Reference number(s)
3171-A

RESTRICTED INDICATION ENHANCED SPECIALTY GUIDELINE MANAGEMENT

ACTHAR GEL (repository corticotropin injection)

POLICY

I. INDICATIONS

The Restricted indication Enhanced Specialty Guideline Management (RI eSGM) 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 if all of the approval criteria are met.

Infantile spasms: as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age

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. **Multiple Sclerosis:** treatment of acute exacerbations of multiple sclerosis in adults
B. **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
C. **Collagen Diseases:** during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
D. **Dermatologic Diseases:** severe erythema multiforme, Stevens-Johnson syndrome
E. **Allergic States:** serum sickness
F. **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
G. **Respiratory Diseases:** symptomatic sarcoidosis
H. **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

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

II. CRITERIA FOR INITIAL APPROVAL

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

III. CONTINUATION OF THERAPY

Infantile Spasms
Authorization of 3 months may be granted to members requesting Acthar Gel for continuation of therapy when the member has shown substantial clinical benefit from therapy.

IV. REFERENCES

1. Acthar Gel [package insert]. Hazelwood, MO: Mallinckrodt Pharmaceuticals, Inc.; March 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.