, IV dexamethasone, or high dose oral steroids) as determined by clinical notes ***OR***
2. The member has documented intolerance (i.e. severe anaphylaxis) to corticosteroids determined by poor tolerance of an intravenous (IV methylprednisolone, IV dexamethasone) or oral (high dose oral steroids) treatment trials ***AND***
3. The member must be diagnosed with any of the following:
    - *ENDOCRINE DISORDERS*
        - Nonsuppurative thyroiditis; Hypercalcemia associated with cancer
    - *NERVOUS SYSTEM DISORDERS*
        - acute exacerbations of multiple sclerosis
    - *RHEUMATIC DISORDERS*
        - As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
            - Psoriatic arthritis (PsA); Rheumatoid arthritis (RA); Juvenile rheumatoid arthritis (JIA); Ankylosing spondylitis (AS); Acute and subacute bursitis; Acute nonspecific tenosynovitis; Acute gouty arthritis; Post-traumatic arthritis; Synovitis of osteoarthritis; Epicondylitis
    - *COLLAGEN DISEASES*
        - During an exacerbation or as maintenance therapy:
            - Systemic lupus erythematosus; Systemic dermatomyositis (polymyositis); Acute rheumatic carditis
    - *DERMATOLOGIC DISEASES*
        - Pemphigus; Bullous dermatitis herpetiformis; Severe erythema multiforme (Stevens-Johnson Syndrome); Exfoliative dermatitis; Severe psoriasis; Severe seborrheic dermatitis; mycosis fungoides
    - *ALLERGIC STATES*
        - Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment:
            - Seasonal or perennial allergic rhinitis; Bronchial asthma; Contact dermatitis; 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; Herpes zoster ophthalmicus; Iritis and iridocyclitis; Diffuse posterior uveitis and choroiditis; Optic neuritis; Sympathetic ophthalmia; Chorioretinitis; Anterior segment inflammation; Allergic corneal marginal ulcers.
    - *RESPIRATORY DISEASES:*
        - 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 DISEASES:*
        - For palliative management of: Leukemias and lymphomas in adults; Acute leukemia of childhood.
    - *EDEMATOUS STATE:*
        - To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
    - *GASTROINTESTINAL DISEASES:*

        - 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 concurrently with appropriate antituberculous chemotherapy; Trichinosis with neurologic or myocardial involvement.

Multiple Sclerosis
In addition to the above criteria, the member should (unless contraindicated) currently be treated with an immunomodulator agent (i.e. Novantrone, Betaseron, Avonex, Rebif, Copaxone, Tysabri) to reduce the frequency of MS exacerbations, therefore reducing administration of H.P. Acthar Gel.

Also, pseudoexacerbations precipitated by infection, especially urinary tract infection (UTI), stress or pain, premenstrual syndrome (PMS), excessive exercise and overheating, heat exposure, or drug abuse, which usually occur for 24 hours or less from onset of symptoms and do not involve CNS inflammatory processes, should be ruled out by physician.

Diagnostic Testing
H.P. Acthar Gel is FDA indicated for diagnostic testing of adrenocortical function. In such cases, H.P. Acthar Gel is not part of a pharmacy benefit but may be covered as a medical benefit.

Duration of Authorization:
If approved, up to a one year authorization may be granted.

Evidence for Preventative Treatment in Multiple Sclerosis
On the basis of several consistent Class I studies, IFN-β has been demonstrated to reduce the attack rate (whether measured clinically or by MRI) in patients with MS or with clinically isolated syndromes who are at high risk for developing MS.(5) On the basis of Class I evidence, glatiramer acetate has been demonstrated to reduce the attack rate (whether measured clinically or by MRI) in patients with RRMS. On the basis of several consistent Class II and III studies, mitoxantrone probably reduces the clinical attack rate and reduces attack-related MRI outcomes in patients with relapsing MS.(6) Natalizumab reduces measures of disease activity such as clinical relapse rate, Gd-enhancement, and new and enlarging T2 lesions in patients with relapsing MS.(7)

Additional Information:

CPT Codes / HCPCS Codes / ICD-9 Codes

HCPCS codes covered if selection criteria are met:

- J0800 Injection, corticotropin, up to 40 units

ICD-9 codes covered if selection criteria are met:

- 011.0 - 011.96 Pulmonary tuberculosis [when used concurrently with antituberculous chemotherapy]
- 013.0-013.06 Tuberculous meningitis [with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy]
- 053.20-053.29 Herpes zoster dermatitis of eyelid [severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa]
- 124 Trichinosis [with neurologic or myocardial involvement]
- 135 Sarcoidosis [symptomatic]
- 200.00 - 208.91 Malignant neoplasm of lymphatic and hematopoietic tissue [for palliative management of leukemias and lymphomas in adults, acute leukemia of childhood]

- 245.0 - 245.9 Thyroiditis [nonsuppurative]
- 274.0 Gouty arthropathy [acute]
- 275.42 Hypercalcemia [with cancer]
- 283.0 Autoimmune hemolytic anemias [acquired]
- 284.01 Constitutional red cell aplasia
- 284.89 Other specified aplastic anemias [erythroblastopenia] [RBC anemia]
- 287.4 Secondary thrombocytopenia [in adults]
- 340 Multiple sclerosis [acute exacerbations]
- 345.60 - 345.61 Infantile spasms [West syndrome]
- 360.11 Sympathetic uveitis [severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa]
- 360.19 Other endophthalmitis [severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa]
- 363.00 - 363.22 Chorioretinal inflammations [severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa]
- 364.00 - 364.3 Iridocyclitis [severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa]
- 370.00 - 370.9 Keratitis [severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa]
- 372.14 Other chronic allergic conjunctivitis [severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa]
- 377.30 - 377.39 Optic neuritis [severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa]
- 390 - 392.9 Acute rheumatic fever [During an exacerbation or as maintenance therapy in selected cases]
- 477.0 - 477.9 Allergic rhinitis [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 493.00 - 493.02 Extrinsic asthma [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 503 Pneumoconiosis due to other inorganic dust [berylliosis]
- 506.0 Bronchitis and pneumonitis due to fumes and vapors [aspiration pneumonitis]
- 507.0 Pneumonitis due to inhalation of food or vomitus [aspiration pneumonitis]
- 518.3 Pulmonary eosinophilia [Loffler's syndrome not manageable by other means]
- 535.4 Other specified gastritis [allergic gastritis] [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 555.0 - 555.9 Regional enteritis [to tide the patient over a critical period of the disease]
- 556.0 - 556.9 Ulcerative colitis [to tide the patient over a critical period of the disease]
- 558.3 Allergic gastroenteritis and colitis [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 581.0 - 581.9 Nephrotic syndrome [to induce diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type]
- 690.10 - 690.18 Seborrheic dermatosis [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 692.0 - 692.6 Contact dermatitis and other eczema due to detergents, oils and greases, solvents, drugs and medicines in contact with skin, other medical products, food in contact with skin, or plants [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 693.0 - 693.9 Dermatitis due to substances taken internally [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 694.0 Dermatitis herpetiformis
- 694.4 Pemphigus
- 695.1 Erythema multiforme [severe] [Stevens-Johnson syndrome]
- 696.0 - 696.1 Psoriasis [severe]
- 708.0 Allergic urticaria [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 710.0 - 710.9 Diffuse diseases of connective tissue [During an exacerbation or as maintenance therapy in selected cases]
- 714.0 - 714.33 Rheumatoid arthritis [as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) including selected cases of juvenile rheumatoid arthritis]

- 715.00 - 715.98 Osteoarthritis [synovitis of] [as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation)]
- 716.10 - 716.19 Traumatic arthropathy
- 720.0 Ankylosing spondylitis
- 726.0 - 727.9 Peripheral enesthopathies and other disorders of synovium, tendon, and bursa [acute and subacute bursitis] [acute nonspecific tenosynovitis]
- 995.1 Angioneurotic edema [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 995.20 - 995.29 Other and unspecified adverse effect of drug, medicinal and biological substance [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 995.3 Allergy, unspecified [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 999.4 Anaphylactic shock due to serum [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- 999.5 Other serum reaction [severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment]
- V77.99 Special screening for other and unspecified endocrine, nutritional, metabolic, and immunity disorders [diagnostic testing of adrenocortical function]

Resources:

1. Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. Neurology. 1989;39:969-971.
2. Filippini G, Brusaferri F, Sibley WA, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database of Syst Rev. 2000;(4):CD001331.
3. Barnes MP, Bateman DE, Cleland PG, et al. Intravenous methylprednisolone for multiple sclerosis in relapse. J Neurol Neurosurg Psychiatry. 1985;48:157-159.
4. Milanese C, La Mantia L, Salmaggi A, et al. Double-blind randomized trial of ACTH versus dexamethasone versus methylprednisolone in multiple sclerosis bouts. Eur Neurol. 1989;29:10-14.
5. Goodin DS, Frohman EM, Garmany GP Jr, Halper J, Likosky WH, Lublin FD, Silberberg DH, Stuart WH, van den Noort S. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology 2002 Jan 22;58(2):169-78.
6. D.S. Goodin, B.G. Arnason, P.K. Coyle, E.M. Frohman and D.W. Paty. The use of mitoxantrone (Novantrone) for the treatment of multiple sclerosis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2003;61;1332-1338
7. D. S. Goodin, B. A. Cohen, P. O'Connor, L. Kappos and J. C. Stevens. Assessment: The use of natalizumab (Tysabri) for the treatment of multiple sclerosis (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2008;71;766-773
8. Questcor Pharmaceuticals, Inc. H.P. Acthar® Gel (repository corticotropin injection). Prescribing Information. Union City, CA: Questcor Pharmaceuticals; revised January 2006. Available at: http://www.acthar.com/Pdf/Acthar_PI.pdf. Accessed October 2009.
9. Burton JM, O'Connor PW, Hohol M, Beyene J. Oral versus Intravenous Steroids for Treatment of Relapses in Multiple Sclerosis. Cochrane Database of Systematic Reviews 2009, Issue 3. Art. No.: CD006921. DOI: 10.1002/14651858.CD006921.pub2.

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