

Reference number(s)
1848-A

# INDICATION-SPECIFIC SPECIALTY GUIDELINE MANAGEMENT

## ACTHAR GEL (repository corticotropin injection)

### POLICY

#### I. INDICATIONS

The indication-specific Specialty Guideline Management (SGM) program provides coverage for specific, but not all FDA labeled or compendial supported drug use 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 if all of the approval criteria are met.

- A. **Infantile spasms:** 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 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 for these conditions is considered not medically necessary and is not a covered benefit.

- A. **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<sup>1</sup>
- B. **Collagen Diseases:** during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)<sup>1</sup>
- C. **Dermatologic Diseases:** severe erythema multiforme, Stevens-Johnson syndrome<sup>1</sup>
- D. **Allergic States:** serum sickness<sup>1</sup>
- E. **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<sup>1</sup>
- F. **Respiratory Diseases:** symptomatic sarcoidosis<sup>1</sup>
- G. **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<sup>1</sup>

#### II. 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 outcomes of the most recent trial with IV methylprednisolone, including dosage and duration of treatment.

#### III. CRITERIA FOR INITIAL APPROVAL

##### A. Infantile Spasms

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

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#### **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).

### **IV. CONTINUATION OF THERAPY**

#### **A. Infantile Spasms**

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 for Acthar therapy when all initial authorization criteria are met.

### **V. REFERENCES**

1. Acthar Gel [package insert]. Hazelwood, MO: Mallinckrodt Pharmaceuticals, Inc.; July 2019.
2. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia*. 2010;51:2175-2189.
3. Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: Medical treatment of infantile spasms: Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2012;78:1974-1980.
4. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. *Cochrane Database Syst Rev*. 2013;6:CD001770.
5. Riikonen R. Recent advances in pharmacotherapy of infantile spasms. *CNS Drugs* 2014; 28:279-290.
6. Pavone P, et al. Infantile spasms syndrome, West Syndrome and related phenotypes: what we know in 2013. *Brain & Development* 2014; 739-751.
7. Citterio A, La Mantia L, Ciucci G, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. *Cochrane Database Syst Rev* 4:CD001331.
8. 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.
9. Berkovich R, Agius MA. Mechanisms of action of ACTH in the management of relapsing forms of multiple sclerosis. *Ther Adv Neurol Disord* 2014; 7(2):83-96.
10. Frohman EM, Shah A, Eggenberger E, et al. Corticosteroids for multiple sclerosis: I. Application for treatment exacerbations. *Neurotherapeutics* 2007; 4(4): 618-626.
11. Sellebjerg F, Barnes D, Filippini G, et al. EFNS guidelines on treatment of multiple sclerosis relapses: report of an EFNS task force on treatment of multiple sclerosis. *European Journal of Neurology* 2005; 12:939-946.