Corticotropin Products

Humana

Pharmacy Coverage Policy

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Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio
Policy Type: Prior Authorization

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

Description

H.P. Acthar Gel (repository corticotropin injection) is a highly purified sterile preparation of the adrenocorticotropic hormone (ACTH) in 16% gelatin to provide a prolonged release after intramuscular or subcutaneous injection. Purified Cortrophin Gel (repository corticotropin injection) is a porcine derived purified sterile preparation of ACTH in 15% gelatin to provide a prolonged release after intramuscular or subcutaneous injection.

H.P. Acthar Gel (repository corticotropin injection) and Purified Cortrophin Gel stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances.

H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in children under 2 years of age. It is also indicated for the treatment of the following conditions after failed corticosteroid therapy: Acute exacerbations of multiple sclerosis (MS) and other medical conditions, including endocrine disorders (nonsuppurative thyroiditis; hypercalcemia associated with cancer), rheumatic disorders (as adjunctive therapy for short-term administration in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis; 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 in selected cases of: 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; Loefler's syndrome not manageable by other means; berylliosis; fulminating or disseminated pulmonary tuberculosis when used concurrently with antituberculous chemotherapy; aspiration pneumonitis), hematologic disorders (acquired hemolytic anemia; secondary thrombocytopenia in adults; erythroblastopenia; congenital (erythroid) hypoplastic anemia), neoplastic diseases (for palliative management of: leukemias and lymphomas in adults; acute leukemia of childhood), edematous state (induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that are due to lupus erythematosus), gastrointestinal disease (ulcerative colitis; regional enteritis), tuberculous meningitis; and trichinosis with neurologic or myocardial involvement.

Purified Cortrophin Gel (repository corticotropin injection) is indicated for short-term administration to tide the patient over an acute episode or exacerbation in rheumatic disorders including psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, and acute gouty arthritis; during an exacerbation or as maintenance therapy in select cases of collagen diseases (systemic lupus erythematosus, systemic dermatomyositis [polymyositis]); dermatologic diseases (severe erythema multiforme [Stevens-Johnson syndrome], severe psoriasis); allergic states (atopic dermatitis, serum sickness); ophthalmic diseases (severe acute and chronic allergy and inflammatory processes involving the eye and its adnexa); respiratory diseases (symptomatic sarcoidosis); edematous states to induce a diuresis or a remission of proteinuria in the nephrotic

syndrome without uremia of the idiopathic type or that due to lupus erythematosis; and acute exacerbations of multiple sclerosis.

Although repository corticotropin is FDA-approved for these conditions, it has limited therapeutic value, and is rarely used.

H.P. Acthar Gel (repository corticotropin injection) is also used in the diagnostic testing of adrenocortical function.

Repository corticotropin injection is available as H.P. Acthar Gel and Purified Cortrophin Gel in 5 ml multi-dose vial containing 80 USP units per mL.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Corticotropin Products (H.P. Acthar Gel and Purified Cortrophin Gel) will require prior authorization. These agents may be considered medically necessary when the following criteria are met:

Diagnostic testing of adrenocortical function

- Contraindication or intolerance to cosyntropin.

West syndrome (infantile spasms)

- Member has a diagnosis of West syndrome (i.e. infantile spasms)

Acute exacerbations of Multiple Sclerosis (MS), Rheumatoid Arthritis, Nephrotic Syndrome, and other steroid-responsive conditions
Initial Criteria:

- The member must be experiencing an acute exacerbation of multiple sclerosis; OR
- The member is experiencing an exacerbation of Rheumatoid Arthritis, Nephrotic Syndrome, or another steroid-responsive condition; **AND**
- The member has contraindications or intolerance to corticosteroids that are not expected to also occur with repository corticotropin injection.

Reauthorization Criteria

- There is documented evidence of disease response to treatment as indicated by improvement in symptoms.

Corticotropin Products (H.P. Acthar Gel, Purified Cortrophin Gel) will be initially approved for 6 months duration.
Reauthorization: Corticotropin Products (H.P. Acthar Gel) will be approved for 6 months duration.

Coverage Corticotropin Products (H.P. Acthar Gel, Purified Cortrophin Gel) therapy is not

Limitations

considered medically necessary for members with the following concomitant conditions:

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Corticotropin Products (H.P. Acthar Gel, Purified Cortrophin Gel)

Corticotropin Products (H.P. Acthar Gel, Cortrophin Gel) have limited therapeutic value in those conditions responsive to corticosteroid therapy, and is rarely used; in such cases, corticosteroid therapy is considered to be the treatment of choice. In addition, there is a lack of clinical studies comparing the effectiveness of repository corticotropin to corticosteroids in corticosteroid-responsive conditions. Repository corticotropin has the potential for inducing significant adverse effects that are not reversible. The product labeling notes that the chronic administration of more than 40 units daily may be associated with uncontrollable adverse effects. Corticotropin may only suppress symptoms and signs of chronic diseases without altering the natural course of the disease.

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.

Repository corticotropin injection has been used as a treatment for West syndrome (infantile spasms) which is a very rare and potentially life-threatening form of epilepsy that typically begins in the first year of life. According to a report of the American Academy of Neurology and the Child Neurology Society (2004) on the treatment of IS, repository corticotropin is effective for the short-term treatment of IS and the resolution of hypsarrhythmia.

In 2009, the U.S. FDA approved another drug, the oral medication, Sabril (Vigabatrin) as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms for

whom the potential benefits outweigh the potential risks of vision loss.

Cohen-Sadan (2009) reported on a long-term follow-up of children with West syndrome treated with ACTH or vigabatrin. The medical records of 28 normal MRI West syndrome cases were reviewed for seizure development and cognitive outcome in relation to treatment type and timing. The authors concluded that for West syndrome "ACTH and vigabatrin appear to be equally effective in the short term if treatment is administered within one month of symptom onset. On long-term follow-up, early ACTH treatment appeared to yield a better outcome than early vigabatrin or late ACTH treatment in terms of both cognition and seizure development."
The use of corticotropin is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of peptic ulcer, congestive heart failure, or hypertension. It is also contraindicated in the treatment of primary adrenal insufficiency, hypercortisolism, or any condition associated with these disorders.

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

H.P. Acthar Gel; repository corticotropin injection; Purified Cortrophin Gel; intramuscular; subcutaneous; pharmacy

References

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3. Cohen-Sadan S, Kramer U, Ben-Zeev B, et al. Multicenter long-term follow-up of children with idiopathic West syndrome: ACTH versus vigabatrin. Eur J Neurol. 2009 Apr;16(4):482-487.
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Revised January 2022.

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