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DRUG POLICY

Repository Corticotropin Injection

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Repository Corticotropin Injection drug policy is to provide coverage for specific, but not all FDA labeled or compendial supported drug use based on plan design and the scope of the benefit. This program provides coverage for Acthar Gel for the treatment of infantile spasms and exacerbations of multiple sclerosis and coverage for Purified Cortrophin Gel for the treatment of exacerbations of multiple sclerosis if all of the approval criteria are met.

Covered indications:

- A. **Infantile spasms (Acthar Gel only):** as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- B. **Multiple Sclerosis:** treatment of acute exacerbations of multiple sclerosis in adults

Other indications

The use of Acthar Gel and Purified Cortrophin Gel for the treatment of all other indications listed in the FDA product labeling has not been proven to be superior to conventional therapies (e.g., corticosteroids, immunosuppressive agents) and has a significantly higher cost than the standard of care agents. Use of Acthar and Purified Cortrophin Gel for these conditions is unproven and considered not medically necessary.

A. **Acthar Gel:**

- 1. **Rheumatic Disorders:** as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis

2. **Collagen Diseases:** during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
3. **Dermatologic Diseases:** severe erythema multiforme, Stevens-Johnson syndrome
4. **Allergic States:** serum sickness
5. **Ophthalmic Diseases:** severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
6. **Respiratory Diseases:** symptomatic sarcoidosis
7. **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

B. Purified Cortrophin Gel:

1. **Rheumatic Disorders:** as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis; ankylosing spondylitis; acute gouty arthritis.
2. **Collagen Diseases:** during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
3. **Dermatologic Diseases:** severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis
4. **Allergic States:** atopic dermatitis, serum sickness
5. **Ophthalmic Diseases:** severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
6. **Respiratory Diseases:** symptomatic sarcoidosis
7. **Edematous State:** to induce a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review for requests for treatment of multiple sclerosis exacerbations: chart notes detailing the outcome of the most recent trial with IV methylprednisolone, including dosage and duration of treatment.

Exclusions

- A. Coverage of Purified Cortrophin Gel for the treatment of infantile spasms will be excluded.
- B. Use of Acthar Gel in combination with Purified Cortrophin Gel will be excluded.

Initial Criteria For Approval

1. Infantile Spasms (Acthar Gel only)

Authorization of 4 weeks may be granted for treatment of infantile spasms in members who are less than 2 years of age.

2. Multiple Sclerosis

Authorization of 3 weeks may be granted for treatment of acute exacerbations of multiple sclerosis when the member has had an inadequate response to a trial of IV methylprednisolone (for the current exacerbation).

Continuation of Therapy

1. Infantile Spasms (Acthar Gel only)

Authorization of 4 weeks may be granted to members requesting Acthar Gel for continuation of therapy when the member has shown substantial clinical benefit from therapy.

2. Multiple Sclerosis

Authorization of 3 weeks may be granted for members requesting re-authorization of repository corticotropin therapy when ALL initial authorization criteria are met.

Acthar Gel (repository corticotropin injection) and Purified Cortrophin Gel (repository corticotropin injection) are considered **not medically necessary** for members with a diagnosis of Infantile Spasms or Multiple Sclerosis who do not meet the criteria set forth above. All other indications are considered **not medically necessary** and are not a covered benefit.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0800, repository corticotropin, 40 units.
- J3490, unclassified drugs (when classified as Purified Cortrophin Gel)
- J3590, unclassified biologics (when classified as Purified Cortrophin Gel)

REFERENCES

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POLICY HISTORY

Policy #: 05.01.22

Original Effective Date: January 2009

Reviewed: February 2022

Revised: February 2022

Current Effective Date: April 1, 2022