Reference number(s)
1848-A

LIMITED INDICATION SPECIALTY GUIDELINE MANAGEMENT

ACTHAR GEL (repository corticotropin injection)
PURIFIED CORTROPHIN GEL (repository corticotropin injection)

POLICY

I. INDICATIONS

The Limited Indication Specialty Guideline Management (LI SGM) program provides coverage for specific, but not all FDA labeled or compendial supported drug uses based on plan design and the scope of the pharmacy 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.

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

The use of Acthar 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 considered not medically necessary and is not a covered benefit.

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 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 States**: to include a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

All other indications are considered experimental/investigational and not medically necessary.

II. 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.

III. 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.

IV. CRITERIA FOR INITIAL APPROVAL

A. 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.

B. 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).

V. CONTINUATION OF THERAPY

A. 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.

B. 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.

VI. REFERENCES

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